Sexually Transmitted Diseases

The prevalence of syphilis from the early HIV period is correlated with peak HIV prevalence at a country level

--Manuscript Draft--

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The prevalence of syphilis from the early HIV period is correlated with peak HIV prevalence at a country level

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Short summary

This study found that populations with generalized HIV epidemics had a higher prevalence of syphilis in the pre-HIV period.

Abstract

Background

Could we have predicted national peak HIV based on syphilis prevalence in the 1990s? Earlier studies have shown positive correlations between various STIs at different population levels. In this paper we test the hypothesis that there was a residual variation in the national prevalence rates of syphilis and that these rates could predict subsequent peak-HIV prevalence rates.

Methods

This analysis uses linear regression to evaluate the country-level relationship between antenatal syphilis prevalence (1990-1999) and peak HIV prevalence.

Results

A moderately strong association is found for the 76 countries with data available (R^2 = 0.53, $P < 0.001$). The association was weakened but remained significantly positive when we adjusted for the type of syphilis testing used and the prevalence of circumcision.

Conclusion

Syphilis prevalence in the 1990s predicted approximately 52% of the variation in peak HIV prevalence. Populations with generalized HIV epidemics had a higher prevalence of syphilis in the pre-HIV period. This finding provides additional rationale to carefully monitor sexual behavior, sexual networks and STI incidence in these populations.

Keywords: antenatal syphilis, HIV, generalized HIV epidemics

Introduction

Previous studies have found positive correlations between the prevalence of various STIs at different levels of aggregation. At the level of ethnic/racial groups, studies have found a relationship between the prevalence of HIV and syphilis (1, 2), HSV-2 (2, 3), chlamydia (1) and gonorrhea (1). At a national level peak HIV prevalence has been found to be correlated with HSV-2 prevalence in women (3). At the world-regional level HIV prevalence was correlated with the prevalence of HSV-2, gonorrhea, chlamydia, syphilis and trichomonas but this relationship was only statistically significant in the case of HSV-2 and gonorrhea (4).

In this paper we extend these analyses to assess if the prevalence of syphilis from the early HIV period is correlated with peak HIV prevalence at a country level. We chose syphilis as the widespread testing for syphilis in routine antenatal care means that there are more data available from population-based samples for syphilis in the early HIV period than there is for other STIs (4-7). An advantage of using the peak HIV prevalence as the measure for HIV prevalence is that this measure helps avoid the HIV introduction time bias which is caused by the widely differing times that the HIV epidemics began (8).

Further, we take into consideration the impact of circumcision on HIV and syphilis prevalence since this has been shown to reduce the acquisition of HIV and syphilis in men, which in turn likely results in a lower prevalence of these infections in populations where circumcision is more uniform (5-7).

Methods

Antenatal syphilis data for 1980 to 2010 were taken from an Institute for Health Metrics and Evaluation (IHME) database on the prevalence of syphilis in low risk populations compiled for GBD 2010 (9). The IHME data sources included UNAIDS epidemiologic fact sheets, UNGASS country progress reports, reports from country specific surveillance systems, WHO reports on syphilis epidemiology, and unpublished data from correspondence with GBD 2010 collaborators. These were supplemented by a systematic literature review of syphilis seroprevalence (most recent PubMed search was October 2011). To be included, a study needed to provide data on the prevalence of syphilis in populations considered representative of the general population and have a sample size of 100. Data from high-risk populations (e.g. MSM, sex workers and STI clinic attendees) were excluded (9-12).

For each country we extracted the studies conducted in antenatal populations between 1990 and 1999 and used the median of these studies as a proxy for the national prevalence of antenatal syphilis (termed the *syphilis prevalence* variable). The period 1990-1999 was chosen as this was the first decade for which sufficient data was available in the dataset and the beginning of this period predates the year that most countries attained their first peak HIV prevalence.

For the *adjusted syphilis prevalence* we generated new syphilis prevalence estimates adjusted according to the syphilis-testing algorithm used since different types of testing algorithms influence the estimates of prevalence. Studies that use

both a treponemal and a non-treponemal test to diagnose infection are regarded as offering the most accurate measure of active syphilis infection (13). We applied correction factors to different syphilis testing algorithms used based on a systematic review and meta-analysis that estimated the proportion of pregnancies with "probable active syphilis" according to the of testing methodology used in the study (14).

National peak HIV prevalence was obtained for 149 countries for which HIV prevalence estimates were available from 1990 to 2009 in the Global Health Observatory Data Repository of the World Health Organization (http://apps.who.int/gho/data/node.main.622). These estimates are based on population-based testing, antenatal clinical surveillance and epidemic models (15). From this data we derived the *peak HIV prevalence* variable which was defined as the highest national HIV prevalence in 15 to 49 year-old between the years 1990-2009 (median year 1998, interquartile range 1996-2005) (16).

We controlled for the national circumcision prevalence in our adjusted analyses. The national prevalence rates of male circumcision as of December 2006 were taken from a World Health Organization and Joint United Nations Programme on HIV/AIDS publication. These estimates were based on Demographic and Health Survey data or from other published sources (17). Countries were classified as having circumcision prevalence rates < 20%, 20 - 80% or >80%.

Simple linear regression was used to evaluate the relationship between syphilis prevalence and peak HIV prevalence – unadjusted, adjusted for laboratory testing

used, and adjusted for circumcision prevalence. Because the severity and heterogeneity of the HIV epidemics have been greater in sub-Saharan Africa than elsewhere the analyses were repeated limited to the countries of sub Saharan Africa. All analyses were performed in STATA 12.0 (StataCorp LP, College Station, TX, USA).

Results

We found a moderately strong association between syphilis prevalence and peak HIV prevalence for the 76 countries with data available ($R^2 = 0.53$, $P < 0.001$; Figure 1). The association was weakened but remained significantly positive when we adjusted for the type of syphilis testing used ($R^2 = 0.34$, $P < 0.001$). The inclusion of the circumcision prevalence variable did not attenuate the association. For every 1% increase in syphilis there was a 1.5% (95% CI 1.2-1.9; n = 76) and 2.0% (95% CI 1.3-2.6; n = 69) increase in HIV prevalence in the models using the unadjusted and adjusted syphilis prevalence estimates, respectively. In the models including circumcision these figures changes to 1.6% (95% CI 1.2-2.0; n = 69) and 1.9% (95% CI 1.3 to 2.5; n = 76), respectively. A similar positive association was found when we restricted the analyses to 28 countries of sub-Saharan Africa ($R^2 = 0.69$, $P < 0.001$, for unadjusted syphilis prevalence versus peak HIV prevalence).

Discussion

This study found a positive association between syphilis prevalence during the period 1990-1999 and peak-HIV prevalence at a country level. Syphilis prevalence in the 1990s predicted approximately 52% of the variation in peak HIV prevalence. This same relationship has been found at the levels of individuals (18, 19), ethnic/racial

groups (1, 2) and world regions (4). For example, a study that assessed this relationship at the ethnic group level in the United States of America and South Africa found a strong positive association between syphilis prevalence (predating peak HIV prevalence) and HIV prevalence (2). However, not all studies have found this positive association (19). The fact that the same positive association has been found between HIV and other STIs at the levels of individuals, ethnic/racial groups and countries (2, 4) reduces the chance that this relationship is explained by confounding, or is due to an ecological or other form of bias. Rather, this association suggests that either syphilis played a significant role in the spread of HIV, or that both are determined by the same or similar factors.

There are a number of limitations with this type of retrospective study; chief amongst these is the quality of the syphilis prevalence data. Peak HIV data was only reported for 149 countries and we only had combined HIV and syphilis data for 76 countries. Of the countries with data, prevalence estimates were based on relatively small or somewhat selected samples that may not be representative of the general population. Specifically, many of the studies are from urban areas and are studies of women presenting for antenatal care. It would also would have been optimal to have had an earlier range syphilis prevalence estimates since some countries started attaining their peak HIV prevalences in the early/mid 1990's, such as Uganda where HIV peaked in 1991. We controlled for the effect of circumcision rates on the association between syphilis and peak HIV prevalence, but we cannot exclude the possibility that there are other confounders that we have not controlled for. We performed a regression of syphilis data *versus* modeled estimates of HIV. Ideally data *versus* data or estimates *versus* estimates would be compared. The effect of

each of these data and methodological limitations would dilute the strength of an association between syphilis and peak HIV prevalence.

A syphilis testing regime correction factor was also included in the analysis and when this factor was applied the association between syphilis and HIV was weakened. This could be explained by the fact that syphilis prevalences were overestimated in the studies that only use antibody testing which cannot distinguish reinfections from previous infections. The correction factors have not been validated in separate studies and hence they may lead to inaccurate prevalence estimates which is an alternative explanation for the observed attenuation in HIV/syphilis association.

There is increasing evidence that AIDS mortality played a role in the remarkable decline of syphilis prevalence in general populations in Southern and Eastern Africa (20-22) and MSM populations in North America (23). In high income countries, the widespread availability of antiretroviral therapy has led to a decline in AIDS mortality and partly as a result, MSM sexual networks are returning towards a high-risk pre-AIDS structure with a concomitant increase in syphilis and other STIs (24, 25). It is important to appreciate that populations with generalized HIV epidemics had a higher prevalence of other STIs such as syphilis in the pre-HIV period (2) as this provides an additional rationale to carefully monitor sexual behavior, sexual networks and STI incidence in these populations to allow for the early detection of any return towards to a pre HIV risk configuration (20).

Figure 1. Association between peak HIV prevalence and the median prevalence of syphilis (expressed as a percentage) in all studies performed between the years 1990-1999 in antenatal women in 76 countries unadjusted for testing strategy (R^2 = 0.53, $P < 0.001$, n = 76). Blue colored dots in the figure indicate countries located in sub-Saharan Africa; red colored dots indicate non-sub-Saharan African countries.

References

1. Morris M, Kurth AE, Hamilton DT, et al. Concurrent partnerships and HIV prevalence disparities by race: linking science and public health practice. Am J Public Health. 2009;99(6):1023-31.

2. Kenyon C, Osbak K, Buyze J. The prevalence of HIV by ethnic group is correlated with HSV-2 and syphilis prevalence in Kenya, South Africa, the United Kingdom and the United States. Interdiscip Perspect Infect Dis. 2014:Article ID 284317.

3. Kenyon C, Colebunders R, Hens N. Determinants of generalized herpes simplex virus-2 epidemics: the role of sexual partner concurrency. Int J STD AIDS. 2013;24(5):375-82.

4. Kenyon C, Colebunders R, Buyze J. Classification of incidence and prevalence of certain sexually transmitted infections by world regions. Int J of Infec Dis. 2014;18:73-80.

5. Weiss HA, Thomas SL, Munabi SK, et al. Male circumcision and risk of syphilis, chancroid, and genital herpes: a systematic review and meta-analysis. Sex Transm Infect. 2006;82(2):101-9.

6. Wamai RG, Morris BJ, Bailis SA, et al. Male circumcision for HIV prevention: current evidence and implementation in sub-Saharan Africa. J Int AIDS Soc. 2011;14:49.

7. Auvert B, Buve A, Lagarde E, et al. Male circumcision and HIV infection in four cities in sub-Saharan Africa. AIDS. 2001;15:S31.

8. Kenyon C, Colebunders R, Voeten H, et al. Peak HIV prevalence: a useful outcome variable for ecological studies. Int J Infect Dis. 2013;17(5):e286-8.

9. Lozano R, Naghavi M, Foreman K, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2095-128.

10. World Health Organization. Prevalence and incidence of selected sexually transmitted infections, Chlamydia trachomatis, Neisseria gonorrhoeae, syphilis, and Trichomonas vaginalis: methods and results used by the WHO to generate 2005 estimates. Geneva World Health Organization; 2011.

11. Rowley J, Toskin I, Ndowa F, et al. Global incidence and prevalence of selected curable sexually transmitted infections, 2008: World Health Organization; 2012.

12. Meredith S, Hawkes S, Schmid G, et al.The global elimination of congenital syphilis: rationale and strategy for action. 2007.

13. Tramont E. Syphilis In: Mandell GL, Bennett JE and Dolin R. Principles and Practice of Infectious Diseases 7th ed, Churchill Livingstone Inc. 2010.

14. Ham DC, Lin C, Newman L, et al. Improving global estimates of syphilis in pregnancy by diagnostic test type: A systematic review and meta-analysis. Int J Gynaecol Obstet. 2015;130 Suppl 1:S10-4.

15. UNAIDS. Methodology –Understanding the HIV estimates. Geneva: UNAIDS, 2014.

16. Kenyon CR, Buyze J. No association between gender inequality and peak HIV prevalence in developing countries - an ecological study. AIDS Care. 2015;27(2):150-9.

17. Weiss H. Male Circumcision: Global Trends and Determinants of Prevalence, Safety, and Acceptability. World Health Organization, 2008. 9291736333.

18. Nelson KE, Eiumtrakul S, Celentano D, et al. The association of herpes simplex virus type 2 (HSV-2), Haemophilus ducreyi, and syphilis with HIV infection in young men in northern Thailand. J Acquir Immune Defic Syndr Hum Retrovirol. 1997;16(4):293-300.

19. Buve A, Weiss HA, Laga M, et al. The epidemiology of gonorrhoea, chlamydial infection and syphilis in four African cities. AIDS. 2001;15 Suppl 4:S79-88.

20. Kenyon CR, Osbak K, Chico RM. What underpins the decline in syphilis in Southern and Eastern Africa? An exploratory ecological analysis. Int J Infect Dis. 2014;29:54-61.

21. Kenyon CR, Osbak K, Buyze J, Chico RM. The changing relationship between bacterial STIs and HIV prevalence in South Africa - an ecological study. Int J STD AIDS. 2015;26(8):556-64.

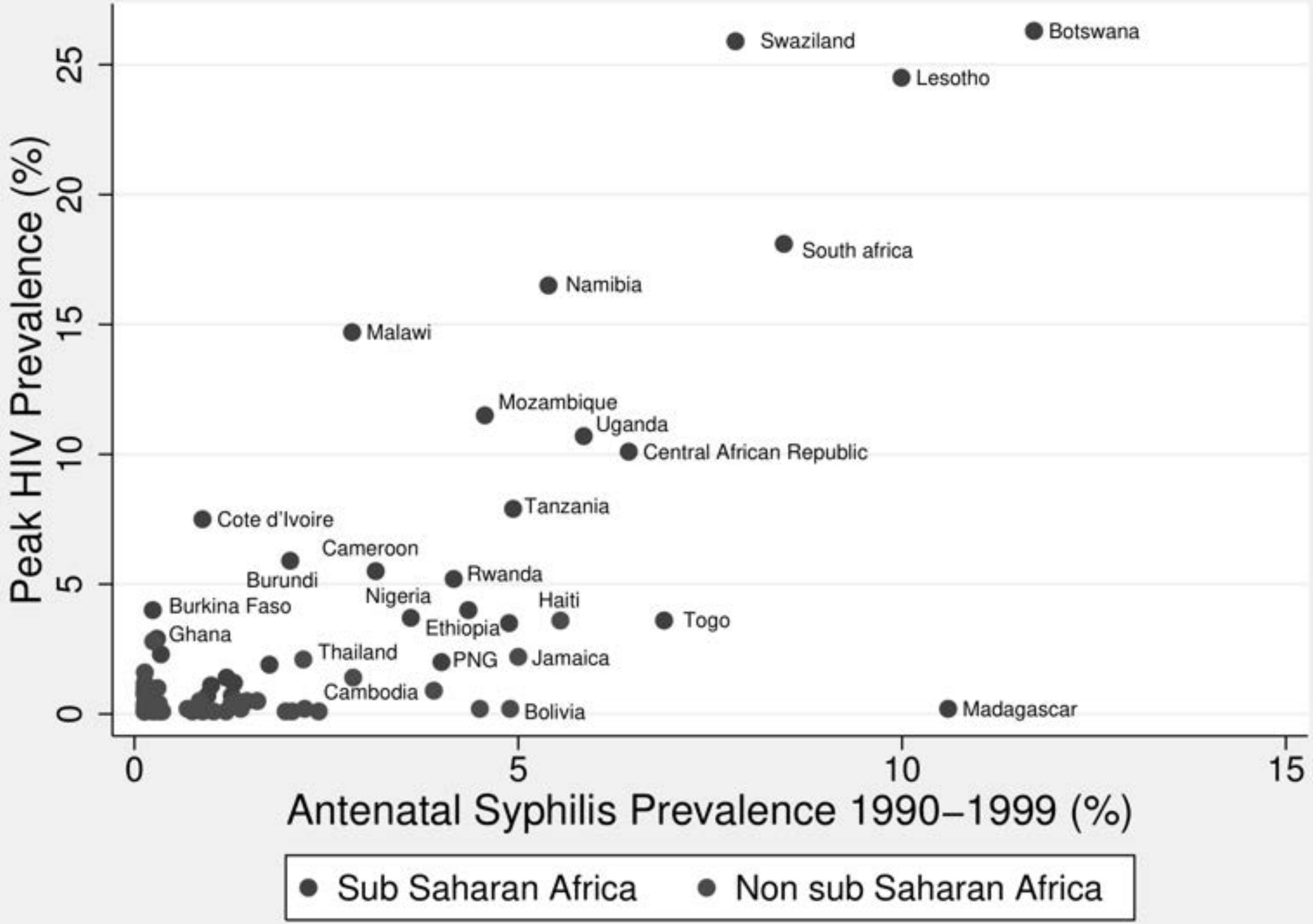
22. Johnson LF, Dorrington RE, Bradshaw D, et al. The effect of syndromic management interventions on the prevalence of sexually transmitted infections in South Africa. Sex Reprod Healthc. 2011;2(1):13-20.

23. Chesson HW, Dee TS, Aral SO. AIDS mortality may have contributed to the decline in syphilis rates in the United States in the 1990s. Sex Transm Dis. 2003;30(5):419-24.

24. Chesson HW, Gift TL. Decreases in AIDS mortality and increases in primary and secondary syphilis in men who have sex with men in the United States. Jaids-J Acq Imm Def. 2008;47(2):263-4.

25. Fenton KA, Imrie J. Increasing rates of sexually transmitted diseases in homosexual men in Western europe and the United States: why? Infect Dis Clin North Am. 2005;19(2):311-31.

Figure


Swaziland
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Burundi
Rwanda
Nigeria
Haiti
Burkina Faso
Ethiopia
Togo
Ghana
Thailand
PNG
Jamaica
Cambodia
Bolivia
Madagascar
Peak HIV Prevalence (%)
0
5
10
15
20
25
0
5
10
15
Antenatal Syphilis Prevalence 1990–1999 (%)
Sub Saharan Africa
Non sub Saharan Africa

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Voluntary Medical Male Circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets

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Manuscript Number:	PONE-D-19-03571R1
Article Type:	Research Article
Full Title:	Voluntary Medical Male Circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets
Short Title:	VMMC and unintended consequences of service-delivery targets in Kenya
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Keywords:	voluntary medical male circumcision; VMMC; targets; public health intervention targets; HIV prevention; VMMC mobilization; VMMC demand creation; VMMC sensitization; public health intervention; service-delivery targets; VMMC recruitment; Ethics; Kenya; western Kenya; qualitative research
Abstract:	Abstract Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female-to-male HIV transmission. Since 2007, VMMC has been a key component of the United States President's Emergency Plan for AIDS Relief's (PEPFAR) strategy to mitigate the HIV epidemic in countries with high HIV prevalence and low circumcision rates. To ensure intended effects, PEPFAR sets ambitious annual circumcision targets and provides funding to implementation partners to deliver local VMMC services. In Kenya to date, 1.9 million males have been circumcised; in 2017, 60% of circumcisions were among 10-14-year-olds. We conducted a qualitative field study to learn more about VMMC program implementation in Kenya. The study setting was a region in Kenya with high HIV prevalence and low male circumcision rates. From March 2017 through April 2018, we carried out in-depth interviews with 29 VMMC stakeholders, including "mobilizers", HIV counselors, clinical providers, schoolteachers, and policy professionals. Additionally, we undertook observation sessions at 14 VMMC clinics while services were provided and observed mobilization activities at 13 community venues including, two schools, four public marketplaces, two fishing villages, and five inland villages. Analysis of interview transcripts and observation field notes revealed multiple unintended consequences linked to the pursuit of targets. Ebbs and flows in the availability of school-age youth together with the drive to meet targets may result in increased burdens on clinics, long waits for care, potentially misleading mobilization practices, and deviations from the standard of care. Our findings indicate shortcomings in the quality of procedures in VMMC programs in a low-resource setting, and more importantly, that the pursuit of ambitious public health targets may lead to compromised service delivery, consent practices, and protocol adherence. There is a need to develop improved or alternative systems to balance the goal of increasing service uptake with the responsible conduct of VMMC.
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Response to Reviewers:	We have revised our manuscript, "Voluntary Medical Male Circumcision for HIV

	prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets" in accordance with our two reviewers' recommendations. These revisions include those aimed to mask the exact location of this study as well as the individuals and organizations involved in it, including removing the "western" from "western Kenya" in the original title. To reduce the risk of deductive disclosure and protect the privacy and confidentiality of our research participants, we have revised our manuscript to be intentionally vague about the location of the study and have made extensive efforts to ensure that our individual participants and their employers (VMMC implementation partners or IPs) cannot be identified.
Additional Information:	
Question	Response
Financial Disclosure Enter a financial disclosure statement that describes the sources of funding for the work included in this submission. Review the submission guidelines for detailed requirements. View published research articles from *PLOS ONE* for specific examples. This statement is required for submission and **will appear in the published article** if the submission is accepted. Please make sure it is accurate. **Unfunded studies** Enter: *The author(s) received no specific funding for this work.* **Funded studies** Enter a statement with the following details: • Initials of the authors who received each award • Grant numbers awarded to each author • The full name of each funder • URL of each funder website • Did the sponsors or funders play any role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript? • **NO** - Include this sentence at the end of your statement: *The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.* • **YES** - Specify the role(s) played. * typeset	This research was funded by the U.S. National Institute of Mental Health grant number 3R01MH102125-03S1 (Luseno, W. K., Principal Investigator) https://www.nimh.nih.gov/index.shtml The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
Competing Interests	The authors have declared that no competing interests exist.

Use the instructions below to enter a competing interest statement for this submission. On behalf of all authors, disclose any competing interests that could be perceived to bias this work—acknowledging all financial support and any other relevant financial or non-financial competing interests. This statement **will appear in the published article** if the submission is accepted. Please make sure it is accurate. View published research articles from *PLOS ONE* for specific examples. **NO authors have competing interests** Enter: *The authors have declared that no competing interests exist.* **Authors with competing interests** Enter competing interest details beginning with this statement: *I have read the journal's policy and the authors of this manuscript have the following competing interests: [insert competing interests here]* * typeset	
Ethics Statement Enter an ethics statement for this submission. This statement is required if the study involved: • Human participants • Human specimens or tissue • Vertebrate animals or cephalopods • Vertebrate embryos or tissues • Field research Write "N/A" if the submission does not require an ethics statement. General guidance is provided below. Consult the submission guidelines for detailed instructions. **Make sure that all**	The institutional review boards of the Pacific Institute for Research and Evaluation (PIRE) and the Kenya Medical Research Institute (KEMRI) approved all study activities, including all the informed consent procedures described above. Locally, the county-level Ministries of Health and Education and the directors of each IP gave us approval to conduct this research. In-depth interview participants were offered the option to provide either written or verbal informed consent to participate. We requested and were granted a waiver of Documentation of Informed Consent for these interviews since the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The type of informed consent (verbal or written) for each participant was recorded in a file by a research staff member. Most interviewees (28 of the 29) chose written consent. Signed consent forms were stored securely at KEMRI. We also conducted observation sessions within VMMC clinics and during mobilization activities in non-clinical settings (e.g., fishing villages, schools, markets). Research staff provided information about the study to those in charge of VMMC facilities. VMMC recruiters known as “mobilizers” provided verbal informed consent to participate, which

information entered here is included in the Methods section of the manuscript. **Format for specific study types** **Human Subject Research (involving human participants and/or tissue)** • Give the name of the institutional review board or ethics committee that approved the study • Include the approval number and/or a statement indicating approval of this research • Indicate the form of consent obtained (written/oral) or the reason that consent was not obtained (e.g. the data were analyzed anonymously) **Animal Research (involving vertebrate animals, embryos or tissues)** • Provide the name of the Institutional Animal Care and Use Committee (IACUC) or other relevant ethics board that reviewed the study protocol, and indicate whether they approved this research or granted a formal waiver of ethical approval • Include an approval number if one was obtained • If the study involved *non-human primates*, add *additional details* about animal welfare and steps taken to ameliorate suffering • If anesthesia, euthanasia, or any kind of animal sacrifice is part of the study, include briefly which substances and/or methods were applied **Field Research** Include the following details if this study involves the collection of plant, animal, or other materials from a natural setting: • Field permit number • Name of the institution or relevant body that granted permission	was noted/confirmed by our research staff who followed a script for administering informed consent procedures). We sought, and were granted, a Waiver of Documentation of Informed Consent for the recruiters and/or mobilizers based on the reason that the research presented no more than minimal risk of harm to subjects and involved no procedures for which written consent is normally required outside of the research context (See International Ethical Guidelines for Health-related Research Involving Humans, CIOMS, 2016, Guideline 9, p. 34-35, https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf). Concerning the observations that took place at VMMC clinics and during mobilization activities in public spaces, neither written nor verbal consent was sought from VMMC clients or their parents since they were observed in the context of a clinic which in this part of Kenya is a de facto public space, and seeking formal consent was not feasible. Study staff approached a clinical officer (or another staff member who could authorize our research activity) at the clinic to explain the research project and the proposed observation. Prior to in-school observation sessions, school authorities and teachers were informed about the research and gave us permission to conduct the research activities. We sought and received a waiver of informed consent for adolescents and their parents (if in attendance) as well as from other individuals in attendance at the clinic (e.g., doctors, nurses, etc.) for the following reasons: the nature of this part of the research was observational and low risk; we were not collecting individual-level data; the waiver would not adversely affect their rights and welfare; the observational data could not be feasibly collected without the waiver; the research had important social value; and the only identifiable record linking the participant and the research would be the consent document, creating a principal risk for potential harm from a breach of confidentiality. This waiver is also consistent with the guidance in the International Ethical Guidelines for Health-Related Research Involving Humans (2016) by the Council for International Organizations of Medical Sciences (CIOMS, Guideline 10, p.37). The ethics committees at the Pacific Institute for Research and Evaluation (PIRE) and the Kenya Medical Research Institute (KEMRI) both approved all our consent procedures.
Data Availability Authors are required to make all data underlying the findings described fully available, without restriction, and from the time of publication. PLOS allows rare exceptions to address legal and ethical	No - some restrictions will apply

concerns. See the PLOS Data Policy and FAQ for detailed information. A Data Availability Statement describing where the data can be found is required at submission. Your answers to this question constitute the Data Availability Statement and **will be published in the article**, if accepted. **Important**: Stating 'data available on request from the author' is not sufficient. If your data are only available upon request, select 'No' for the first question and explain your exceptional situation in the text box. Do the authors confirm that all data underlying the findings described in their manuscript are fully available without restriction?	
Describe where the data may be found in full sentences. If you are copying our sample text, replace any instances of XXX with the appropriate details. • If the data are **held or will be held in a public repository**, include URLs, accession numbers or DOIs. If this information will only be available after acceptance, indicate this by ticking the box below. For example: *All XXX files are available from the XXX database (accession number(s) XXX, XXX.).* • If the data are all contained **within the manuscript and/or Supporting Information files**, enter the following: *All relevant data are within the manuscript and its Supporting Information files.* • If neither of these applies but you are able to provide **details of access elsewhere**, with or without limitations, please do so. For example: *Data cannot be shared publicly because of [XXX]. Data are available from the XXX Institutional Data Access / Ethics Committee (contact via XXX) for researchers who meet the criteria for access to confidential data.*	We conducted a small, qualitative study that gathered sensitive data via in-person, in-depth interviews and field observation sessions. Our participants were VMMC stakeholders including VMMC policy professionals, clinical service providers (e.g., surgeons, nurses, infection prevention officers), VMMC and HIV counsellors, local school teachers, and VMMC client recruiters known as "mobilizers". Identification of participants through deductive disclosure could lead to harm, particularly harm to livelihood and reputation. To reduce the risk of deductive disclosure and protect the privacy and confidentiality of our research participants, we have revised our manuscript to be intentionally vague about the exact location of the study. However, if our data are made publicly available, even in an anonymized form, there remains a risk that the participating stakeholders and/or their employers (local NGOs that receive funding as "Implementation Partners" from PEPFAR, etc. to carry out circumcisions in Kenya) could be identified. This risk of deductive disclosure was our reviewers' top concern. As such, there are strong ethical reasons not to make our data publicly available. Based on advice from our Institutional Review Board (IRB), we have determined that we cannot make the data publicly available because we did not obtain consent from our participants to share their data for other research purposes. Contact information for the PIRE IRB is: Elysia Oudemans-Tilley, Director of Research Integrity and Compliance, PIRE, phone 301-755-2757, oudemans@pire.org.

The data underlying the results presented in the study are available from (include the name of the third party and contact information or URL). • This text is appropriate if the data are owned by a third party and authors do not have permission to share the data. * typeset	
Additional data availability information:	

Title: Voluntary medical male circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets

Short title: VMMC and unintended consequences of service-delivery targets in Kenya

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Abstract

Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female-to-male HIV transmission. Since 2007, VMMC has been a key component of the United States President's Emergency Plan for AIDS Relief's (PEPFAR) strategy to mitigate the HIV epidemic in countries with high HIV prevalence and low circumcision rates. To ensure intended effects, PEPFAR sets ambitious annual circumcision targets and provides funding to implementation partners to deliver local VMMC services. In Kenya to date, 1.9 million males have been circumcised; in 2017, 60% of circumcisions were among 10-14-year-olds. We conducted a qualitative field study to learn more about VMMC program implementation in Kenya.

The study setting was a region in Kenya with high HIV prevalence and low male circumcision rates. From March 2017 through April 2018, we carried out in-depth interviews with 29 VMMC stakeholders, including "mobilizers", HIV counselors, clinical providers, schoolteachers, and policy professionals. Additionally, we undertook observation sessions at 14 VMMC clinics while services were provided and observed mobilization activities at 13 community venues including, two schools, four public marketplaces, two fishing villages, and five inland villages. Analysis of interview transcripts and observation field notes revealed multiple unintended consequences linked to the pursuit of targets. Ebbs and flows in the availability of school-age youth together with the drive to meet targets may result in increased burdens on clinics, long waits for care, potentially misleading mobilization practices, and deviations from the standard of care.

Our findings indicate shortcomings in the quality of procedures in VMMC programs in a low-resource setting, and more importantly, that the pursuit of ambitious public health targets may lead to compromised service delivery, consent practices, and protocol adherence. There is a need to develop improved or alternative systems to balance the goal of increasing service uptake with the responsible conduct of VMMC.

INTRODUCTION

Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female to male HIV transmission.[1-3] Since 2007, VMMC has been a key component of the Joint United Nations Program on HIV/AIDS (UNAIDS) strategy for ending AIDS by 2030 and a top priority of the United States Agency for International Development (USAID) and the United States President's Emergency Plan for AIDS Relief (PEPFAR) to combat HIV in sub-Saharan Africa.[4, 5] Between 2007 and 2018, almost 19 million PEPFAR-supported circumcisions were performed in 14 priority World Health Organization (WHO) designated countries in eastern and southern Africa (ESA); 10% (more than 1.9 million) of these MCs took place in Kenya.[6] From early on, Kenya was ahead of other countries in VMMC scale-up, meeting 34% of its target in 2012 compared to 16% achieved by the next best country.[7] With a consistent record of meeting national VMMC uptake goals that sets it apart from other countries,[8] Kenya is often presented as a leading VMMC success story in ESA.[4, 9]

The United States (US), via PEPFAR, took an early lead in funding VMMC for HIV prevention programs in ESA. In 2016, PEPFAR spent over 15 million US dollars (USD) for VMMC services in Kenya alone.[10] These funds are distributed to VMMC implementing partners (IPs) in Kenya and other ESA countries to establish and maintain VMMC services within designated catchments in regions of high HIV prevalence and low levels of male circumcision (MC).[11, 12] These IPs include non-governmental organizations (NGOs), community-based organizations, faith-based organizations, or other non-profit or for profit entities. Each IP is accountable to its funding body via in-country intermediates and is required to keep accurate records and to make regular reports concerning the services provided, numbers of circumcisions performed, and observed adverse events.[13, 14]

As a part of this process, epidemiological model-informed quotas or "targets" are set by funders for the number of MCs to be performed within a given timeframe (e.g., annually). In 2016, 264,490 PEPFAR-funded MCs were performed in Kenya,[15] thus exceeding the 2016

target of 240,000 MCs.[16] In Kenya, PEPFAR has identified 11 VMMC underserved, priority counties.[16] In 2017, the coverage rates for 15-29 year-old males among all priority counties were reported to be approaching or to have reached 80%,[16] though more recent studies have called into question these coverage estimates.[17] To achieve this goal of 80% MC coverage within all these underserved areas by 2019, PEPFAR Kenya set a target of 300,000 new MCs in 2017, a 25% increase from the 2016 target.[16] In 2014, Kenya began offering VMMC services to boys aged 10-14 years citing "high demand for MC amongst this age group", cultural preference, and pre-sexual debut and/or less sexual activity as the rationale.[18] Between October 2016 and September 2017, 227,272 PEPFAR-sponsored MCs were performed in Kenya; 60% of these were among boys aged between 10-14 years, 23% were among 15-19 year-olds, and 14% were among 20-29 year-olds.[15] Among all priority-designated counties in Kenya, UNAIDS estimates cited by PEPFAR suggest that an additional 290,000 MCs may be needed to achieve 80% MC coverage among 10-29 year-olds, or an additional 500,000 to achieve 90% coverage by 2021.[16]

Previous research has highlighted ethical and practical concerns associated with VMMC implementation for HIV prevention.[19] Among school-going adolescent and young adult males in ESA, these concerns include recruitment practices (referred to as mobilization in VMMC programs),[20] consent and assent,[21] and access to follow-up care.[22] Additional issues include adolescent understanding of VMMC's purpose,[23] MC's relevant benefits and risks,[21, 24, 25] and the importance of HIV protective behaviors following circumcision.[26] A 2014 assessment of VMMC quality of care across four countries (Kenya, South Africa, Tanzania, Zimbabwe) identified deficiencies including providers' failures to adhere to national VMMC best-practice guidelines and a lack of equipment and supplies at VMMC clinics.[27] Similarly, a 2017 report prepared for review by USAID identified multiple "quality gaps" in VMMC implementation, including adverse events, low client follow-up rates, and inconsistent messaging to clients.[28]

During research for a parent study on the responsible conduct of HIV research in adolescent populations in Kenya we received anecdotal reports from local health leaders and community stakeholders that raised concerns about the ethical implementation of VMMC among adolescents. Given the known ethical and practical concerns linked to VMMC implementation across ESA, we set out to conduct a qualitative study to learn more about VMMC practices "on the ground" in Kenya. Presented below, an analysis of the qualitative data we collected revealed that the pressure to meet funder-set service-delivery targets appear to generate some unintended consequences concerning the services provided and/or standards maintained by VMMC IPs.

METHODS

HIV prevalence in Kenya in 2017 was 4.8% overall among individuals aged 15–49, with a range at the county level of between 0.1% and 21.0%.[29] This study was conducted in an area of Kenya with elevated rates of HIV and historically low uptake of MC. From March 2017 through April 2018, we conducted in-depth interviews with 29 VMMC stakeholders (21 males and 8 females), including schoolteachers, program recruiters (known locally as "mobilizers"), HIV counsellors, clinical providers, and policy professionals (e.g., local VMMC technical advisors). Table 1 lists these stakeholder interviewee categories, the number of stakeholders from each IP or school, and descriptions of each category's role or links to VMMC program implementation. In addition to these interviews, we conducted field observation sessions at VMMC clinics located in the research area.

Table 1. Stakeholder interviewee categories, number of interviewees' and their employers, and descriptions of stakeholders' involvement in VMMC.

Stakeholders	Interviewees/ employers	Involvement in VMMC
School teachers N=6	5 primary schools and 1 high school	Many adolescents are mobilized for VMMC at school; teachers facilitate access to students for VMMC mobilizers, are a source of information for students and parents, and often help to distribute and collect consent forms.
Mobilizers N=9	IP A: 5 IP B: 3 IP C: 1	Mobilizers are recruiters of VMMC "clients" (individuals who receive VMMC services). They are paid to conduct informational outreach activities, including "health talks" in schools, and to ensure that VMMC facilities have access to adequate numbers of clients to meet targets.

Counselors N=4	IP A: 2 IP B: 2	VMMC counsellors inform boys about VMMC benefits and risks, as well as post-circumcision wound care and healing best practices. They oversee consent and assent and conduct HIV counselling and testing.
Clinical providers N=7	IP A: 4 IP B: 1 IP D: 1 IP E: 1	Clinical providers perform circumcisions and provide post-procedure care, at VMMC facilities. These include clinical officers (surgeons), nurses, and infection prevention officers. Nurses assist clinical officers during circumcisions. Infection prevention officers oversee the surgical instruments, sanitary practices, and waste collection and disposal.
Policy makers N=3	IP A: 1 IP B: 1 GOK: 1	Policymakers are individuals involved in, or with in-depth knowledge concerning, VMMC practices and policies in Kenya.

VMMC, Voluntary Medical Male Circumcision; IP, Implementation partner; GOK, Government of Kenya.

To recruit stakeholders for interviews, our Community Liaison Officer asked for assistance from authorities at the regional Ministry of Health, Ministry of Education, and Health Department. Additionally, we sought approval from six VMMC IP NGOs to conduct interviews with their staff members and observation sessions at their clinics (see Table 1). Two of these IPs approved our request to conduct interviews and observation sessions (IPs A and B). Three of these IPs gave their approval for interviews but declined our request to conduct observation sessions (IPs C, D, E). One IP declined to approve both interviews and observation sessions. These authorities and IPs assisted us to identify local VMMC professionals with at least three years of experience related to policy, clinical services, counselling, or mobilization. In turn, VMMC mobilizers helped us to identify teachers involved with in-school VMMC mobilization activities referred to as "health talks". Once identified, our Community Liaison Officer and study coordinator (FSO) contacted potential participants in person or via telephone and inquired regarding their willingness to take part in an interview. Out of the 38 stakeholders contacted, 32 agreed to take part in an interview; of these, 29 were available to attend the interview. Out of the 23 mobilizers, counsellors, clinical providers, and policy professionals interviewed, 12 were employed by IP A, seven by IP B, one by IP C, one by IP D, and one by IP E (see Table 1). An additional policy professional interviewee was employed by the Government of Kenya. The six teachers we interviewed came from five different local primary schools and one high school.

Based on preliminary fieldwork in the region in 2016, we developed interview guides for each stakeholder category via an iterative process that relied heavily on the input and experience of our Kenyan team members (WKL, BO, FSO, DK). These guides included questions related to careers, roles, and experiences with VMMC, use of targets/quotas, clinical/mobilization protocols and practices, record keeping/documentation, informed consent, HIV testing, benefits and risks, training, the structure/hierarchy of VMMC IP organizations, and remuneration (see S1 Interview Guides).

Study participation was voluntary, and all participants gave consent before interviews began. Stakeholder interviews were conducted by AG in English (Swahili and English in one interview). These interviews took place in quiet, secluded locations, lasted up to 90 minutes, and were audio-recorded with permission. Kenyan team members who are fluent in English, Swahili, and the local language listened to the audio-recorded interviews and translated and transcribed them in English. The transcription process involved three steps. First, audio-recorded interviews were transcribed verbatim. Second, the transcriber conducted quality assurance by reading the transcript while re-listening to the audio. Third, the transcriber submitted the English transcript and the audio file to the Study Coordinator (FSO) for final review and designation as the final version of the transcript. Any portions of interviews that contained Swahili were first transcribed in Swahili before being checked, translated to English, and rechecked for accuracy by the Study Coordinator. Each interviewee received 500 Kenyan shillings (approximately 5 USD) for their time and transportation.

A Kenyan nurse and public health worker who is knowledgeable about VMMC clinical procedures and is fluent in English, Swahili, and the local language (BO) was our primary field observer. He conducted two- to five-hour observation sessions at 14 VMMC clinics run by the two NGOs (six administered by IP A and eight by IP B) and alongside the mobilization team activities at 13 community venues (six from IP A and seven from IP B). These venues/activities included two schools (health talks), four public marketplaces (mobilization

among local motorcycle taxi drivers), two fishing villages (informational speeches, music, skits; referred to as "roadshows"), and five inland villages (door-to-door adolescent mobilization). The nurse/public health worker documented what he observed in detailed field notes. A medical anthropologist (AG) supervised observation activities.

We identified four health facility levels (levels 2, 3, 4, and 5) for VMMC observation. Level 2 facilities include dispensaries and small clinics usually run by nurses that provide basic outpatient care to up 10,000 people. Level 3 facilities are health centers that serve populations up to 30,000 and are staffed by midwives, nurses, clinical officers, and occasionally doctors. They provide basic curative and preventive, minor surgical and reproductive health services. Level 4 facilities are primary, high-volume referral hospitals that serve populations of 100,000 people. Services offered include curative and preventive care and surgeries and emergency services that are not available at smaller facilities. Level 5 facilities serve larger populations. They focus on specialized services and provide clinical supervision and support to lower level, primary referral facilities.[30, 31]

Our Kenya-based research team selected VMMC clinics to ensure that we conducted observations at a variety of facility levels in various sub-counties, as well as during relatively active (more than 30; up to 100 or more) and slow periods (less than 15) circumcisions per day. Out of the 14 VMMC facilities we observed, two were Level 2, six were Level 3, five were Level 4, and one was Level 5. Upon arrival at each facility, BO, our Community Liaison Officer, or our Study Coordinator (FSO) informed facility staff members about our research and provided them with details concerning their IP's approval for our observations to take place before they gave verbal consent. Observation sessions tended to coincide with the arrival of adolescent VMMC clients and their subsequent intake, counselling, testing, and circumcision. The mobilization teams associated with these clinics were identified and approached outside of the clinical setting for permission to observe their activities (e.g., mobilization events at schools or public markets). Before these observation sessions began,

members of the mobilization teams gave their verbal consent to be observed. Prior to beginning in-school observation sessions, school authorities and teachers were informed about the research and gave us permission to conduct the research activities.

The institutional review boards of the Pacific Institute for Research and Evaluation (PIRE) and the Kenya Medical Research Institute (KEMRI) approved all study activities, including all the informed consent procedures described above. Locally, the county-level Ministries of Health and Education and the directors of each IP gave us approval to conduct this research.

Analysis

Kenyan team members translated and transcribed the audio-recorded interviews and checked the final transcripts for accuracy. U.S.-based team members conducted an early analysis of interviewee transcripts and observation-obtained field notes. The potential for the pursuit of VMMC targets to contribute to unintended consequences emerged during early data analysis. We created the codebook to define and identify themes related to the use of targets in VMMC policy and service delivery.[32] Two team members then independently reviewed and coded the full set of transcripts and field notes using MAXQDA 12[33]. Any coding discrepancies were discussed and resolved by the two coders. Code reports were produced and reviewed, and quotes were selected to illustrate typical responses for each theme. We present these quotes below, along with corroborating field observations, and participant demographics and identification numbers.

RESULTS

To meet VMMC quotas, local IPs communicate target numbers to their VMMC clinics and to the mobilizers who are responsible for supplying these clinics with clients to circumcise. The numbers of adolescent clients who undergo VMMC vary across the year, depending on the relative availability of clients and/or the ability of mobilizers to access them.

Implications of the pursuit of VMMC targets

Data collected from the stakeholder interviews and field notes suggest that funder-designated targets for VMMC service delivery effectively motivate mobilizers and clinic staff. As one 33-year-old, male mobilization supervisor put it, "…target or quotas act as the engine to make us do a lot of work and ensure that there is continuous [flow of clients]" [Mobilizer 1]. For mobilizers especially, monthly remuneration (and their future employment) depends on referring enough clients to the clinic each week; failing means earning less, regardless of the amount of time and effort invested in mobilization. From our interviews we learned that while most mobilization supervisors receive a base salary from their IPs regardless of the targets, other lower-level, subcontracted "associate" mobilizers or "peer educators" only receive payment by providing clients and meeting targets. Describing the competition this system fosters among mobilizers, a 28-year-old, male community-level mobilizer explained, "…we are paid upon reaching the target […] so we are really competing, until somebody may grab your clients before you know it" [Mobilizer 2]. For VMMC clinics, achieving targets is essential to the continued funding of their respective IPs. A 49-year-old, male mobilization supervisor offered, "…targets… are about funding, and [if] you don't reach your target, you don't get funding" [Mobilizer 3]. However, data analysis revealed that beyond motivating staff members, the pursuit of targets may introduce problems for VMMC implementation. Presented below, these areas of concern relate to the ebb and flow periods of VMMC client availability (referred to with reference to agricultural "seasonality" elsewhere),[34, 35] and the resulting increased burdens on clinic resources and staff, long waits for clients, potentially misleading or problematic mobilization practices, including possibly undue inducements) questionable uses of social pressure, and circumcision of children under age ten. By undue inducements, we mean benefits (monetary or non-monetary) that are used to motivate prospective participants (in this case adolescents or young adults) to join a study—benefits that may be inappropriate because of their potential to distort a participant's understanding

of the study.[36] A final issue that we link to the pursuit of targets is the reduced quality of clinical care.

Variations in VMMC client availability: "high and low seasons"

Adolescent client availability for circumcision rises and falls throughout the year, primarily due to school schedules: schools do not allow VMMC mobilization to take place on school grounds near the time of exams or other especially busy periods in the year. This results in "high" and "low" seasons for VMMC among these age groups. As Mobilizer 1 explained:

> There are times when they are having exams, or when exams are approaching, or when there is athletics or ball [soccer]; when those are taking place, we don't get people coming… we end up having zero clients cut [circumcised]. And you know, when there are zero clients cut, all the pressure comes to the mobilization supervisor because the surgeons will be saying, 'We are ready to cut, where are the clients?' So the buck stops on me as the mobilizer; so it is not a very easy task.

Likewise, a 30-year-old, female mobilization supervisor offered, "We bank on schools so much. And now, when they are taking their exams, you can't pick a child from school [….] …when schools are so engaged, then definitely I will not meet that target" [Mobilizer 4]. Recognizing the need to strategize VMMC service provision around local school schedules (and client availability), some IPs may institute "Rapid Results Initiatives" or similar short-term drives aimed at increasing dramatically the number of MCs conducted during school holidays.[9, 37] If funding is insufficient, or if IPs are otherwise unable to commit the resources (e.g., personnel, transportation, clinics, and medical supplies) needed for these drives, then targets may go unmet.

Increased burden on VMMC facilities and staff

VMMC clinical teams are generally comprised of at least one surgeon, surgical assistant, counsellor, and infection prevention officer. During the high season, efforts to meet targets may push some teams to circumcise more clients than the approved quota to be conducted per day per team. In 2015, this limit was 15 circumcisions per day.[18] In 2018, we observed an IP internal document dated December 2017 that was posted to the wall in a public space

of one of the clinics in which we conducted observations. This memo made clear that the IP was aware that "some teams are circumcising over and above the safe maximum number of clients per team" and that this limit is 25 clients per day. During one observation session on a high season day at a Level 4 facility, we counted over 100 boys waiting to be circumcised at a clinic with four surgical beds. At this same facility in the low season, less than half this number may be circumcised in a month (see Fig 1). On days when an unexpectedly high number of boys are mobilized for circumcision, VMMC teams may be left scrambling to call in additional staff. As one 39-year-old, male Clinical Officer explained: "If the number is high, you have to get those who are locum [temporary, fill-in staff]; for instance, like today, if the number is beyond 60 you have to get those for locum because one counselor cannot handle 60 clients. So we do arrangements prior and we talk to the office and ask them to give us assistance [Provider 1]"

Fig 1. VMMC Progress Chart for 2017 displayed on the wall of a clinic.

Referred to as "moonlighting" by our interviewees, VMMC staff may sometimes work extra hours, late into the evening, and/or over weekends or holidays when they would not normally be expected to work (for which they receive extra compensation) in order to handle large client loads, meet current targets, or make up for previous months when a lack of clients meant targets were missed. One 33-year-old, female counselor explained, "Yeah, you are put into pressure and you have to get the targets. We always know we have to get our targets, come what may. So we do moonlight to get those targets" [Counselor 1]. Similarly, a 39-year-old male Clinical Officer told us: "…if the number is high sometimes we can extend to weekends; and based on the clients flow like now… schools are going to be closed, and hence the number of clients is going to be high. So tomorrow [Good Friday] we may work" [Provider 2].

While severe adverse events (AEs) beyond minor swelling, bleeding, or infection are rare,[38] when they do occur a few of our interviewees suggested that provider fatigue may

be a contributing factor. Referencing one case, a 42-year-old male VMMC Clinical Officer offered:

> Then the other factor is the high numbers given as targets annually. So if you look at the number of clients you should do, you get fatigued along the line because remember you stand all day. So if you do 20 clients or 25 clients in a day, every day, say from Monday to Friday, it is a hell of a tiresome job…. So most of those AEs [are] attributed to fatigue, because if you look at the timings of most of the AEs, it is usually late in the evening, after lunch, afternoon; so it has always been attributed to high volume in terms of target, and then fatigue, then people not following the protocol. You find somebody, because he wants to finish faster, they want to split [meaning the surgeon and the assistant each operate on their own] instead of [following] MC protocol [and working together]…. It reaches a point where you have to split where everyone is doing [operating alone] because the number is high…. [Provider 3]

Long waits at VMMC clinics

Another unintended consequence of targets for school-aged clients is the long waits they may experience at VMMC clinics before and after MC, especially during the high season. Despite mobilizer claims about the short duration of the procedure, inadequate numbers of vehicles to transport boys, rough road conditions (especially during the rainy season), and sometimes understaffed and under-resourced VMMC clinics mean that adolescents may spend hours waiting to be circumcised and then to be ferried back home. While making observations at one Level 3 facility, boys arrived for circumcision at approximately 8am; due to the staff's late arrival (and possibly understaffing), circumcisions began at 12.30pm. At 4.15pm, when we left, these children were still waiting at the facility for transportation home. Some of the children were crying and saying that they want the pain "to find them at home". One child stated, "We were told it will only take 20 minutes. This is not 20 minutes!" According to one 32-year-old, male primary school teacher, "…one day I attended a facility and [found] that a number of people are to be cut, but the officers who are doing this are just two. So they will do it up to very late [in the evening] and these boys are just there hungry, just with one bottle of soda which will not sustain them" [Teacher 1].

Suggestions of misleading or questionable mobilization practices

Data collected during interviews and observations suggest that the drive to meet targets may lead some VMMC mobilizers to use misleading or otherwise questionable mobilization

practices to increase the number of adolescents they can refer for circumcision. As Mobilizer 1 explained:

> Another thing is the peer mobilizers, yeah, someone wants to meet his or her targets and that is the time that they engage in what I called the uncouth methods, whereby the end justifies the means; whichever means that can make those clients come out. So you end up having the clients coming, but they are not coming for the VMMC the way we want it. They have been pushed; they have been coerced…yeah. This one is happening because of these targets. So that is the downside of the targets.

These practices are sometimes blatant: during one door-to-door village mobilization, the mobilizer kept referring to himself as "doctor" although he had no medical training. Another mobilizer, a 38-year-old male who referred to himself as a "VMMC champion" explained how he pays boys to help him mobilize their friends:

> For us we are calling it 'broking [brokering] system'. So after the exercise, you tell him to go… and convince a friend and bring a friend… [….] For me I am using my own system being that we are not even allowed to give children money. But for me, because I have a target, and if I get my target, I am expecting 10800 KES [108 USD]. So I do divide this 10800 KES; maybe if he brings me two boys, I can give him up to 50 KES. I can even give out 100 KES [1 USD]. The moment I give that money, 50 bob, to that boy, he is going to bring me more four boys. So the more he bring boys for instance if they are four, I give 100-150 KES. At the end of the day, I will hit my target [Mobilizer 5].

Other times, these practices are subtler and easy to overlook. During a promotional skit in which mobilizers played the roles of a husband, wife, and brother all discussing VMMC, the message to the audience was one of strong female preference for circumcised men. The wife told her husband, "Go and cut your *firimbi* [whistle] … go and remove that sleeve of a sweater. That whistle is not going inside me…don't blow the whistle inside me. I have refused…. I am not giving you [sex]." Later, when the husband's brother arrived, he explained that his wife is refusing to have sex. In response, his brother said, "I was passing here to tell you to go for circumcision. Look at me, I have gone and I am fine. I am now a clean person. Do you want your wife to conceive and have children?" Explaining the benefits, his brother offered that MC reduces HIV risk by 60% and enhances cleanliness ("you avoid smelling") and prevents cervical cancer ("women whose husbands have been circumcised don't get cervical cancer").

While VMMC does reduce HIV incidence rates by 60%[39-41] or more,[42, 43] it is misleading to suggest that MC inherently reduces an individual's risk of infection by 60% if the differences between absolute and relative risk are left unexplained. Similarly, while studies suggest that female preference for circumcised males exists,[44-46] it may also be misleading to generalize about female preferences during recruitment efforts. Furthermore, though MC does reduce the risk of human papillomavirus transmission from men to women, thereby reducing their risk for cervical cancer,[47] it is false to claim that women whose husbands are circumcised do not or cannot get cervical cancer.

This practice of emphasizing the benefits (including reducing the time needed to bathe and risk of acquiring penile cancer) and incentives related to MC while downplaying the risks was common among our participants. The most commonly discussed risks included temporary pain, minor swelling, and bleeding, while the Government of Kenya VMMC consent form (see S2 Government of Kenya consent form) in use at this time lists risks including bleeding, swelling, pain, infection, injury, numbness, sensitivity loss, mutilation, amputation, and HIV infection. These latter, more severe but rarer adverse events did not feature in the health talks and other mobilization activities we observed.

According to interviewees, food, money, water, sanitation, clothing, and other basic needs are issues of concern for many adolescents' households. During health talks, some mobilizers emphasized the incentives that boys will receive (e.g., sodas and/or new underwear) following circumcision—items that may be significant inducements among impoverished children. During a village mobilization effort, one mother explained her reluctance to let her son be circumcised: "…this one is small. Even his heart was there because those who have come from circumcision are 'seducing' their friends to go also. They are telling them, 'go and it is not painful.' They are also giving people sodas. So that soda is what brings them nearer. I told this boy not to sneak, but to wait and I will take him there…." Offering a similar analysis, Provider 3 told us:

> Sometimes they also entice them for us; in the facility we give them a bottle of soda, Fanta to be specific because one, some of the boys come probably from poor families, they haven't had a meal in the morning or breakfast and sometimes stay in the clinic for more than two hours, three hours and thus to maintain their sugars. [But] that one [soda] becomes a bait, especially for the young ones "We will give you a soda; we pick you with a vehicle" …which is actually wrong because, it is like enticing a client which you are not supposed to, but that is how they [mobilizers] ply their trade.

However, according to our interviewees and as we observed first hand, clinics sometimes lack sodas and/or underwear to give to clients.

Social pressure

All six of the teachers we interviewed recognized social pressure as a primary motivator for MC among adolescents. During observations of mobilization activities, we saw firsthand how mobilizers sometimes make use of or encourage peer pressure to promote circumcision, including through the use of abusive and/or stigmatizing language. During a health talk in front of a large group of boys at a primary school, one male mobilizer referred to foreskins as the "sleeve of a sweater" and "cold *matumbo*" [boiled goat intestines]; at the end of the talk, he implored those who still had their "whistles" to have them removed. He also told them: "Those who are still having the foreskin, you are the ones who are going to spread the diseases. In the future, you are the ones who are going to spread the HIV virus." Later that same day, the mobilizer asked a large group of older students," How many of you wish to get the HIV virus? If you don't want to get the HIV virus, the only option is to remove the foreskin." Revealing his awareness of this type of language and messaging within VMMC mobilization, Provider 3 explained:

> This is demeaning and they try to create some peer pressure. Like when you go to those mass cuts in high schools, probably they registered like 100 clients, you would likely get another probably 30 or so who, because of the peer pressure, just jump into it. But if it was like walking from home to hospital and demanding for the service, they are not likely to have gone. But now that it is here, and so and so has gone and is my friend, I have to be in it.

Circumcision of children

Current VMMC for HIV prevention guidelines and national protocols approved for use in Kenya require that adolescent clients must be at least ten years of age.[48] Despite this directive, interviews and observations confirmed that VMMC staff sometimes mobilize and

circumcise boys who are under ten years of age in order to boost their numbers to meet targets. When asked about potential links between targets, mobilizer strategies, and underage circumcision, Provider 3 offered:

> Yes, they bend the rules… because you know sometimes our current age according to WHO is 10 years and above. But when they [mobilizers] go to the field and get a nine-year-old for example, they coach this client and the parent, because we insist on seeing the consent. We always insist they put the ID and telephone number of the parent [on the consent form]. When they come to the facility, we [call to] confirm the age and whether the parent has consented for the child to be circumcised. And you know, they will tell you 'yes I am 10 years old', but when you look at the guy, he is probably 8 or....

We observed evidence for the mobilization of underage boys at ten of the 14 VMMC facilities we visited for observation, including boys (and their mobilizers) who readily admitted that they were underage. However, as Mobilizer 1 noted, age verification is not easy or straightforward in Kenya: "Yes, we have had some cases where children try to adjust their age. For instance, he is eight years old, but insists he is ten years old; and they are even able to calculate that they were born on this date and in this year. Being that we don't have a way to verify that… then later you realize that this boy is underage." Yet, during observations made during school health talks, as well as during community-based door-to-door mobilization activities, we frequently observed mobilizers not asking boys their ages, opting instead to ask for their class in school as a proxy for their age.

Reduced quality of clinical care

Under pressure to meet targets, some Clinical Officers and other VMMC medical staff find ways to speed up the clinical process. For example, as we were told during interviews and observed firsthand at multiple VMMC facilities, providers may opt not to take patient medical histories or conduct preoperative examinations (e.g., blood pressure, weight, preexisting conditions, etc.) and/or 30-minute post-operative check-ins, and yet fill in the requisite forms as if these activities had been completed. Other avenues for time-saving included, rushing circumcisions, inadequate stitching, splitting surgical utensil and bandage packs between patients, not following recommended protocols or procedures (e.g., the dorsal slit method for circumcision), and stacking patients one after another with little pause in between, which

raises additional sanitary and privacy concerns. According to an experienced VMMC surgeon:

> We cut a lot of corners and I will give you an example: […] so because of speed, you find that while one client is dressing [after circumcision], the other one is [already] undressing. Ideally, it is supposed [to be] that you finish with this client, you give [them] instructions on how to take medication and all that, but because of the high volume, you find that some of us we are not the ones giving out the medication. We assign somebody randomly, you know, who will be giving out the medication and the refreshment and so [the] information [they provide to the client] may not be correct. [….] Sometimes even the vitals of post-operation 30 minutes after [circumcision] are not done. It is skipped, or somebody else does [it] – probably a receptionist who is nonmedical, just to fulfill the requirements of the form. [This] is wrong because you are supposed to do the circumcision and the client rests for 30 minutes in a bed or a couch, then after that, you do the vitals then you discharge. Oh, even the wound care instructions, [that] information may not sink in for the client because it is presented so fast and there may not be [time] for questions. Yeah, there are so many corners we cut. [….] …at a clinic last year, I saw them hold that yellow form [medical files] and going through [and just] check, check, check… adding blood pressure, adding all these things, just filling them in [without actually measuring blood pressure, etc.]. [Provider 3].

One assistant surgeon, a 25-year-old female nurse, claimed her record time for completing a circumcision was six minutes. She too associated VMMC targets with client overload, and with rushing surgeries and an increase in adverse events. She explained:

> Sometimes you compete cutting clients and the clients are too much. The average time for a client's [circumcision] is between 12 to 20 minutes. So when the clients are too much, and you want to meet your targets, you will perform the surgery a bit fast. So upon that you will have [an] adverse event and maybe a child will come back with a bleeder [an oozing artery or other blood vessel] you did not close [suture] well [Provider 4].

Despite these concerns, it was beyond the scope of our study to determine whether an increase in major or minor adverse events was associated with high volume periods. This issue should be addressed by future research.

Target alternatives

When asked about possible improvements to VMMC implementation and potential alternatives to the use of targets, interviewees made two suggestions. The first was to move away from active VMMC mobilization toward more passive strategies like those used by sites that provide walk-in HIV testing services in Kenya. The second was to keep donor targets, but to lower them to make them more possible to achieve. As Mobilizer 1 put it, "[VMMC] should be a walk-in thing where people are circumcised at their time of

convenience…. Basically, I [don't] have problems with targets, but what I have issues with is the extremely large targets. A situation where the surgeon strains to meet the target. And I know when the surgeon is strained, the probability of having adverse events is high." Citing a similar alternative, as well as the implementation of more reasonable targets, Provider 1 offered:

> The targets will dilute VMMC as a practice because the number is overwhelming. Imagine if you start working at 8.00am and you want to do circumcision [until] around 10 pm… it is a long day. So targets should be at least reasonable. So from my side, I can talk about the targets, and the targets [should be] revised ….okay. Another thing is for instance… it should be incorporated to be like a clinic, in that if I come to the hospital I can even walk into the VMMC clinic. Not that I am being coerced to go for circumcision, but it should be part of us [an integrated part of the healthcare system]. You know the issue of targets is forcing people to go around looking for (clients) per day. It should be like a TB clinic. Yeah, like a walk-in clinic. So anybody can just come at his own time.

Yet another provider, when asked about the effects of targets on mobilizers, made comments that suggest the importance of improved communication as a means to decrease target burden on mobilizers for the benefit of all: "They [mobilizers] are a bit intimidated [by high targets]. So when they [VMMC technical advisors, program coordinators, etc.] set targets without consulting them, sometimes they even go slow and yeah, it affects our performance [numbers of clients to be circumcised]" [Provider 4].

DISCUSSION

Much effort has been made in epidemiological modelling of VMMC to determine who, when, and where to circumcise, and how many circumcisions will be necessary in order to curb the ESA HIV epidemic.[49-55] Yet in South Africa and elsewhere, studies have indicated that the pursuit of targets (for uptake of combination antiretroviral therapy) may be at odds with quality of care.[56] This study identifies multiple unintended consequences linked directly or indirectly to the use of targets in VMMC services in Kenya. As detailed above, these include pressures associated with VMMC client availability, extra burdening of facilities, overworked clinical staff, deviations from the standard of care, and long waits at the clinic.

In 2008, soon after the randomized controlled trials on HIV and male circumcision, and in advance of global efforts to implement VMMC, UNAIDS issued guidance for program decision-makers on human rights, ethics, and legal considerations.[57] This guidance advocates for a human rights based approach to the implementation of VMMC programs that ensure that the procedure is carried out safely, under conditions of informed consent, and without coercion or discrimination. On this basis, the UNAIDS guidance also explicitly states that, "target numbers of procedures, incentives to men, and incentives to providers should be avoided."[57] Similarly, PEPFAR guidelines have cautioned IPs against using targets to motivate mobilization or tethering VMMC remuneration to the number of procedures performed in order to avoid coercion.[13] According to the latest version of these guidelines, PEPFAR funded IPs who reward mobilizers are:

> …required to reward a team of mobilizers… so that any reward is based upon collective (versus individual) success. [This] approach limits the likelihood of coercion by separating any immediacy of reward resulting from an individual mobilizer referring a particular client. Mechanisms that further minimize perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.[14]

Despite these guidelines, our data suggest that this stated preference for team rather than individual targets may be misplaced, or at least may not make as much of a difference as intended, since teams may still be incentivized to use misleading or otherwise questionable practices. While individual mobilizers may not receive an immediate payment on a per-client basis, they may be remunerated individually once they collectively (as a team) meet or surpass a given target. By coupling target achievement to remuneration, targets provide pressure to help ensure that adequate numbers of adolescent circumcisions take place. Yet perversely, target pressure sometimes leads mobilization teams and providers to choose ethically dubious, but rational strategies to increase uptake, reduce effort, and/or shorten circumcision times to accomplish more MCs per day. Unfortunately, such strategies carry potentially deleterious outcomes for the boys this intervention is intended to protect. Moreover, they may not be in keeping with the ethics and human rights values to which VMMC funders and IPs purport to adhere.

565 Such strategies may include the mobilization of preadolescent clients, imbalanced
566 discussions of benefits versus risks, abusive language and exploitation of social pressure to
567 drive demand, and even dangerous shortcuts (e.g., rushing surgeries). One solution might
568 involve increased efforts to ensure that target achievement is entirely uncoupled from staff
569 remuneration: mobilizers could draw salaries like the community health workers already
570 working in the same communities—salaries that do not depend on targets. However, future
571 research is needed to determine whether target alternative programs, such as the integrated
572 healthcare/walk-in clinic/passive models suggested by our interviewees, can achieve the
573 necessary number of MCs and do so without overly increasing costs. Indeed, efforts in
574 Zimbabwe to integrate VMMC services into routine healthcare are encouraging,[58] and
575 endeavors to integrate VMMC services in Kenya are already planned.[48] Yet, the
576 performance based financial incentives used in Zimbabwe have been shown to be
577 problematic[59] and our data suggest that this model would lead to similar issues in Kenya.
578
579 Concerning mobilizer messaging, others have previously criticized the PEPFAR-endorsed
580 tactic of claiming as a "key message"[13] the benefit of a "60% reduction" in HIV risk.[20, 60-
581 63] During observations of VMMC mobilization activities in our study area, it became clear
582 that few mobilizers and adolescent clients truly understood what the cited 60% reduction
583 statistic would mean for them. More often, adolescents seemed confused and asked
584 mobilizers to explain the "missing 40%". Although some researchers have suggested moving
585 beyond VMMC mobilization messages that emphasize HIV risk reduction to those that focus
586 on a spectrum of benefits, including "hygiene, appearance, attractiveness to partners, peer
587 norms, and modernity",[64] our data suggest that mobilization strategies that rely on peer
588 pressure may be equally problematic. For instance, is it ethical (or accurate) to suggest that
589 to be circumcised is to be "modern" when less than 40% of men globally are circumcised
590 and only a few high-income countries, including the US, have relatively high rates of MC [65,
591 66] (and even in the US, rates of MC have been falling)?[67-69] For similar reasons, the
592 practice of public health workers persuading boys to become circumcised by claiming that

their future female partners will definitely prefer them that way (and reject them if they are not) should be questioned if not discouraged.[45] In an effort to improve VMMC messaging, future studies could test the effectiveness of providing mobilizers with training in ethical conduct, as well as on the benefits versus risks of MC and how fairly and effectively to communicate this information to adolescents.

The practice of using in-school health talks for VMMC mobilization warrants special ethical scrutiny. Not only do teachers and other school authorities often attend these talks—individuals who may have undue influence over boys' circumcision decisions—but the group-based nature of the talks, and the openness with which adolescent circumcision status is discussed and mobilization takes place, make these environments ripe for coercion. Recruitment of students for research in schools by teachers and other school authorities is discouraged by ethicists for similar reasons.[70] One possible solution might be to separate health talks from VMMC recruitment: mobilizers could conduct health talks one day and schedule a day to return. In a private setting on this second day, mobilizers could answer boys' questions, discuss consent and assent, and take down the details of any boy who would like to proceed with MC.

In January 2019, our research team presented study findings to policy professionals and program officials at a VMMC stakeholder meeting in Kenya. In the discussion that followed, we considered various solutions to the ethical and practical concerns highlighted here. One strategy we discussed to address the problem of high and low seasons of client availability and improve the quality of care provided at VMMC clinics was for funders and IPs to collaborate to develop "smart targets" that rise and fall with low and high seasons to match more efficiently resources and mobilization efforts to client demand and availability. As a part of this process, IP technical advisors could also work closely with school administrators in their catchment areas to find ways to conduct more MCs throughout the school year while minimizing the impact on educational activities and progress. Stakeholders also recognized

621 that the training and awareness of mobilizers, counsellors, and clinic staff needs to be
622 strengthened and that quality assurance measures should be enhanced and better
623 monitored. Future studies should test the cost and feasibility of improving these aspects of
624 care under real-world conditions.

625

626 **LIMITATIONS**

627 This is a qualitative study with very limited generalizability. Although we used purposive or
628 convenience sampling methods in this study, efforts were made to select facilities of various
629 sizes (levels 2-5), and to work equally with VMMC clinical staff and mobilization teams from
630 both IP organizations. In addition, we conducted mobilization and clinic observation sessions
631 during both the "high" and "low" VMMC seasons, including separate visits to a Level 3 and a
632 Level 4 VMMC clinic on high and low volume days.

633

634 This study relied on in-depth interviews and clinic observations. As in most qualitative
635 studies of this kind, interviewee responses could be subject to social desirability bias. While
636 we cannot exclude entirely the possibility of this bias, we made clear that we were only
637 interested in interviewees' honest recollections of, and reflections on, their VMMC
638 experiences. Moreover, the fact that interviewees were often critical of VMMC practices and,
639 for instance, in the case of some clinical providers, admitted to cutting corners in care
640 suggests that this type of bias may be less of an issue in this study.

641

642 Finally, our presence as observers at VMMC facilities and during mobilization activities may
643 have changed the behavior of staff members and clients. We anticipated this possibility early
644 on and in response, chose a two-pronged approach method (i.e., in-depth interviews and
645 observations) to ensure the quality of data. This potential bias was also considered during
646 data analysis and presentation for publication. For instance, all findings based on
647 observations were cross-verified by data from in-depth interviews, and vice versa.

CONCLUSION

When VMMC for HIV prevention first began to be implemented in ESA, much attention was paid to the ethical, human rights, and legal considerations by the organizations that were (and are) involved in it. Since then, much of the discourse has been replaced by programmatic and technical guidance concerning how best to meet ambitious VMMC targets, with less attention to the broader effects of pursuing targets in the field. As our research shows, those considerations have not gone away. VMMC funders, governmental organizations, and IPs remain strongly committed to human rights and ethical values in the pursuit of public health goals. As such, they have a robust interest in information about how VMMC programs are implemented on the ground in Kenya and across ESA. These ethical considerations should be given more weight in future research and in the routine quality assurance checks conducted by IPs and funders, and where feasible, by independent authorities.

Further research is required to consider more fully the benefits versus risks associated with targets in mobilization activities and to develop improved or alternative systems through which to drive VMMC uptake. While PEPFAR already monitors VMMC clinical standards and practices (including recordkeeping) through the Site Improvement through Monitoring (SIMs) scheme, future partnerships between funders, IPs, and local civil society organizations could be fostered or strengthened to avoid the unintended consequences noted above and to ensure that clients receive the best of available care. At a minimum, funders and governmental authorities should take on more target-setting input from IPs, including mobilizers and other staff on the ground, in an iterative and ongoing way. While it may not be reasonable or wise to call for the complete abandonment of the use of targets, given their necessity to intervention modelling and program budgeting, it is justified to be more critical of their use and aware of their potential unintended consequences.

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References

1. Weiss HA. Male circumcision as a preventive measure against HIV and other sexually transmitted diseases. Current Opinion In Infectious Diseases. 2007;20(1):66-72. PubMed PMID: 17197884.
2. Sharma SC, Raison N, Khan S, Shabbir M, Dasgupta P, Ahmed K. Male circumcision for the prevention of human immunodeficiency virus (HIV) acquisition: a meta-analysis. BJU International. 2018;121(4):515-26. doi: 10.1111/bju.14102. PubMed PMID: 128818736.
3. Fink AJ. A possible explanation for heterosexual male infection with AIDS. The New England journal of medicine. 1986;315(18):1167-.
4. Reed JB, Njeuhmeli E, Thomas AG, Bacon MC, Bailey R, Cherutich P, et al. Voluntary Medical Male Circumcision: An HIV Prevention Priority for PEPFAR. Journal of acquired immune deficiency syndromes (1999). 2012;60(0 3):S88-S95. doi: 10.1097/QAI.0b013e31825cac4e. PubMed PMID: PMC3663585.
5. Hines JZ, Ntsuape OC, Malaba K, Zegeye T, Serrem K, Odoyo-June E, et al. Scale-Up of Voluntary Medical Male Circumcision Services for HIV Prevention - 12 Countries in Southern and Eastern Africa, 2013-2016. MMWR Morbidity And Mortality Weekly Report. 2017;66(47):1285-90. doi: 10.15585/mmwr.mm6647a2. PubMed PMID: 29190263.
6. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR Panorama Spotlight Washington, D.C.: PEPFAR; 2019 [cited 2019 11 June]. Available from: https://data.pepfar.gov/.
7. Reed JB, Njeuhmeli E, Thomas AG, Thomas AG, Bacon MC, Bailey R, et al. Voluntary medical male circumcision: An HIV prevention priority for PEPFAR. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2012;60(Suppl 3):S88-S95. PubMed PMID: 2012-20414-003.
8. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Kenya Country Operational Plan (COP/ROP) 2018 Strategic Direction Summary. Washington, D.C.: 2018.
9. Mwandi Z, Murphy A, Reed J, Chesang K, Njeuhmeli E, Agot K, et al. Voluntary medical male circumcision: translating research into the rapid expansion of services in Kenya, 2008-2011. Plos Medicine. 2011;8(11):e1001130-e. doi: 10.1371/journal.pmed.1001130. PubMed PMID: 22140365.
10. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR 2018 Annual Report to Congress. In: PEPFAR, editor. Washington, D.C.2018.
11. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR Country/Regional Operational Plan (COP/ROP) Guidance 2017. Washington, D.C.: U.S. Department of State, 2017 18 January 2017. Report No.
12. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR 2018 Country Operational Plan Guidance for Standard Process Countries. Washington, D.C.: 2018.
13. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR best practices for voluntary medical male circumcision site operations: A service guide for site operations. PEPFAR Washington, DC; 2013.
14. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR's best practices for voluntary medical male circumcision site operations: A service guide for site operations. 2nd ed. Washington, D.C.: PEPFAR (U.S. President's Emergency Plan for AIDS Relief),; 2017.
15. Davis SM, Hines JZ, Habel M, Grund JM, Ridzon R, Baack B, et al. Progress in voluntary medical male circumcision for HIV prevention supported by the US President's Emergency Plan for AIDS Relief through 2017: longitudinal and recent cross-sectional programme data. BMJ open. 2018;8(8):e021835.
16. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Kenya Country Operational Plan (COP) 2017: Strategic Direction Summary. Washington, D.C.: Services UDoHaH; 2017 21 April 2017. Report No.
17. Kripke K, Opuni M, Odoyo-June E, Onyango M, Young P, Serrem K, et al. Data triangulation to estimate age-specific coverage of voluntary medical male circumcision for HIV prevention in four Kenyan counties. PloS one. 2018;13(12):e0209385.

18. National AIDS and STI Control Program (NASCOP). National Voluntary Medical Male Circumcision Strategy 2014/15 - 2018/19. Nairobi: Government of Kenya, 2015.
19. Rennie S, Muula AS, Westreich D. Male circumcision and HIV prevention: ethical, medical and public health tradeoffs in low-income countries. Journal Of Medical Ethics. 2007;33(6):357-61. PubMed PMID: 17526688.
20. Masukume G. The ethics of claiming a 60% reduction in HIV acquisition from voluntary medical male circumcision. South African Journal of Bioethics and Law. 2014;7(1):4-.
21. Friedland BA, Apicella L, Schenk KD, Sheehy M, Hewett PC. How informed are clients who consent? A mixed-method evaluation of comprehension among clients of male circumcision services in Zambia and Swaziland. AIDS And Behavior. 2013;17(6):2269-82. doi: 10.1007/s10461-013-0424-1. PubMed PMID: 23392912.
22. Schenk KD, Friedland BA, Sheehy M, Apicella L, Hewett PC. Making the cut: Evidence-based lessons for improving the informed consent process for voluntary medical male circumcision in Swaziland and Zambia. AIDS Education and Prevention. 2014;26(2):170-84. doi: 10.1521/aeap.2014.26.2.170. PubMed PMID: 2014-13016-007.
23. Kaufman MR, Dam KH, Van Lith LM, Hatzold K, Mavhu W, Kahabuka C, et al. Voluntary medical male circumcision among adolescents: a missed opportunity for HIV behavioral interventions. AIDS (London, England). 2017;31 Suppl 3:S233-S41. doi: 10.1097/QAD.0000000000001484. PubMed PMID: 28665881.
24. Schenk K, Friedland B, Apicella L, Sheehy M, Munjile K, Hewett P. On the cutting edge: Improving the informed consent process for adolescents in Zambia undergoing male circumcision for HIV prevention. Vulnerable Children and Youth Studies. 2012;7(2):116-27. PubMed PMID: 27370100.
25. Kaufman MR, Patel EU, Dam KH, Packman ZR, Van Lith LM, Hatzold K, et al. Counseling Received by Adolescents Undergoing Voluntary Medical Male Circumcision: Moving Toward Age-Equitable Comprehensive Human Immunodeficiency Virus Prevention Measures. Clinical Infectious Diseases. 2018;66:S213-S20. doi: 10.1093/cid/cix952. PubMed PMID: 128906093.
26. Kaufman MR, Patel EU, Dam KH, Packman ZR, Van Lith LM, Hatzold K, et al. Impact of Counseling Received by Adolescents Undergoing Voluntary Medical Male Circumcision on Knowledge and Sexual Intentions. Clinical Infectious Diseases. 2018;66:S221-S8. doi: 10.1093/cid/cix973. PubMed PMID: 128906098.
27. Jennings L, Bertrand J, Rech D, Harvey SA, Hatzold K, Samkange CA, et al. Quality of voluntary medical male circumcision services during scale-up: a comparative process evaluation in Kenya, South Africa, Tanzania and Zimbabwe. Plos One. 2014;9(5):e79524-e. doi: 10.1371/journal.pone.0079524. PubMed PMID: 24801073.
28. University Research Company. Potential Solutions to Common Quality Gaps in VMMC Programs. Maryland: USAID Appying Science to Strengthen and Improve Systems Project, 2017.
29. National AIDS Control Council (NACC) and National AIDS and STIs Control Programme (NASCOP). Kenya HIV Estimates Report 2018. Nairobi: Kenya Ministry of Health, 2018.
30. Muga R, Kizito P, Mbayah M, Gakuruh T. Overview of the health system in Kenya. Kenya service provision assessment (KSPA 2004) survey URL: https://dhsprogram com/pubs/pdf/spa8/02chapter2 pdf [accessed 2018-03-20][WebCite Cache ID 6y3kFHBkt]. 2005.
31. Kimathi L. Challenges of the Devolved Health Sector in Kenya: Teething Problems or Systemic Contradictions? Africa Development. 2017;42(1):55-77.
32. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. Health services research. 2007;42(4):1758-72. Epub 2007/02/09. doi: 10.1111/j.1475-6773.2006.00684.x. PubMed PMID: 17286625; PubMed Central PMCID: PMCPMC1955280.
33. VERBI Software. MAXQDA 12. Berlin, Germany2016.

34. Frade S, Rech D, Spyrelis A, Machaku M, Mavhu W, Omondi D, et al. Seasonal patterns in voluntary medical male circumcision (VMMC) in South Africa, Kenya, Tanzania and Zimbabwe. 6th South African AIDS Conference; 18-21 June; Durban2013.
35. Gold E, Mahler H, Boyee D. Overcoming seasonality in scaling up voluntary medical male circumcision. A case study from Tanzania. 2015.
36. Macklin R. On paying money to research subjects: 'due' and 'undue' inducements. Irb. 1981;3(5):1-6. Epub 1981/05/01. PubMed PMID: 11649367.
37. Curran K, Njeuhmeli E, Mirelman A, Dickson K, Adamu T, Cherutich P, et al. Voluntary Medical Male Circumcision: Strategies for Meeting the Human Resource Needs of Scale-Up in Southern and Eastern Africa. PLOS Medicine. 2011;8(11):e1001129. doi: 10.1371/journal.pmed.1001129.
38. Herman-Roloff A, Bailey RC, Agot K. Factors associated with the safety of voluntary medical male circumcision in Nyanza province, Kenya. Bulletin Of The World Health Organization. 2012;90(10):773-81. doi: 10.2471/BLT.12.106112. PubMed PMID: 23109745.
39. Gray R, Kigozi G, Serwadda D, Makumbi F, Watya, et al. Male circumcision for HIV prevention in men in Rakai, Uganda. Lancet. 2007;369(9562):657-66.
40. Bailey R, Moses S, Parker C, Agot K, Maclean I, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. Lancet. 2007;369(9562):643-56.
41. Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 trial. PLoS medicine. 2005;3(5):e226.
42. Gray R, Kigozi G, Kong X, Ssempiija V, Makumbi F, Wattya S, et al. The effectiveness of male circumcision for HIV prevention and effects on risk behaviors in a posttrial follow-up study. AIDS (London, England). 2012;26(5):609-15. Epub 2012/01/03. doi: 10.1097/QAD.0b013e3283504a3f. PubMed PMID: 22210632; PubMed Central PMCID: PMCPMC4296667.
43. Auvert B, Taljaard D, Rech D, Lissouba P, Singh B, Shabangu D, et al., editors. Effect of the Orange Farm (South Africa) male circumcision roll-out (ANRS-12126) on the spread of HIV. 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention; 2011.
44. Riess TH, Achieng MM, Bailey RC. Women's beliefs about male circumcision, HIV prevention, and sexual behaviors in Kisumu, Kenya. PloS one. 2014;9(5):e97748-e. doi: 10.1371/journal.pone.0097748. PubMed PMID: 24844845.
45. Osaki H, Mshana G, Wambura M, Grund J, Neke N, Kuringe E, et al. 'If you are not circumcised, i cannot say yes': The role of women in promoting the uptake of voluntary medical male circumcision in Tanzania. PloS one. 2015;10(9). PubMed PMID: 2016-03432-001.
46. Kaufman MR, Dam KH, Sharma K, Van Lith LM, Hatzold K, Marcell AV, et al. Females' Peer Influence and Support for Adolescent Males Receiving Voluntary Medical Male Circumcision Services. Clinical Infectious Diseases. 2018;66:S183-S8. doi: 10.1093/cid/cix1057. PubMed PMID: 128906100.
47. Morris BJ, Hankins CA, Banerjee J, Lumbers ER, Mindel A, Klausner JD, et al. Does Male Circumcision Reduce Women's Risk of Sexually Transmitted Infections, Cervical Cancer, and Associated Conditions? Frontiers in public health. 2019;7.
48. National AIDS and STI Control Program (NASCOP). National Voluntary Medical Male Circumcision Strategy 2014/15-2018/19. Nairobi: National AIDS and STI Control Program (NASCOP),, 2015.
49. Njeuhmeli E, Forsythe S, Reed J, Opuni M, Bollinger L, Heard N, et al. Voluntary medical male circumcision: modeling the impact and cost of expanding male circumcision for HIV prevention in eastern and southern Africa. PLoS medicine. 2011;8(11):e1001132.
50. Blaizot S, Maman D, Riche B, Mukui I, Kirubi B, Ecochard R, et al. Potential impact of multiple interventions on HIV incidence in a hyperendemic region in Western Kenya: a modelling study. BMC Infectious Diseases. 2016;16(1):189. doi: 10.1186/s12879-016-1520-4.

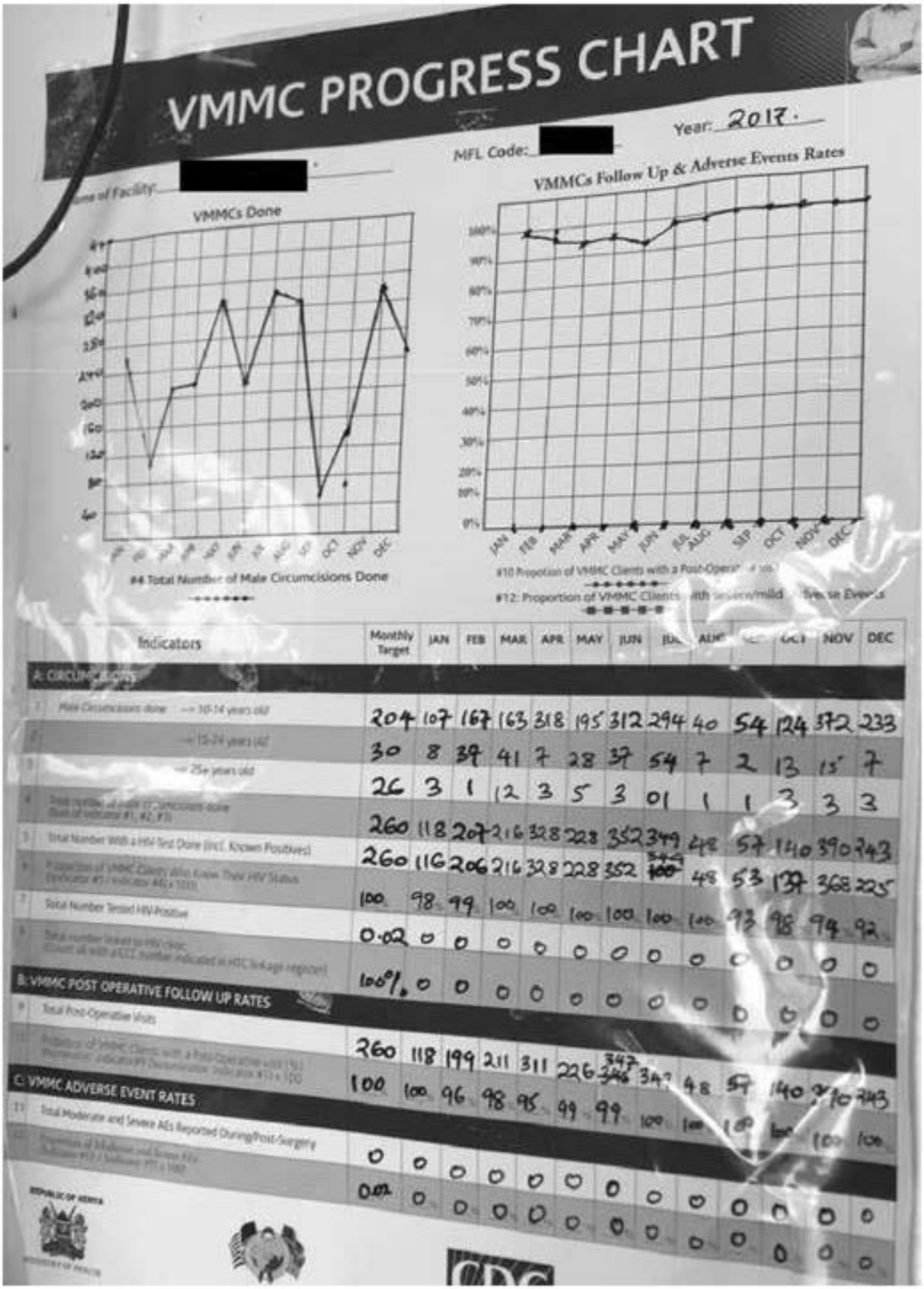
827 51. Hankins C, Warren M, Njeuhmeli E. Voluntary Medical Male Circumcision for HIV Prevention:
828 New Mathematical Models for Strategic Demand Creation Prioritizing Subpopulations by Age and
829 Geography. PloS one. 2016;11(10):e0160699-e. doi: 10.1371/journal.pone.0160699. PubMed PMID:
830 27783613.
831 52. Kripke K, Chimbwandira F, Mwandi Z, Matchere F, Schnure M, Reed J, et al. Voluntary Medical
832 Male Circumcision for HIV Prevention in Malawi: Modeling the Impact and Cost of Focusing the Program
833 by Client Age and Geography. PloS one. 2016;11(7):1-11. doi: 10.1371/journal.pone.0156521. PubMed
834 PMID: 116789851.
835 53. Kripke K, Okello V, Maziya V, Benzerga W, Mirira M, Gold E, et al. Voluntary Medical Male
836 Circumcision for HIV Prevention in Swaziland: Modeling the Impact of Age Targeting. PLOS ONE.
837 2016;11(7):e0156776. doi: 10.1371/journal.pone.0156776.
838 54. Kripke K, Vazzano A, Kirungi W, Musinguzi J, Opio A, Ssempebwa R, et al. Modeling the Impact of
839 Uganda's Safe Male Circumcision Program: Implications for Age and Regional Targeting. PLOS ONE.
840 2016;11(7):e0158693. doi: 10.1371/journal.pone.0158693.
841 55. McGillen JB, Stover J, Klein DJ, Xaba S, Ncube G, Mhangara M, et al. The emerging health impact
842 of voluntary medical male circumcision in Zimbabwe: An evaluation using three epidemiological models.
843 PLOS ONE. 2018;13(7):e0199453. doi: 10.1371/journal.pone.0199453.
844 56. de Kok BC, Widdicombe S, Pilnick A, Laurier E. Doing patient-centredness versus achieving public
845 health targets: A critical review of interactional dilemmas in ART adherence support. Social Science &
846 Medicine. 2018;205:17-25. doi: https://doi.org/10.1016/j.socscimed.2018.03.030.
847 57. HIV/AIDS JUNPo. Safe, voluntary, informed male circumcision and comprehensive HIV
848 prevention programming: guidance for decision-makers on human rights, ethical and legal
849 considerations. Safe, voluntary, informed male circumcision and comprehensive HIV prevention
850 programming: guidance for decision-makers on human rights, ethical and legal considerations. 2008.
851 58. Feldacker C, Makunike-Chikwinya B, Holec M, Bochner AF, Stepaniak A, Nyanga R, et al.
852 Implementing voluntary medical male circumcision using an innovative, integrated, health systems
853 approach: experiences from 21 districts in Zimbabwe. Global health action. 2018;11(1):1414997-. doi:
854 10.1080/16549716.2017.1414997. PubMed PMID: 29322867.
855 59. Feldacker C, Bochner AF, Herman-Roloff A, Holec M, Murenje V, Stepaniak A, et al. Is it all about
856 the money? A qualitative exploration of the effects of performance-based financial incentives on
857 Zimbabwe's voluntary male medical circumcision program. PloS one. 2017;12(3):1-15. doi:
858 10.1371/journal.pone.0174047. PubMed PMID: 121877066.
859 60. Green LW, Travis JW, McAllister RG, Peterson KW, Vardanyan AN, Craig A. Male circumcision
860 and HIV prevention: Insufficient evidence and neglected external validity. American journal of
861 preventive medicine. 2010;39(5):479-82.
862 61. Gwandure C. The ethical concerns of using medical male circumcision in HIV prevention in Sub-
863 Saharan Africa. South African Journal of Bioethics and Law. 2011;4(2):89-94.
864 62. Van Howe RS, Storms MR. How the circumcision solution in Africa will increase HIV infections.
865 Journal of public health in Africa. 2011;2(1):e4-e. doi: 10.4081/jphia.2011.e4. PubMed PMID: 28299046.
866 63. Svoboda JS, Adler PW, Van Howe RS. Circumcision Is Unethical and Unlawful. The Journal Of
867 Law, Medicine & Ethics: A Journal Of The American Society Of Law, Medicine & Ethics. 2016;44(2):263-
868 82. doi: 10.1177/1073110516654120. PubMed PMID: 27338602.
869 64. Sgaier SK, Reed JB, Thomas A, Njeuhmeli E. Achieving the HIV Prevention Impact of Voluntary
870 Medical Male Circumcision: Lessons and Challenges for Managing Programs. PLOS Medicine.
871 2014;11(5):e1001641. doi: 10.1371/journal.pmed.1001641.
872 65. Morris BJ, Wamai RG, Henebeng EB, Tobian AA, Klausner JD, Banerjee J, et al. Estimation of
873 country-specific and global prevalence of male circumcision. Population Health Metrics. 2016;14(1):4.
874 doi: 10.1186/s12963-016-0073-5.

875 66. Weiss H, Polonsky J, Bailey R, Hankins C, Halperin D, Schmid G. Male circumcision: global trends
876 and determinants of prevalence, safety and acceptability. World Health Organization and the Joint
877 United Nations Programme on HIV/AIDS (UNAIDS). 2007.
878 67. Owings M, Uddin S, Williams S. Trends in circumcision for male newborns in US hospitals. NCHS
879 health notes: Citeseer; 2013.
880 68. Morris BJ, Bailis SA, Wiswell TE, editors. Circumcision rates in the United States: rising or falling?
881 What effect might the new affirmative pediatric policy statement have? Mayo Clinic Proceedings; 2014:
882 Elsevier.
883 69. Mor Z, Kent CK, Kohn RP, Klausner JD. Declining Rates in Male Circumcision amidst Increasing
884 Evidence of its Public Health Benefit. PloS one. 2007;2(9):e861. doi: 10.1371/journal.pone.0000861.
885 70. Bonham VH, Morenso JD. Research with captive populations: Prisoners, students, and soldiers.
886 In: Emanuel EJ, Grady CC, Crouch RA, Lie RK, Miller FG, Wendler DD, editors. The Oxford Handbook of
887 Clinical Research Ethics. Oxford: Oxford University Press; 2008.

888 **Supporting information:**

889 S1 Interview guides: The stakeholder interview guides used in this study.

890 S2 VMMC consent form: The Government of Kenya consent form for use in voluntary medical
891 male circumcision.


VMMC PROGRESS CHART
Year: 2017
MFL Code: [redacted]
Name of Facility: [redacted]
VMMCs Done
#4 Total Number of Male Circumcisions Done
VMMCs Follow Up & Adverse Events Rates
#10 Proportion of VMMC Clients with a Post-Operative
#12: Proportion of VMMC Clients with severe/mild Adverse Events
JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC
Indicators
Monthly Target
JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC
A: CIRCUMCISIONS
Male Circumcisions done — 10-14 years old
204 107 167 163 318 195 312 294 40 54 124 372 233
— 15-24 years old
30 8 39 41 7 28 37 54 7 2 13 15 7
— 25+ years old
26 3 1 12 3 5 3 01 1 1 3 3 3
Total number of male circumcisions done (Sum of indicators #1, #2, #3)
260 118 207 216 328 228 352 349 48 57 140 390 243
Total Number With a HIV Test Done (Incl. Known Positives)
260 116 206 216 328 228 352 348 48 53 137 368 225
Proportion of VMMC Clients who Know Their HIV Status (Indicator #5 / Indicator #6) x 100
100 98 99 100 100 100 100 100 100 93 98 94 92
Total Number Tested HIV-Positive
0.02 0 0 0 0 0 0 0 0 0 0 0 0 0
Total number linked to HIV clinic (Count all with a CCC number indicated in HDC linkage register)
100% 0 0 0 0 0 0 0 0 0 0 0 0 0
B: VMMC POST OPERATIVE FOLLOW UP RATES
Total Post-Operative Visits
260 118 199 211 311 226 347 346 348 48 57 140 390 243
Proportion of VMMC Clients with a Post-Operative visit (%) (Numerator: Indicator #9 Denominator: Indicator #1) x 100
100 100 96 98 95 99 99 100 100 100 100 100 100 100
C: VMMC ADVERSE EVENT RATES
Total Moderate and Severe AEs Reported During/Post-Surgery
0 0 0 0 0 0 0 0 0 0 0 0 0 0
Proportion of Moderate and Severe AEs (Indicator #11 / Indicator #9) x 100
0.01 0 0 0 0 0 0 0 0 0 0 0 0 0
REPUBLIC OF KENYA
MINISTRY OF HEALTH
CDC

Title: Voluntary mMedical mMale cCircumcision for HIV prevention among adolescents in ~~western~~ Kenya: unintended consequences of pursuing service-delivery targets

Short title: VMMC and unintended consequences of service-delivery targets in Kenya

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Abstract

Background: Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female-to-male HIV transmission. Since 2007, VMMC has been a key component of the United States President's Emergency Plan for AIDS Relief's (PEPFAR) strategy to mitigate the HIV epidemic in countries with high HIV prevalence and low circumcision rates. To ensure intended effects, PEPFAR sets ambitious annual circumcision targets and provides funding to implementation partners, usually non-governmental organizations, to deliver local VMMC services. In Kenya to date, over 1.96 million males have been circumcised; in 2017, 60% of circumcisions were among 10-14-year-olds. We hypothesized conducted a qualitative field study that to learn more about VMMC program implementation in Kenya pressure among VMMC field staff to meet service-delivery targets might have deleterious effects on VMMC recruitment practices ("mobilization") and service standards.

Methods and Findings: We conducted this study inThe study setting was a region inof Kenya with high HIV prevalence and low male circumcision ratesthe Nyanza region of western Kenya. From March 2017 through April 2018, we carried out in-depth interviews with 29 VMMC stakeholders, including "mobilizers", HIV counselors, clinical providers, schoolteachers, and policy professionals. Additionally, we undertook observation sessions at 14 VMMC clinics while services were provided and observed mobilization activities at 13 community venues including, two schools, four public marketplaces, two fishing villages, and five inland villages. We conducted an early analysis of interview transcripts and observation-obtained field notes to create a codebook following the Framework Analysis approach. Two team members then independently reviewed and coded the full set of transcripts and field notes using MAXQDA 12 in order to define and identify themes related to the use of targets in VMMC policy and service delivery. This Aanalysis of interview transcripts and observation field notes revealed multiple unintended consequences linked to the pursuit of targets. The Ebbs and flows in the availability of male school-age youth only during short periods ("VMMC seasonality"), together with the drive to meet targets, may resulted in overburdening increased burdens onof clinics resources and staff, long waits for care, potentially misleading coercive and deceptive mobilization practices, peer pressure, circumcision of children under the approved age of 10 years, and deviations from the standard of care. This is a qualitative study with limited generalizability and interviewee responses could be subject to social desirability bias. We present findings that were crosschecked by both interview and observation data.

Conclusions: Our findings indicate shortcomings in the quality of procedures in VMMC programs in a low-resource setting, and more importantly, that the pursuit of ambitious public health targets can may lead to compromised service delivery, consent practices, and protocol adherence. There is a need to develop improved or alternative systems to balance the goal of increasing VMMC service uptake with the responsible conduct of VMMC. At a minimum, funders, government authorities, and implementation partner organizations should be more aware of the deleterious effects target setting may have during VMMC implementation. Further research is needed to consider more fully the advantages and disadvantages associated with the use of VMMC targets. While public health implementation programs will likely always require

use of service delivery targets, stakeholders should be more critical of their use and seek to mitigate their negative impacts.

INTRODUCTION

Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female to male HIV transmission.[1-3] Since 2007, VMMC has been a key component of the Joint United Nations Program on HIV/AIDS (UNAIDS) strategy for ending AIDS by 2030 and a top priority of the United States Agency for International Development (USAID) and the United States President's Emergency Plan for AIDS Relief (PEPFAR) ~~and the Centers for Disease Control and Prevention (CDC)~~ to combat HIV in sub-Saharan Africa.[4, 5] Between 2007 and 2018~~7~~, ~~well over~~ almost 19~~5~~ million PEPFAR-supported circumcisions were performed in 14 priority World Health Organization (WHO) designated countries in eastern and southern Africa (ESA); 10~~1~~% (more than 1.9~~6~~ million) of these MCs took place in Kenya.[6] From early on, Kenya was ahead of other countries in VMMC scale-up, meeting 34% of its target in 2012 compared to 16% achieved by the next best country.[7] With a consistent record of meeting national VMMC uptake goals that sets it apart from other countries,[8] Kenya is often presented as a leading VMMC success story in ESA.[4, 9]

~~Through PEPFAR and the CDC, t~~The United States (US), via PEPFAR, took an early lead in funding VMMC for HIV prevention programs in ESA. In 2016, PEPFAR spent over 15 million US dollars (USD) for VMMC services in Kenya alone.[10] These funds are distributed to VMMC implementing partners (IPs) in Kenya and other ESA countries to establish and maintain VMMC services within designated catchments in regions of high HIV prevalence and low levels of male circumcision (MC).[11, 12] These IPs include non-governmental organizations (NGOs), community-based organizations, faith-based organizations, or other non-profit or for profit entities. Each IP is accountable to its funding body via in-country intermediates and is required to keep accurate records and to make regular reports concerning the services provided, numbers of circumcisions performed, and observed adverse events.[13, 14]

As a part of this process, epidemiological model-informed quotas or "targets" are set by funders for the number of MCs to be performed within a given timeframe (e.g., ~~monthly, quarterly, or~~ annually). In 2016, 264,490 PEPFAR-funded MCs were performed in Kenya,[15] thus exceeding the 2016 target of 240,000 MCs.[16] In Kenya, PEPFAR has identified 11 VMMC underserved-, priority counties.[16] In 2017, the coverage rates for 15-29 year-old males among all priority counties were reported to be approaching or to have reached 80%,[16] though more recent studies have called into question these coverage estimates.[17], ~~primarily in the Nyanza and Rift Valley regions.~~[17]To achieve thise stated goal of 80% MC coverage ~~among males aged between 15-29 years within~~ within all these ~~counties~~underserved areas by 2019, PEPFAR Kenya set a target of 300,000 new MCs in 2017, a 25% increase from the 2016 target.[16] In 2014, Kenya began offering VMMC services to boys aged 10-14 years citing "high demand for MC amongst this age group", cultural preference, and pre-sexual debut and/or less sexual activity as the rationale.[18] ~~In~~ Between October 2016 and September 2017, 227,272 PEPFAR-sponsored MCs were performed in Kenya; 60% of these were among boys aged between 10-14 years, ~~and~~ 23% were among 15-19 year-olds, and 14% were among 20-29 year-olds.[15] Among all priority-designated counties in Kenya, UNAIDS~~PEPFAR~~ estimates cited by PEPFAR suggest that an additional 290,000 MCs ~~are~~ may be needed to achieve 80% MC coverage among 10-29 year-olds, or an additional 500,000 to achieve 90% coverage by 2021.[16]

Previous research has highlighted ethical and practical concerns associated with VMMC implementation for HIV prevention.[19] Among school-going adolescent and young adult males in ESA, these concerns include recruitment practices (referred to as mobilization in VMMC programs),[20] consent and assent,[21] and access to follow-up care,.[22] Additional issues include ~~as well as~~ adolescent understanding of VMMC's purpose,[23] ~~its~~ MC's relevant benefits and risks,[21, 24, 25] and the importance of HIV protective behaviors following circumcision.[26] ~~Additionally, a~~A 2014 assessment of VMMC quality of care across four countries (Kenya, South Africa, Tanzania, Zimbabwe) identified deficiencies

including providers' failures to adhere to national VMMC best-practice guidelines and a lack of equipment and supplies at VMMC clinics.[27] Similarly, a 2017 report prepared for review by USAID identified multiple "quality gaps" in VMMC implementation, including adverse events, low client follow-up rates, and inconsistent messaging to clients.[28]

During research for a parent study on the responsible conduct of HIV research in adolescent populations in Kenya we received anecdotal reports from local health leaders and community stakeholders that raised concerns about the ethical implementation of VMMC among adolescents. Given the known ethical and practical concerns linked to VMMC implementation across ESA, we set out to conduct a qualitative study to learn more about VMMC practices "on the ground" in Kenya. Presented below, an analysis of the qualitative data we collected revealed that the pressure to meet funder-set service-delivery targets appear to generate some unintended consequences concerning the services provided and/or standards maintained by VMMC IPs. ~~Given the ethical and practical concerns linked to VMMC implementation across ESA, and the standard use of funder-determined targets to drive adolescent mobilization, we set out to consider what effects these targets might have on the responsible conduct of VMMC practices in Kenya. Directing our interest was the hypothesis that the pressure to meet targets might lead to some unintended consequences concerning the services provided and/or standards maintained by VMMC IPs.~~

METHODS

HIV prevalence in Kenya in 2017 was 4.8% overall among individuals aged 15–49, with a range at the county level of between 0.1% and 21.0%.[29] This study was conducted in an area of Kenya with elevated rates of HIV and historically low uptake of MC. ~~the Nyanza region of western Kenya — the area near Lake Victoria with the highest HIV prevalence and lowest rates of MC in the country.~~[30] From March 2017 through April 2018, we conducted in-depth interviews with 29 VMMC stakeholders (21 males and 8 females), including schoolteachers, program recruiters (known locally as "mobilizers"), HIV counsellors, clinical

providers, and policy professionals (e.g., local VMMC technical advisors). Table 1 lists these stakeholder interviewee categories, the number of stakeholders from each IP or school, and describes descriptions of each category's their roles or links to VMMC program implementation. In addition to these interviews, we conducted field observation sessions at VMMC clinics located in the research area.

Table 1. SVMMC stakeholder interviewee categories, number of interviewees' and their employers, and descriptions of VMMC stakeholders' involvement in VMMC.

Stakeholders	Interviewees/ employers	Involvement in VMMC
School teachers N=6	5 primary schools and 1 high school	Many adolescents are mobilized for VMMC at school; teachers facilitate access to students for VMMC mobilizers, are a source of information for students and parents, and often help to distribute and collect consent forms. Teachers also sometimes accompany pupils to VMMC facilities.
Mobilizers N=9	IP A: 5 IP B: 3 IP C: 1	Mobilizers are recruiters of VMMC "clients" (individuals who receive VMMC services). They are paid to conduct informational outreach activities, including "health talks" in schools, and to ensure that VMMC facilities have access to adequate numbers of clients to meet targets.
Counselors N=4	IP A: 2 IP B: 2	VMMC counsellors inform boys about VMMC benefits and risks, as well as post-circumcision wound care and healing best practices. They oversee consent and assent and conduct HIV counselling and testing.
Clinical providers N=7	IP A: 4 IP B: 1 IP D: 1 IP E: 1	Clinical providers perform circumcisions and provide post-procedure care, at VMMC facilities. These include clinical officers (surgeons), nurses, and infection prevention officers (IPOs). Nurses assist clinical officers during circumcisions. Infection prevention officers IPOs oversee the surgical instruments, sanitary practices, and waste collection and disposal.
Policy makers N=3	IP A: 1 IP B: 1 GOK: 1	Policymakers are individuals involved in, or with in-depth knowledge concerning, VMMC practices and policies in Kenya.

VMMC, Voluntary Medical Male Circumcision; IP, Implementation partner; GOK, Government of Kenya.

To recruit stakeholders for interviews, our Community Liaison Officer (CLO) asked for assistance from approached authorities at the regional Ministry of Health, Ministry of Education, and Health Department. Additionally, we sought approval from six VMMC IP NGOs to conduct interviews with their staff members and observation sessions at their clinics (see Table 1). Two of these IPs approved our request to conduct interviews and observation sessions (IPs A and B). Three of these IPs gave their approval for interviews but declined our request to conduct observation sessions (IPs C, D, E). One IP declined to approve both interviews and observation sessions. , and VMMC IPs (in this case, five

NGOs) to gain approval for this project. These authorities and IPs assisted us to identify local VMMC professionals with at least three years of experience related to policy, clinical services, counselling, or mobilization. In turn, VMMC mobilizers helped us to identify teachers involved with in-school VMMC mobilization activities referred to as "health talks". Once identified, our Community Liaison OfficerCLO and study coordinator (FSO) contacted potential participants in person or via telephone, and inquired regarding their willingness to take part in an interview. Out of the 38 stakeholders contacted, 32 agreed to take part in an interview; of these, 29 were available to attend the interview. Out of the 23 mobilizers, counsellors, clinical providers, and policy professionals interviewed, 12 were employed by IP A, seven by IP B, one by IP C, one by IP D, and one by IP E (see Table 1). An additional policy professional interviewee was employed by the Government of Kenya. The six teachers we interviewed came from five different local primary schools and one high school.

Based on preliminary fieldwork in the region in 2016, we developed interview guides for each stakeholder category via an iterative process that relied heavily on the input and experience of our Kenyan team members (WKL, BO, FSO, DK). These guides included questions related to careers, roles, and experiences with VMMC, use of targets/quotas, clinical/mobilization protocols and practices, record keeping/documentation, informed consent, HIV testing, benefits and risks, training, the structure/hierarchy of VMMC IP organizations, and remuneration. (see S1 Interview Guides).

Study participation was voluntary, and all participants gave consent before interviews began. Stakeholder iInterviews were (conducted by BO and by AG in English (Swahili and English in one interview). These interviews took place in quiet, secluded locations, lasted up to 90 minutes, and were audio-recorded with permission. Kenyan team members who are fluent in English, Swahili, and the local language listened to the audio-recorded interviews and translated and transcribed them in English. The transcription process involved three steps. First, audio-recorded interviews were transcribed verbatim. Second, the transcriber

conducted quality assurance by reading the transcript while re-listening to the audio. Third, the transcriber submitted the English transcript and the audio file to the Study Coordinator (FSO) for final review and designation as the final version of the transcript. Any portions of interviews that contained Swahili were first transcribed in Swahili before being checked, translated to English, and rechecked for accuracy by the Study Coordinator. Each interviewee received 500 Kenyan shillings (approximately 5 USD) for their time and transportation.

~~In addition to interviews, we~~ A Kenyan nurse and public health worker who is knowledgeable about VMMC clinical procedures and is fluent in English, Swahili, and the local language (BO) was our primary field observer. He conducted two- to five-hour observation sessions at 14 VMMC clinics run by the two NGOs (six administered by ~~organization~~ IP A and eight by ~~organization~~ IP B) and alongside the mobilization team activities at 13 community venues (six ~~run by~~from ~~organization~~ IP A and seven ~~by~~ from ~~organization~~ IP B). These venues/activities included two schools (health talks), four public marketplaces (mobilization among local motorcycle taxi drivers), two fishing villages (informational speeches, music, skits; referred to as "roadshows"), and five inland villages (door-to-door adolescent mobilization). ~~The nurse/public health worker A Kenyan nurse and public health worker who is knowledgeable about VMMC clinical procedures and fluent in English, Swahili, and the Luo language (BO) carried out the observation sessions and documented what he observed in detailed field notes. A medical anthropologist (AG) supervised these observation activitiess.~~ ~~The two NGO IPs selected for observation activities were the only IPs providing VMMC services in our research area during our data collection period. A Kenyan nurse and public health worker who is knowledgeable about VMMC clinical procedures and fluent in English, Swahili, and the Luo language (BO) carried out the observation sessions and documented what he observed in detailed field notes. A medical anthropologist (AG) supervised these observations.~~

We identified four health facility levels (levels 2, 3, 4, and 5) for VMMC observation. Level 2 facilities include dispensaries and small clinics usually run by nurses that provide basic outpatient care to up 10,000 people. Level 3 facilities are health centers that serve populations up to 30,000 and are staffed by midwives, nurses, clinical officers, and occasionally doctors. They provide basic curative and preventive, minor surgical and reproductive health services. Level 4 facilities are primary, high-volume referral hospitals that serve populations of 100,000 people. Services offered include curative and preventive care and surgeries and emergency services that are not available at smaller facilities. Level 5 facilities serve larger populations. They focus on specialized services and provide clinical supervision and support to lower level, primary referral facilities.[31, 32]

We Our Kenya-based research team selected VMMC clinics to ensure that we conducted observations at a variety of facility levels in various sub-counties, as well as during relatively active (more than 30; up to 100 or more) and slow periods (less than 15) circumcisions per day. We conducted observations atOut of the 14 VMMC facilities inwe which we conducted observedations, two were Level 2 facilities, six were Level 3 facilities, five were Level 4 facilities, and one was Level 5 facility. Upon arrival at each facility, we BO, our Community Liaison Officer, or our Study Coordinator (FSO) informed facility staff members about our research and provided them with details concerning their organization's IP's approval for our observations to take place before they gave verbal consent. Observation sessions lasted between one and four hours and tended to coincide with the arrival of adolescent VMMC clients and their subsequent, intake, counselling, testing, and circumcision. The mobilization teams associated with these clinics were identified and approached outside of the clinical setting for permission to observe their activities (e.g., mobilization events at schools or public markets). Before these observation sessions began, members of the mobilization teams gave their verbal consent for observationto be observed. Prior to beginning in-school observation sessions, school authorities and teachers were informed about the research and gave us permission to conduct the research activities.

The institutional review boards of the Pacific Institute for Research and Evaluation (PIRE), ~~University of North Carolina at Chapel Hill,~~ and the Kenya Medical Research Institute (KEMRI) approved all study activities, including all the informed consent procedures described above. Locally, the county-level Ministries of Health and Education, and the directors of each ~~of the two IP organizations (A and B)~~ gave us approval to conduct this research ~~at their respective implementation sites~~.

Analysis

Kenyan team members translated and transcribed the audio-recorded interviews and checked the final transcripts for accuracy. U.S.-based team members conducted an early analysis of interviewee transcripts and observation-obtained field notes. The potential for the pursuit of VMMC targets to contribute to unintended consequences emerged during early data analysis. We created the codebook to define and identify themes related to the use of targets in VMMC policy and service delivery~~to create a codebook following the Framework Analysis approach~~.[33] Two team members then independently reviewed and coded the full set of transcripts and field notes using MAXQDA 12[34]. ~~in order to define and identify themes related to the use of targets in VMMC policy and service delivery.~~ Any coding discrepancies were discussed and resolved by the two coders. Code reports were produced and reviewed, and quotes were selected to illustrate typical responses for each theme. We present these quotes below, along with corroborating field observations, ~~including~~ and participant demographics and identification numbers.

RESULTS

To meet VMMC quotas, local IPs communicate ~~monthly~~ target numbers~~s~~ to their VMMC clinics and ~~they oversee and through~~to ~~the hierarchy of regional, sub-county, and community-level~~ the mobilizers who are responsible for supplying these clinics with clients to circumcise. The numbers of adolescent clients who undergo VMMC ~~targets~~ vary across the

year, depending on the relative availability of clients and/or the ability of mobilizers to access them.

Implications of the pursuit of VMMC targets

Data collected from the stakeholder interviews and field notes suggest that funder-designated targets for VMMC service delivery ~~mobilization~~ effectively motivate mobilizers and clinic staff.~~;~~ As one 33-year-old, male mobilization supervisor put it, "…target or quotas act as the engine to make us do a lot of work and ensure that there is continuous [flow of clients]" [Mobilizer 1]. For mobilizers especially, monthly remuneration (and their future employment) depends on referring ~~a sufficient number of~~enough clients to the clinic each week; failing means earning less, ~~or even nothing at all,~~ regardless of the amount of time and effort invested in mobilization. From our interviews we learned that while most mobilization supervisors receive a base salary from their IPs regardless of the targets, other lower-level, subcontracted "associate" mobilizers or "peer educators" only receive payment by providing clients and meeting targets. Describing the competition this system fosters among mobilizers, a 28-year-old, male community~~-~~level mobilizer explained, "…we are paid upon reaching the target […] so we are really competing, until somebody may grab your clients before you know it" [Mobilizer 2]. For VMMC clinics, achieving targets is essential to the continued funding of their respective IPs. ~~As a~~ 49-year-old, male mobilization supervisor offered, "…targets… are about funding, and [if] you don't reach your target, you don't get funding" [Mobilizer 3]. However, data analysis revealed that beyond motivating staff members, the pursuit of targets may introduce~~not only that targets motivate, but also~~ the ~~potentially problematic nature of targets for~~problems for VMMC implementation. ~~-~~Presented below, these areas of concern relate to the ebb and flow periods of VMMC client availability (referred to with reference to agricultural "seasonality" elsewhere),[35, 36] and the resulting ~~overburdening~~ increased burdens on~~of~~ clinic resources and staff, long waits for clients, potentially ~~coercive and deceptive~~misleading or problematic mobilization practices, (including possibly undue inducements), ~~peer~~ questionable uses of social pressure, and

circumcision of children under age ten~~10~~. By undue inducements, we mean benefits (monetary or non-monetary) that are used to motivate prospective participants (in this case adolescents or young adults) to join a study—benefits that may be inappropriate because of their potential to distort a participant's understanding of the study [37]. A final issue that we link to the pursuit of targets is ~~and the cutting of corners in clinical care~~reduced quality of clinical care.

Variations in ~~VMMC seasonality~~client availability: "high and low seasons"

Adolescent client availability for circumcision rises and falls throughout the year, primarily due to school schedules: schools do not allow VMMC mobilization to take place on school grounds near the time of exams or other especially busy periods in the year. This results in "high" and "low" seasons for VMMC among these age groups. As Mobilizer 1 explained:

> There are times when they are having exams, or when exams are approaching, or when there is athletics or ball [soccer]; when those are taking place, we don't get people coming… we end up having zero clients cut [circumcised]. And you know, when there are zero clients cut, all the pressure comes to the mobilization supervisor because the surgeons will be saying, 'We are ready to cut, where are the clients?' So the buck stops on me as the mobilizer; so it is not a very easy task.

Likewise, a 30-year-old, female mobilization supervisor offered, "We bank on schools so much. And now, when they are taking their exams, you can't pick a child from school [….] …when schools are so engaged, then definitely I will not meet that target" [Mobilizer 4]. Recognizing the need to strategize VMMC service provision around local school schedules (and client availability), some IPs may institute "Rapid Results Initiatives" or similar short-term drives aimed at increasing dramatically the number of MCs conducted during school holidays.[9, 38] If funding is insufficient, or if IPs are otherwise unable to commit the resources (e.g., personnel, transportation, clinics, and medical supplies) needed for these drives, then targets may go unmet.

~~Overburdened~~ Increased burden on VMMC facilities and staff

VMMC clinical teams are generally comprised of at least one surgeon, surgical assistant, counsellor, and infection prevention officer. During the high season, efforts to meet targets may push some teams to circumcise more clients than the approved quota to be conducted per day per team ~~clinics may be pushed beyond the approved limit of 15 circumcisions per day per VMMC team (a surgeon, surgical assistant, counsellor, and infection prevention officer).~~ In 2015, this limit was 15 circumcisions per day.[18] In 2018, we observed an IP internal document dated December 2017 that was posted to the wall in a public space of one of the clinics in which we conducted observations. This memo made clear that the IP was aware that "some teams are circumcising over and above the safe maximum number of clients per team" and that this limit is 25 clients per day. During one observation session on a high season day at a Level 4 facility, we counted over 100 boys waiting to be circumcised at a clinic with four surgical beds. At this same facility in the low season, less than half this number may be circumcised in a month (see Figure 1). On days when an unexpectedly high number of boys are mobilized for circumcision, VMMC teams may be left scrambling to call in additional staff. As one 39-year-old, male Clinical Officer explained: "If the number is high, you have to get those who are locum [temporary, fill-in staff]; for instance, like today, if the number is beyond 60 you have to get those for locum because one counselor cannot handle 60 clients. So we do arrangements prior and we talk to the office and ask them to give us assistance [Provider 1]"

Figure 1. VMMC Progress Chart for 2017 displayed on the wall of a clinic.

~~Oftentimes~~ Referred to as "moonlighting" by our interviewees, VMMC staff may sometimes ~~need to~~ work extra hours, late into the evening, ~~—referred to as "moonlighting"—~~ and/or over weekends or holidays when they would not normally be expected to work (for which they receive extra compensation) in order to handle large client loads, meet current targets, or make up for previous months when a lack of clients meant targets were missed. ~~O~~As ~~one~~ 33-year-old, female counselor ~~put it~~explained, "Yeah, you are put into pressure and you have to get the targets. We always know we have to get our targets, come what may. So we

do moonlight to get those targets" [Counselor 1]. Similarly, a 39-year-old male Clinical Officer told us: "…if the number is high sometimes we can extend to weekends; and based on the clients flow like now… schools are going to be closed, and hence the number of clients is going to be high. So tomorrow [Good Friday] we may work" [Provider 2].

While ~~MC-associated~~severe adverse events (AEs) beyond minor swelling, bleeding, or infection ~~may be relatively~~are ~~rare~~,[39] when they do occur~~are known to occur~~, a few of our interviewees suggested that provider fatigue may be a contributing factor. ~~Describing~~ Referencing one case ~~in which a client's glans was accidently amputated~~, a 42-year-old male VMMC Clinical Officer offered:

> Then the other factor is the high numbers given as targets annually. So if you look at the number of clients you should do, you get fatigued along the line because remember you stand all day. So if you do 20 clients or 25 clients in a day, every day, say from Monday to Friday, it is a hell of a tiresome job…. So most of those AEs [are] attributed to fatigue, because if you look at the timings of most of the AEs, it is usually late in the evening, after lunch, afternoon; so it has always been attributed to high volume in terms of target, and then fatigue, then people not following the protocol. You find somebody, because he wants to finish faster, they want to split [meaning the surgeon and the assistant each operate on their own] instead of [following] MC protocol [and working together]…. It reaches a point where you have to split where everyone is doing [operating alone] because the number is high…. [Provider 3]

~~Offering a similar thought, a 35-year-old, male VMMC Technical Advisor explained:~~

> ~~…you know there is pressure for numbers. I can tell you the truth, and there is a number that is set that the team must do every day to be relevant. You know, and if you are not able to do this number…. but we are given target by the donor. I'm not saying that they are wrong, because to achieve herd immunity, and HIV prevention through VMMC as an intervention strategy, then you have to circumcise many over a short period of time, you know. [….] [But] that pressure for numbers as a surgeon… in an effort to try and circumcise all of them, sometimes you have to miss lunch. And that can cause slipping of the knife or whatever…. [Policy 1]~~

Long waits at VMMC clinics

Another unintended consequence of targets ~~and VMMC seasonality~~ for school-aged clients is the long waits they may experience at VMMC clinics before and after MC, especially during the high season. Despite mobilizer claims about the short duration of the procedure, inadequate numbers of vehicles to transport boys, ~~the~~ rough road conditions ~~of the roads~~ (especially during the rainy season), and ~~often~~ sometimes understaffed and under-resourced VMMC clinics mean that adolescents ~~regularly~~ may spend ~~many~~ hours waiting to be

circumcised and then to be ferried back home. While making observations at onea Level 3 facility, boys arrived for circumcision at approximately 8am; due to the staff's late arrival (and possibly understaffing), circumcisions began at 12.30pm. At 4.15pm, when we left, these children were still waiting at the facility for transportation home. Some of the children were crying and saying that they want the pain "to find them at home". One child stated, "We were told it will only take 20 minutes. This is not 20 minutes!" According to one 32-year-old, male primary school teacher, "…one day I attended a facility and [found] that a number of people are to be cut, but the officers who are doing this are just two. So they will do it up to very late [in the evening] and these boys are just there hungry, just with one bottle of soda which will not sustain them" [Teacher 1].

~~Coercive and deceptive~~Suggestions of misleading or questionable mobilization practices

Data collected during interviews and observations suggest that the dDriven to meet targets may lead some VMMC mobilizers to use misleading or otherwise questionable mobilization practices~~by the need to meet targets, some VMMC mobilizers may turn to coercive or deceptive mobilization practices, including use of undue inducements, in order~~ to increase the number of adolescents they can refer for circumcision. As Mobilizer 1 explained:

> Another thing is the peer mobilizers, yeah, someone wants to meet his or her targets and that is the time that they engage in what I called the uncouth methods, whereby the end justifies the means; whichever means that can make those clients come out. So you end up having the clients coming, but they are not coming for the VMMC the way we want it. They have been pushed; they have been coerced…yeah. This one is happening because of these targets. So that is the downside of the targets.

These practices are sometimes blatant: during one door-to-door village mobilization, the mobilizer kept referring to himself as "doctor" although he had no medical training. Another mobilizer, a 38-year-old male who referred to himself as a "VMMC champion" explained how he pays boys to help him mobilize their friends:

> For us we are calling it 'broking [brokering] system'. So after the exercise, you tell him to go… and convince a friend and bring a friend… [….] For me I am using my own system being that we are not even allowed to give children money. But for me, because I have a target, and if I get my target, I am expecting 10800 KES [108 USD]. So I do divide this 10800 KES; maybe if he brings me two boys, I can give him up to 50 KES. I can even give out 100 KES [1 USD]. The moment I give that money, 50 bob, to that boy, he is going to bring me more four boys.

> So the more he bring boys for instance if they are four, I give 100-150 KES. At the end of the day, I will hit my target [Mobilizer 5].

Other times, these practices are subtler and easy to overlook. During a promotional skit in which mobilizers played the roles of a husband, wife, and brother all discussing VMMC, the message to the audience was one of strong female preference for circumcised men. The wife told her husband, "Go and cut your *firimbi* [whistle] … go and remove that sleeve of a sweater. That whistle is not going inside me…don't blow the whistle inside me. I have refused…. I am not giving you [sex]." Later, when the husband's brother arrived, he explained that his wife is refusing to have sex. In response, his brother said, "I was passing here to tell you to go for circumcision. Look at me,; I have gone and I am fine. I am now a clean person. Do you want your wife to conceive and have children?" Explaining the benefits, his brother offered that MC reduces HIV risk by 60%, and enhances cleanliness ("you avoid smelling") and prevents cervical cancer ("wWomen whose husbands have been circumcised don't get cervical cancer").

While VMMC does reduce HIV incidence rates by 60%[40-42] or more,[43, 44] it is misleading to suggest that MC inherently reduces an individual's risk of infection by 60% if the differences between absolute and relative risk are left unexplained. Similarly, while studies suggest that female preference for circumcised males exists,[45-47] it may also be misleading to generalize about female preferences during recruitment efforts. Furthermore, though MC does reduce the risk of human papillomavirus transmission from men to women, thereby reducing their risk for cervical cancer,[48] it is false to claim that women whose husbands are circumcised do not or cannot get cervical cancer.[40-44]

This practice of emphasizing the benefits (including reducing the time needed to bathe and risk of acquiring penile cancer) and incentives related to MC while downplaying the risks was common among our participants. The most commonly discussed risks included temporary pain, minor swelling, and bleeding, while the Government of Kenya VMMC consent form

(see S2 Government of Kenya consent form) in use at this time lists risks including bleeding, swelling, pain, infection, injury, numbness, sensitivity loss, mutilation, amputation, and HIV infection. These latter, more severe but rarer adverse events did not feature in the health talks and other mobilization activities we observed.

~~Another observed practice among mobilizers was an overemphasis on the incentives that are to be gained through circumcision. The very improbable, but not unheard of, risk of amputation only arose in one surgeon's interview (quoted above) and those with two policymakers.~~

According to interviewees, food, money, water, sanitation, clothing, and other basic needs are issues of concern for many adolescents' households. During health talks, some mobilizers emphasized the incentives that boys will receive (e.g., sodas, ~~bread,~~ and/or new underwear) following circumcision—~~,~~ items that may be significant inducements among impoverished children. During a village mobilization effort, one mother explained her reluctance to let her son be circumcised: "…this one is small. Even his heart was there because those who have come from circumcision are 'seducing' their friends to go also. They are telling them, 'go and it is not painful.' They are also giving people sodas. So that soda is what brings them nearer. I told this boy not to sneak, but to wait and I will take him there…." Offering a similar analysis, Provider 3 told us:

> Sometimes they also entice them for us; in the facility we give them a bottle of soda, Fanta to be specific because one, some of the boys come probably from poor families, they haven't had a meal in the morning or breakfast and sometimes stay in the clinic for more than two hours, three hours and thus to maintain their sugars. [But] that one [soda] becomes a bait, especially for the young ones "We will give you a soda; we pick you with a vehicle" …which is actually wrong because, it is like enticing a client which you are not supposed to, but that is how they [mobilizers] ply their trade.

However, according to our interviewees and as we observed first hand, clinics sometimes lack sodas and/or underwear to give to clients, ~~and we were concerned to find during our observations that none of the clinics seemed to provide bread or other food to waiting adolescents as a matter of normal practice.~~

Imbalanced discussions of benefits versus risks

An analysis of interview transcripts and field notes from health talk observations in which mobilizers described how they discuss VMMC benefits versus risks with adolescent males suggests strong biases in favor of benefits over risks. The benefits most commonly cited during interviews and mobilization activities include "60%" reduction in risk of HIV infection, protection from other sexually transmitted infections, improved male hygiene and "reduced bathing time", and reductions in risk of penile cancer and urinary tract infections, as well as cervical cancer among female partners. Concerning risks, those most commonly discussed included temporary pain, minor swelling, and bleeding. The very improbable, but not unheard of, risk of amputation only arose in one surgeon's interview (quoted above) and those with two policymakers.

Peer Social pressure

All six of the teachers we interviewed teachers recognized peer social pressure as a primary motivator for MC among adolescents. As one, male, 35-year-old Deputy Head Teacher at a primary school put it: "Some of the boys give themselves [go for VMMC] because they have seen others do it; so peer pressure is a great influence. Some people just agree because they have seen their fellows going. They also want to go and have the experience together with their fellows" [Teacher 2]. Other interviewees recalled instances in which their peers subjected uncircumcised adolescents to ridicule and other abuses. As an example, one 35-year-old, male teacher told us: "…they will tell you *tuko poa, lakini wale ambao hawajafanya* [we are fine, but for those who haven't done it] they feel ashamed. Yeah, because these other [circumcised] boys laugh at them" [Teacher 3]. Another teacher, a 37-year-old female, offered statements she was told by a pupil: "'…madam, you know these days almost everybody is circumcised and when we join high school, we will be laughing stocks; when you go to the bathroom, [or] you are bathing [at the lake or river] with somebody who is circumcised, then they will call us girls'" [Teacher 4].

During observations of mobilization activities, we saw firsthand how mobilizers sometimes take advantagemake use of or encourage this peer pressure to encourage boys topromote circumcisione, including by through the useing of abusive and/or stigmatizing language to refer to the uncircumcised. During a health talk in front of a large group of boys at a primary school, one male mobilizer referred to foreskins as the "sleeve of a sweater" and "cold *matumbo"* [boiled goat intestines]; at the end of the talk, he implored those who still had their "whistles" to have them removed. He also told them: "Those who are still having the foreskin, you are the ones who are going to spread the diseases. In the future, you are the ones who are going to spread the HIV virus." Later that same day, the mobilizer asked a large group of older students," How many of you wish to get the HIV virus? If you don't want to get the HIV virus, the only option is to remove the foreskin." Revealing his awareness of this type of language and messaging within VMMC mobilization, Provider 3 explained:

> This is demeaning and they try to create some peer pressure. Like when you go to those mass cuts in high schools, probably they registered like 100 clients, you would likely get another probably 30 or so who, because of the peer pressure, just jump into it. But if it was like walking from home to hospital and demanding for the service, they are not likely to have gone. But now that it is here, and so and so has gone and is my friend, I have to be in it.

Circumcision of children

Current VMMC for HIV prevention guidelines and national protocols approved for use in Kenya require that adolescent clients must be at least ten years of age.[49] Despite this directive, interviews and observations confirmed that VMMC staff sometimes mobilize and circumcise boys who are under ten years of age in order to boost their numbers to meet targets. When asked about potential links between targets, mobilizer strategies, and underage circumcision, Provider 3 offered:

> Yes, they bend the rules… because you know sometimes our current age according to WHO is 10 years and above,, right. But when they [mobilizers] go to the field and get a nine-year-old for example, they coach this client and the parent, because we insist on seeing the consent. We always insist they put the ID and telephone number of the parent [on the consent form]. When they come to the facility, we [call to] confirm the age and whether the parent has consented for the child to be circumcised. And you know, they will tell you 'yes I am 10 years old', but when you look at the guy, he is probably 8 or..., sometimes they don't give the right information. They don't tell them it is painful as they are supposed to tell them the injection is

painful but after the injection… and also after the surgery when the lignocaine or the anesthesia [wears] off, there will be some pain. So they don't tell them that.

We observed evidence for the mobilization of underage boys at ten10 of the 14 VMMC facilities we visited for observation, including boys (and their mobilizers) who readily admitted that they were underage. However, as Mobilizer 1 noted, age verification is not easy or straightforward in Kenya: "Yes, we have had some cases where children try to adjust their age. For instance, he is eight years old, but insists he is ten years old; and they are even able to calculate that they were born on this date and in this year. Being that we don't have a way to verify that… then later you realize that this boy is underage." Yet, during observations made during school health talks, as well as during community-based door-to-door mobilization activities, we frequently observed mobilizers not asking boys their ages, opting instead to ask for their class in school as a proxy for their age. It should be noted that parents and guardians also willfully mislead VMMC providers about the ages of their children.

Cutting corners inReduced quality of clinical care

Under pressure to meet targets, some Clinical Officers and other VMMC medical staff find ways to speed up the clinical process. For example, as we were told during interviews and observed firsthand at multiple VMMC facilities, providers may opt not to take patient medical histories or conduct preoperative examinations (e.g., blood pressure, weight, preexisting conditions, etc.) and/or 30-minute post-operative check-ins, and yet fill in the requisite forms as if these activities had been completed. Other avenues for time-saving included, rushing circumcisions, inadequate stitching, splitting surgical utensil and bandage packs between patients, not following recommended protocols or procedures (e.g., the dorsal slit method for circumcision), and stacking patients one after another with little pause in between, which raises additional sanitary and privacy concerns. According to an experienced VMMC surgeon:

> We cut a lot of corners and I will give you an example: […] so because of speed, you find that while one client is dressing [after circumcision], the other one is [already] undressing. Ideally, it is supposed [to be] that you finish with this client, you give [them] instructions on how to take medication and all that, but because of the high volume, you find that some of us we are not the ones giving out the medication. We assign somebody randomly, you know, who will be giving out the medication and the refreshment and so [the] information [they provide to the client] may not be correct. […] Sometimes even the vitals of post-operation 30 minutes after [circumcision] are not done. It is skipped, or somebody else does [it] – probably a receptionist who is nonmedical, just to fulfill the requirements of the form. [This] is wrong because you are supposed to do the circumcision and the client rests for 30 minutes in a bed or a couch, then after that, you do the vitals then you discharge. Oh, even the wound care instructions, [that] information may not sink in for the client because it is presented so fast and there may not be [time] for questions. Yeah, there are so many corners we cut. […] …at a clinic last year, I saw them hold that yellow form [medical files] and going through [and just] check, check, check… adding blood pressure, adding all these things, just filling them in [without actually measuring blood pressure, etc.]. [rrrr] I remember a case back in the day… we were running out of time, and in the process, we were so fast that we thought we had localized the client, but we had not… you know, then the client was making noise, 'What…! You said you will inject me, but you have not have not injected me.' When [we] looked at the tray, [the anesthetic] was there [unused]. Bringing [circumcisions down] to seven minutes, there a lot of corners which are cut [Provider 3].

One assistant surgeon, a 25-year-old female nurse, claimed her record time for completing a circumcision was six minutes. She too associated VMMC targets with client overload, and with rushing surgeries and an increase in adverse events. She explained:

> Sometimes you compete cutting clients and the clients are too much. The average time for a client's [circumcision] is between 12 to 20 minutes. So when the clients are too much, and you want to meet your targets, you will perform the surgery a bit fast. So upon that you will have [an] adverse event and maybe a child will come back with a bleeder [an oozing artery or other blood vessel] you did not close [suture] well [Provider 4].

When asked to compare the forceps guided method of circumcision with the World Health Organization[5, 50] and Kenyan National AIDS and STI Control Program (NASCOP)[18] recommended dorsal slit procedure, Provider 3, explained that while dorsal slit poses less risk of damage to the glans, it is slower: 15-20 minutes for an experienced surgeon compared to seven minutes with forceps guided. He then added that, "Even now, I can tell you there is a very high possibility that there are some people [surgeons] doing it [forceps guided] just to beat the time."Despite these concerns, it was beyond the scope of our study to determine whether an increase in major or minor adverse events was associated with high volume periods. This issue should be addressed by future research.

Target alternatives

When asked about possible improvements to VMMC implementation and potential alternatives to the use of targets, interviewees made two suggestions. The first was to move away from active VMMC mobilization toward more passive strategies ~~similar to~~like those used by sites that provide walk-in HIV testing services in Kenya. The second was to keep donor targets, but to lower them to make them more possible to achieve. As Mobilizer 1 put it, "[VMMC] should be a walk-in thing where people are circumcised at their time of convenience…. Basically, I [don't] have problems with targets, but what I have issues with is the extremely large targets. A situation where the surgeon strains to meet the target. And I know when the surgeon is strained, the probability of having adverse events is high." Citing a similar alternative, as well as the implementation of more reasonable targets, Provider 1 offered:

> The targets will dilute VMMC as a practice because the number is overwhelming. Imagine if you start working at 8.00am and you want to do circumcision [until] around 10 pm… it is a long day. So targets should be at least reasonable. So from my side, I can talk about the targets, and the targets [should be] revised ….okay. Another thing is for instance… it should be incorporated to be like a clinic, in that if I come to the hospital I can even walk into the VMMC clinic. Not that I am being coerced to go for circumcision, but it should be part of us [an integrated part of the healthcare system]. You know the issue of targets is forcing people to go around looking for (clients) per day. It should be like a TB clinic. Yeah, like a walk-in clinic. So anybody can just come at his own time.

Yet another provider, when asked about the effects of targets on mobilizers, made comments that suggest the importance of improved communication as a means to decrease target burden on mobilizers for the benefit of all: "They [mobilizers] are a bit intimidated [by high targets]. So when they [VMMC technical advisors, program coordinators, etc.] set targets without consulting them, sometimes they even go slow and yeah, it affects our performance [numbers of clients to be circumcised]" [Provider 4].

DISCUSSION

Much effort has been made in epidemiological modelling of VMMC to determine who, when, and where to circumcise, and how many circumcisions will be necessary in order to curb the ESA HIV epidemic.[51-57] Yet in South Africa and elsewhere, studies have indicated that the

pursuit of targets (for uptake of combination antiretroviral therapy) may be at odds with quality of care.[58] This study identifies multiple unintended consequences linked directly or indirectly to the use of targets in VMMC services in ~~western~~ Kenya. As detailed above, these include pressures associated with VMMC ~~seasonality~~ client availability, ~~and~~ extra burdening of ~~overburdened~~ facilities, overworked clinical staff, deviations from the standard of care, and long waits at the clinic.

In 2008, soon after the randomized controlled trials on HIV and male circumcision, and in advance of global efforts to implement VMMC, UNAIDS issued guidance for program decision-makers on human rights, ethics, and legal considerations.[59] This guidance advocates for a human rights based approach to the implementation of VMMC programs that ensure that the procedure is carried out safely, under conditions of informed consent, and without coercion or discrimination. On this basis, the UNAIDS guidance also explicitly states that, "~~T~~target numbers of procedures, incentives to men, and incentives to providers should be avoided."[59] Similarly, PEPFAR guidelines have cautioned IPs against using targets to motivate mobilization or tethering VMMC remuneration to the number of procedures performed in order to avoid coercion.[13] According to the latest version of these guidelines, PEPFAR funded IPs who reward mobilizers are:

> …required to reward a team of mobilizers… so that any reward is based upon collective (versus individual) success. [This] approach limits the likelihood of coercion by separating any immediacy of reward resulting from an individual mobilizer referring a particular client. Mechanisms that further minimize perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.[14]

Despite these guidelines, our data suggest that this stated preference for team rather than individual targets may be misplaced, or at least may not make as much of a difference as intended, since teams may still be incentivized to use ~~coercive and/or deceptive~~misleading or otherwise questionable practices. While individual mobilizers ~~do~~ may not receive an immediate payment on a per-client basis, they ~~are~~ may be remunerated individually once they collectively (as a team) meet or surpass a given target. By coupling target achievement to remuneration, targets provide pressure to help ensure that adequate numbers of

adolescent circumcisions take place. Yet perversely, target pressure sometimes leads mobilization teams and providers to choose ethically dubious, but rational strategies to increase uptake, reduce effort, and/or shorten circumcision times ~~in order to~~to accomplish more MCs per day. Unfortunately, such strategies carry potentially deleterious outcomes for the boys this intervention is intended to protect. Moreover, they may not be in keeping with the ethics and human rights values to which VMMC funders and IPs purport to adhere.

Such strategies may include the mobilization of preadolescent clients, imbalanced discussions of benefits versus risks, abusive language and exploitation of ~~peer~~ social pressure to drive demand, and even dangerous shortcuts ~~that may amount to malpractice~~ (e.g., rushing surgeries ~~or choosing forceps-guided or the dorsal slit method to save time~~). One solution might involve increased efforts to ensure that ~~uncoupling~~ target achievement is entirely uncoupled from staff remuneration; mobilizers could draw salaries like the community health workers already working in the same communities—salaries that do not depend on targets. However, future research is needed to determine ~~if~~ whether target alternative programs, such as the integrated healthcare/walk-in clinic/passive models suggested by our interviewees, ~~could~~ can achieve the necessary number of MCs and do so without overly increasing costs. Indeed, efforts in Zimbabwe to integrate VMMC services into routine healthcare are encouraging,[60] and endeavors to integrate VMMC services in Kenya are already planned.[49] Yet, the performance based financial incentives used in Zimbabwe have been shown to be problematic[61] and our data suggest that this model would lead to similar issues in Kenya.

Concerning mobilizer messaging, others have previously criticized the PEPFAR-endorsed tactic of claiming as a "key message"[13] the benefit of a "60% reduction" in HIV risk.[20, 62-65] During observations of VMMC mobilization activities in our study ~~region~~Nyanza area, it became clear that few mobilizers and adolescent clients truly understood what the cited 60% reduction statistic would mean for them. More often, adolescents seemed confused and

asked mobilizers to explain the "missing 40%". Although some researchers have suggested moving beyond VMMC mobilization messages that emphasize HIV risk reduction to those that focus on a spectrum of benefits, including "hygiene, appearance, attractiveness to partners, peer norms, and modernity",[66] our data suggest that ~~peer-pressure-based~~ mobilization strategies that rely on peer pressure may be equally ~~coercive and~~ problematic~~misleading~~. For instance, is it ethical (or accurate) to suggest that to be circumcised is to be "modern" when less than 40% of men globally are circumcised and only a few high-income countries, including the US, have relatively high rates of MC [67, 68] (and even in the US, rates of MC have been falling)?[69-71] For similar reasons, the practice of public health workers persuading boys to become circumcised by claiming that their future female partners will definitely prefer them that way (and reject them if they are not) should be questioned if not discouraged.~~how is it ethical to suggest that a boy's future female partners will definitely prefer him to be circumcised, and may reject him if he is not?~~[46] In an effort to improve VMMC messaging, future studies could test the effectiveness of providing mobilizers with training in ethical conduct, as well as on the benefits versus risks of MC and how fairly and effectively to communicate ~~them~~ this information to adolescents.

The practice of using in-school health talks for VMMC mobilization warrants special ethical scrutiny. Not only do teachers and other school authorities often attend these talks—individuals who may have undue influence over boys' circumcision decisions—but the group-based nature of the talks, and the openness with which adolescent circumcision status is discussed and mobilization takes place, make these environments ripe for coercion. Recruitment of students for research in schools by teachers and other school authorities is discouraged by ethicists for similar reasons.[72] One possible solution might be to separate health talks from VMMC recruitment: mobilizers could conduct health talks one day and schedule a day to return. In a private setting on this second day, mobilizers could answer boys' questions, discuss consent and assent, and take down the details of any boy who would like to proceed with MC.

In January 2019, our research team presented study findings to policy professionals and program officials at a VMMC stakeholder meeting in ~~western~~ Kenya. In the discussion that followed, we considered various solutions to the ethical and practical concerns highlighted here. One strategy we discussed to address the problem of high and low seasons of ~~VMMC~~ client availability ~~implementation seasonality~~ and improve the quality of care provided at VMMC clinics was for funders and IPs to collaborate to develop "smart targets" that rise and fall with low and high seasons to match more efficiently resources and mobilization efforts to client demand and availability. As a part of this process, IP technical advisors could also work closely with school administrators in their catchment areas to find ways to conduct more MCs throughout the school year while minimizing the impact on educational activities and progress. Stakeholders also recognized that the training and awareness of mobilizers, counsellors, and clinic staff needs to be strengthened and; that quality assurance measures should be enhanced and better monitored.; ~~and that the practice of punishing IPs or mobilizers for failing to meet targets can lead to the unintended consequences revealed in our data.~~

~~To meet high service demand, supplemental funding should be provided to train VMMC clinical providers on the WHO recommended Models for Optimizing Volume and Efficiency (MOVE)[38, 73, 74] or similar methods that emphasize "task-shifting and task-sharing" to increase the number of MCs that can be safely and effectively conducted per day by VMMC clinical staff. Additionally, funders should ensure that IPs provide boys with food and water if extended stays at VMMC facilities are necessary. Similarly, transportation to and from the clinic must be adequate and timely.~~ Future studies should test the cost and feasibility of improving these aspects of care under real-world conditions.

LIMITATIONS

This is a qualitative study with very limited generalizability. Although, we used purposive or convenience sampling methods in this study, efforts were made to select facilities of various sizes (levels 2-5), and to work equally with VMMC clinical staff and mobilization teams from both ~~of the two~~ IP organizations ~~working in the region~~. In addition, we conducted mobilization and clinic observation sessions during both the "high" and "low" VMMC seasons, including separate visits to a Level 3 and a Level 4 VMMC clinic on high and low volume days.

This study relied on in-depth interviews and clinic observations. As in most qualitative studies of this kind, interviewee responses could be subject to social desirability bias. While we cannot exclude entirely the possibility of this bias, we made clear that we were only interested in interviewees' honest recollections of, and reflections on, their VMMC experiences. Moreover, the fact that interviewees were often critical of VMMC practices and, for instance, in the case of some clinical providers, admitted to cutting corners in care suggests that this type of bias may be less of an issue in this study.

Finally, our presence as observers at VMMC facilities and during mobilization activities may have changed the behavior of staff members and clients. We anticipated this possibility early on and in response, chose a two-pronged approach method (i.e., in-depth interviews and observations) ~~in order to~~to ensure the quality of data. This potential bias was also ~~taken into account~~considered during data analysis and presentation for publication. For instance, all findings based on observations were cross-verified by data from in-depth interviews, and vice versa.

CONCLUSION

~~In 2017, a report prepared for review by the United States Agency for International Development identified potential solutions for multiple "quality gaps" in VMMC implementation, including adverse events, low client follow-up rates, and inconsistent~~

~~messaging to clients.~~[28] ~~This document, however, did not include discussion of any ethical issues related to use of VMMC targets.~~ When VMMC for HIV prevention first began to be implemented in ESA, much attention was paid to the ethical, human rights, and legal considerations by the organizations that were (and are) involved in it. Since then, much of the discourse has been replaced by programmatic and technical guidance concerning how best to meet ambitious VMMC targets, with less attention to the broader effects of pursuing targets in the field. As our research shows, those considerations have not gone away. VMMC funders, governmental organizations, and IPs remain strongly committed to human rights and ethical values in the pursuit of public health goals. As such, they have a robust interest in information about how VMMC programs are implemented on the ground in Kenya and across ESA. These ethical considerations should be given more weight in future research and in the routine quality assurance checks conducted by IPs and funders, and where feasible, by independent authorities.

Further research is required to consider more fully the benefits versus risks associated with targets in mobilization activities and to develop improved or alternative systems through which to drive VMMC uptake ~~and hold accountable VMMC IPs~~. While PEPFAR already monitors VMMC clinical standards and practices (including recordkeeping) through the Site Improvement through Monitoring (SIMs) scheme, future partnerships between funders, IPs, and local civil society organizations could be fostered or strengthened to avoid the unintended consequences noted above and to ensure that clients receive the best of available care. At ~~the~~ a minimum, funders and governmental authorities should take on more target-setting input from IPs, including mobilizers and other staff on the ground, in an iterative and ongoing way. While it may not be reasonable or wise to call for the complete abandonment of the use of targets, given their necessity to intervention modelling and program budgeting, it is justified to be more critical of their use and aware of their potential unintended consequences.

Acknowledgements: The content of this paper is solely the responsibility of the authors. We would like to acknowledge the assistance provided by the regional Kenyan Ministries of Health and Education, and local VMMC implementing partner organizations. We owe special thanks to ~~all of~~all our interviewees and observation participants as well as to the members of the Intercounty VMMC Technical Working Group ~~from Kisumu and Siaya Counties~~ for their feedback concerning our findings during a stakeholder meeting in January 2019. We are very grateful for the coding assistance provided by Bonita Iritani. Additionally, we would like to recognize the contributions of Jack Odhiambo Owuor, Idrine Menge, Florence Anyango Otieno, Rogo Betty Fionner, and Rodney Mutula.

References

1. Weiss HA. Male circumcision as a preventive measure against HIV and other sexually transmitted diseases. Current Opinion In Infectious Diseases. 2007;20(1):66-72. PubMed PMID: 17197884.
2. Sharma SC, Raison N, Khan S, Shabbir M, Dasgupta P, Ahmed K. Male circumcision for the prevention of human immunodeficiency virus (HIV) acquisition: a meta-analysis. BJU International. 2018;121(4):515-26. doi: 10.1111/bju.14102. PubMed PMID: 128818736.
3. Fink AJ. A possible explanation for heterosexual male infection with AIDS. The New England journal of medicine. 1986;315(18):1167-.
4. Reed JB, Njeuhmeli E, Thomas AG, Bacon MC, Bailey R, Cherutich P, et al. Voluntary Medical Male Circumcision: An HIV Prevention Priority for PEPFAR. Journal of acquired immune deficiency syndromes (1999). 2012;60(0 3):S88-S95. doi: 10.1097/QAI.0b013e31825cac4e. PubMed PMID: PMC3663585.
5. Hines JZ, Ntsuape OC, Malaba K, Zegeye T, Serrem K, Odoyo-June E, et al. Scale-Up of Voluntary Medical Male Circumcision Services for HIV Prevention - 12 Countries in Southern and Eastern Africa, 2013-2016. MMWR Morbidity And Mortality Weekly Report. 2017;66(47):1285-90. doi: 10.15585/mmwr.mm6647a2. PubMed PMID: 29190263.
6. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR Panorama Spotlight Washington, D.C.: PEPFAR; 2019 [cited 2019 11 June]. Available from: https://data.pepfar.gov/.
7. Reed JB, Njeuhmeli E, Thomas AG, Thomas AG, Bacon MC, Bailey R, et al. Voluntary medical male circumcision: An HIV prevention priority for PEPFAR. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2012;60(Suppl 3):S88-S95. PubMed PMID: 2012-20414-003.
8. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Kenya Country Operational Plan (COP/ROP) 2018 Strategic Direction Summary. Washington, D.C.: 2018.
9. Mwandi Z, Murphy A, Reed J, Chesang K, Njeuhmeli E, Agot K, et al. Voluntary medical male circumcision: translating research into the rapid expansion of services in Kenya, 2008-2011. Plos Medicine. 2011;8(11):e1001130-e. doi: 10.1371/journal.pmed.1001130. PubMed PMID: 22140365.
10. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR 2018 Annual Report to Congress. In: PEPFAR, editor. Washington, D.C.2018.
11. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR Country/Regional Operational Plan (COP/ROP) Guidance 2017. Washington, D.C.: U.S. Department of State, 2017 18 January 2017. Report No.
12. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR 2018 Country Operational Plan Guidance for Standard Process Countries. Washington, D.C.: 2018.
13. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR best practices for voluntary medical male circumcision site operations: A service guide for site operations. PEPFAR Washington, DC; 2013.
14. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR's best practices for voluntary medical male circumcision site operations: A service guide for site operations. 2nd ed. Washington, D.C.: PEPFAR (U.S. President's Emergency Plan for AIDS Relief),; 2017.
15. Davis SM, Hines JZ, Habel M, Grund JM, Ridzon R, Baack B, et al. Progress in voluntary medical male circumcision for HIV prevention supported by the US President's Emergency Plan for AIDS Relief through 2017: longitudinal and recent cross-sectional programme data. BMJ open. 2018;8(8):e021835.
16. U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Kenya Country Operational Plan (COP) 2017: Strategic Direction Summary. Washington, D.C.: Services UDoHaH; 2017 21 April 2017. Report No.
17. Kripke K, Opuni M, Odoyo-June E, Onyango M, Young P, Serrem K, et al. Data triangulation to estimate age-specific coverage of voluntary medical male circumcision for HIV prevention in four Kenyan counties. PloS one. 2018;13(12):e0209385.

18. National AIDS and STI Control Program (NASCOP). National Voluntary Medical Male Circumcision Strategy 2014/15 - 2018/19. Nairobi: Government of Kenya, 2015.
19. Rennie S, Muula AS, Westreich D. Male circumcision and HIV prevention: ethical, medical and public health tradeoffs in low-income countries. Journal Of Medical Ethics. 2007;33(6):357-61. PubMed PMID: 17526688.
20. Masukume G. The ethics of claiming a 60% reduction in HIV acquisition from voluntary medical male circumcision. South African Journal of Bioethics and Law. 2014;7(1):4-.
21. Friedland BA, Apicella L, Schenk KD, Sheehy M, Hewett PC. How informed are clients who consent? A mixed-method evaluation of comprehension among clients of male circumcision services in Zambia and Swaziland. AIDS And Behavior. 2013;17(6):2269-82. doi: 10.1007/s10461-013-0424-1. PubMed PMID: 23392912.
22. Schenk KD, Friedland BA, Sheehy M, Apicella L, Hewett PC. Making the cut: Evidence-based lessons for improving the informed consent process for voluntary medical male circumcision in Swaziland and Zambia. AIDS Education and Prevention. 2014;26(2):170-84. doi: 10.1521/aeap.2014.26.2.170. PubMed PMID: 2014-13016-007.
23. Kaufman MR, Dam KH, Van Lith LM, Hatzold K, Mavhu W, Kahabuka C, et al. Voluntary medical male circumcision among adolescents: a missed opportunity for HIV behavioral interventions. AIDS (London, England). 2017;31 Suppl 3:S233-S41. doi: 10.1097/QAD.0000000000001484. PubMed PMID: 28665881.
24. Schenk K, Friedland B, Apicella L, Sheehy M, Munjile K, Hewett P. On the cutting edge: Improving the informed consent process for adolescents in Zambia undergoing male circumcision for HIV prevention. Vulnerable Children and Youth Studies. 2012;7(2):116-27. PubMed PMID: 27370100.
25. Kaufman MR, Patel EU, Dam KH, Packman ZR, Van Lith LM, Hatzold K, et al. Counseling Received by Adolescents Undergoing Voluntary Medical Male Circumcision: Moving Toward Age-Equitable Comprehensive Human Immunodeficiency Virus Prevention Measures. Clinical Infectious Diseases. 2018;66:S213-S20. doi: 10.1093/cid/cix952. PubMed PMID: 128906093.
26. Kaufman MR, Patel EU, Dam KH, Packman ZR, Van Lith LM, Hatzold K, et al. Impact of Counseling Received by Adolescents Undergoing Voluntary Medical Male Circumcision on Knowledge and Sexual Intentions. Clinical Infectious Diseases. 2018;66:S221-S8. doi: 10.1093/cid/cix973. PubMed PMID: 128906098.
27. Jennings L, Bertrand J, Rech D, Harvey SA, Hatzold K, Samkange CA, et al. Quality of voluntary medical male circumcision services during scale-up: a comparative process evaluation in Kenya, South Africa, Tanzania and Zimbabwe. Plos One. 2014;9(5):e79524-e. doi: 10.1371/journal.pone.0079524. PubMed PMID: 24801073.
28. University Research Company. Potential Solutions to Common Quality Gaps in VMMC Programs. Maryland: USAID Appying Science to Strengthen and Improve Systems Project, 2017.
29. National AIDS Control Council (NACC) and National AIDS and STIs Control Programme (NASCOP). Kenya HIV Estimates Report 2018. Nairobi: Kenya Ministry of Health, 2018.
30. Akullian A, Onyango M, Klein D, Odhiambo J, Bershteyn A. Geographic coverage of male circumcision in western Kenya. Medicine. 2017;96(2):e5885-e. doi: 10.1097/MD.0000000000005885. PubMed PMID: 28079830.
31. Muga R, Kizito P, Mbayah M, Gakuruh T. Overview of the health system in Kenya. Kenya service provision assessment (KSPA 2004) survey URL: https://dhsprogram com/pubs/pdf/spa8/02chapter2 pdf [accessed 2018-03-20][WebCite Cache ID 6y3kFHBkt]. 2005.
32. Kimathi L. Challenges of the Devolved Health Sector in Kenya: Teething Problems or Systemic Contradictions? Africa Development. 2017;42(1):55-77.
33. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. Health services research. 2007;42(4):1758-72. Epub

2007/02/09. doi: 10.1111/j.1475-6773.2006.00684.x. PubMed PMID: 17286625; PubMed Central PMCID: PMCPMC1955280.
34. VERBI Software. MAXQDA 12. Berlin, Germany2016.
35. Frade S, Rech D, Spyrelis A, Machaku M, Mavhu W, Omondi D, et al. Seasonal patterns in voluntary medical male circumcision (VMMC) in South Africa, Kenya, Tanzania and Zimbabwe. 6th South African AIDS Conference; 18-21 June; Durban2013.
36. Gold E, Mahler H, Boyee D. Overcoming seasonality in scaling up voluntary medical male circumcision. A case study from Tanzania. 2015.
37. Macklin R. On paying money to research subjects: 'due' and 'undue' inducements. Irb. 1981;3(5):1-6. Epub 1981/05/01. PubMed PMID: 11649367.
38. Curran K, Njeuhmeli E, Mirelman A, Dickson K, Adamu T, Cherutich P, et al. Voluntary Medical Male Circumcision: Strategies for Meeting the Human Resource Needs of Scale-Up in Southern and Eastern Africa. PLOS Medicine. 2011;8(11):e1001129. doi: 10.1371/journal.pmed.1001129.
39. Herman-Roloff A, Bailey RC, Agot K. Factors associated with the safety of voluntary medical male circumcision in Nyanza province, Kenya. Bulletin Of The World Health Organization. 2012;90(10):773-81. doi: 10.2471/BLT.12.106112. PubMed PMID: 23109745.
40. Gray R, Kigozi G, Serwadda D, Makumbi F, Watya, et al. Male circumcision for HIV prevention in men in Rakai, Uganda. Lancet. 2007;369(9562):657-66.
41. Bailey R, Moses S, Parker C, Agot K, Maclean I, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. Lancet. 2007;369(9562):643-56.
42. Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 trial. PLoS medicine. 2005;3(5):e226.
43. Gray R, Kigozi G, Kong X, Ssempiija V, Makumbi F, Wattya S, et al. The effectiveness of male circumcision for HIV prevention and effects on risk behaviors in a posttrial follow-up study. AIDS (London, England). 2012;26(5):609-15. Epub 2012/01/03. doi: 10.1097/QAD.0b013e3283504a3f. PubMed PMID: 22210632; PubMed Central PMCID: PMCPMC4296667.
44. Auvert B, Taljaard D, Rech D, Lissouba P, Singh B, Shabangu D, et al., editors. Effect of the Orange Farm (South Africa) male circumcision roll-out (ANRS-12126) on the spread of HIV. 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention; 2011.
45. Riess TH, Achieng MM, Bailey RC. Women's beliefs about male circumcision, HIV prevention, and sexual behaviors in Kisumu, Kenya. PloS one. 2014;9(5):e97748-e. doi: 10.1371/journal.pone.0097748. PubMed PMID: 24844845.
46. Osaki H, Mshana G, Wambura M, Grund J, Neke N, Kuringe E, et al. 'If you are not circumcised, i cannot say yes': The role of women in promoting the uptake of voluntary medical male circumcision in Tanzania. PloS one. 2015;10(9). PubMed PMID: 2016-03432-001.
47. Kaufman MR, Dam KH, Sharma K, Van Lith LM, Hatzold K, Marcell AV, et al. Females' Peer Influence and Support for Adolescent Males Receiving Voluntary Medical Male Circumcision Services. Clinical Infectious Diseases. 2018;66:S183-S8. doi: 10.1093/cid/cix1057. PubMed PMID: 128906100.
48. Morris BJ, Hankins CA, Banerjee J, Lumbers ER, Mindel A, Klausner JD, et al. Does Male Circumcision Reduce Women's Risk of Sexually Transmitted Infections, Cervical Cancer, and Associated Conditions? Frontiers in public health. 2019;7.
49. National AIDS and STI Control Program (NASCOP). National Voluntary Medical Male Circumcision Strategy 2014/15-2018/19. Nairobi: National AIDS and STI Control Program (NASCOP),. 2015.
50. World Health Organization (WHO). Male circumcision for HIV prevention. WHO technical advisory group on innovations in male circumcision. Geneva: WHO, 2015 30 September - 2 October 2014. Report No.

51. Njeuhmeli E, Forsythe S, Reed J, Opuni M, Bollinger L, Heard N, et al. Voluntary medical male circumcision: modeling the impact and cost of expanding male circumcision for HIV prevention in eastern and southern Africa. PLoS medicine. 2011;8(11):e1001132.
52. Blaizot S, Maman D, Riche B, Mukui I, Kirubi B, Ecochard R, et al. Potential impact of multiple interventions on HIV incidence in a hyperendemic region in Western Kenya: a modelling study. BMC Infectious Diseases. 2016;16(1):189. doi: 10.1186/s12879-016-1520-4.
53. Hankins C, Warren M, Njeuhmeli E. Voluntary Medical Male Circumcision for HIV Prevention: New Mathematical Models for Strategic Demand Creation Prioritizing Subpopulations by Age and Geography. PloS one. 2016;11(10):e0160699-e. doi: 10.1371/journal.pone.0160699. PubMed PMID: 27783613.
54. Kripke K, Chimbwandira F, Mwandi Z, Matchere F, Schnure M, Reed J, et al. Voluntary Medical Male Circumcision for HIV Prevention in Malawi: Modeling the Impact and Cost of Focusing the Program by Client Age and Geography. PloS one. 2016;11(7):1-11. doi: 10.1371/journal.pone.0156521. PubMed PMID: 116789851.
55. Kripke K, Okello V, Maziya V, Benzerga W, Mirira M, Gold E, et al. Voluntary Medical Male Circumcision for HIV Prevention in Swaziland: Modeling the Impact of Age Targeting. PLOS ONE. 2016;11(7):e0156776. doi: 10.1371/journal.pone.0156776.
56. Kripke K, Vazzano A, Kirungi W, Musinguzi J, Opio A, Ssempebwa R, et al. Modeling the Impact of Uganda's Safe Male Circumcision Program: Implications for Age and Regional Targeting. PLOS ONE. 2016;11(7):e0158693. doi: 10.1371/journal.pone.0158693.
57. McGillen JB, Stover J, Klein DJ, Xaba S, Ncube G, Mhangara M, et al. The emerging health impact of voluntary medical male circumcision in Zimbabwe: An evaluation using three epidemiological models. PLOS ONE. 2018;13(7):e0199453. doi: 10.1371/journal.pone.0199453.
58. de Kok BC, Widdicombe S, Pilnick A, Laurier E. Doing patient-centredness versus achieving public health targets: A critical review of interactional dilemmas in ART adherence support. Social Science & Medicine. 2018;205:17-25. doi: https://doi.org/10.1016/j.socscimed.2018.03.030.
59. HIV/AIDS JUNPo. Safe, voluntary, informed male circumcision and comprehensive HIV prevention programming: guidance for decision-makers on human rights, ethical and legal considerations. Safe, voluntary, informed male circumcision and comprehensive HIV prevention programming: guidance for decision-makers on human rights, ethical and legal considerations. 2008.
60. Feldacker C, Makunike-Chikwinya B, Holec M, Bochner AF, Stepaniak A, Nyanga R, et al. Implementing voluntary medical male circumcision using an innovative, integrated, health systems approach: experiences from 21 districts in Zimbabwe. Global health action. 2018;11(1):1414997-. doi: 10.1080/16549716.2017.1414997. PubMed PMID: 29322867.
61. Feldacker C, Bochner AF, Herman-Roloff A, Holec M, Murenje V, Stepaniak A, et al. Is it all about the money? A qualitative exploration of the effects of performance-based financial incentives on Zimbabwe's voluntary male medical circumcision program. PloS one. 2017;12(3):1-15. doi: 10.1371/journal.pone.0174047. PubMed PMID: 121877066.
62. Green LW, Travis JW, McAllister RG, Peterson KW, Vardanyan AN, Craig A. Male circumcision and HIV prevention: Insufficient evidence and neglected external validity. American journal of preventive medicine. 2010;39(5):479-82.
63. Gwandure C. The ethical concerns of using medical male circumcision in HIV prevention in Sub-Saharan Africa. South African Journal of Bioethics and Law. 2011;4(2):89-94.
64. Van Howe RS, Storms MR. How the circumcision solution in Africa will increase HIV infections. Journal of public health in Africa. 2011;2(1):e4-e. doi: 10.4081/jphia.2011.e4. PubMed PMID: 28299046.
65. Svoboda JS, Adler PW, Van Howe RS. Circumcision Is Unethical and Unlawful. The Journal Of Law, Medicine & Ethics: A Journal Of The American Society Of Law, Medicine & Ethics. 2016;44(2):263-82. doi: 10.1177/1073110516654120. PubMed PMID: 27338602.

66. Sgaier SK, Reed JB, Thomas A, Njeuhmeli E. Achieving the HIV Prevention Impact of Voluntary Medical Male Circumcision: Lessons and Challenges for Managing Programs. PLOS Medicine. 2014;11(5):e1001641. doi: 10.1371/journal.pmed.1001641.
67. Morris BJ, Wamai RG, Henebeng EB, Tobian AA, Klausner JD, Banerjee J, et al. Estimation of country-specific and global prevalence of male circumcision. Population Health Metrics. 2016;14(1):4. doi: 10.1186/s12963-016-0073-5.
68. Weiss H, Polonsky J, Bailey R, Hankins C, Halperin D, Schmid G. Male circumcision: global trends and determinants of prevalence, safety and acceptability. World Health Organization and the Joint United Nations Programme on HIV/AIDS (UNAIDS). 2007.
69. Owings M, Uddin S, Williams S. Trends in circumcision for male newborns in US hospitals. NCHS health notes: Citeseer; 2013.
70. Morris BJ, Bailis SA, Wiswell TE, editors. Circumcision rates in the United States: rising or falling? What effect might the new affirmative pediatric policy statement have? Mayo Clinic Proceedings; 2014: Elsevier.
71. Mor Z, Kent CK, Kohn RP, Klausner JD. Declining Rates in Male Circumcision amidst Increasing Evidence of its Public Health Benefit. PloS one. 2007;2(9):e861. doi: 10.1371/journal.pone.0000861.
72. Bonham VH, Morenso JD. Research with captive populations: Prisoners, students, and soldiers. In: Emanuel EJ, Grady CC, Crouch RA, Lie RK, Miller FG, Wendler DD, editors. The Oxford Handbook of Clinical Research Ethics. Oxford: Oxford University Press; 2008.
73. World Health Organization (WHO). Considerations for implementing models for optimizing the volume and efficiency of male circumcision services Geneva: World Health Organization; 2010 [cited 2019 11 January]. Available from: https://www.malecircumcision.org/sites/default/files/document_library/Considerations%20models.pdf.
74. Mahler HR, Kileo B, Curran K, Plotkin M, Adamu T, Hellar A, et al. Voluntary Medical Male Circumcision: Matching Demand and Supply with Quality and Efficiency in a High-Volume Campaign in Iringa Region, Tanzania. PLOS Medicine. 2011;8(11):e1001131. doi: 10.1371/journal.pmed.1001131.

Supporting information:

S1 Interview guides: The stakeholder interview guides used in this study.

S2 VMMC consent form: The Government of Kenya consent form for use in voluntary medical male circumcision.

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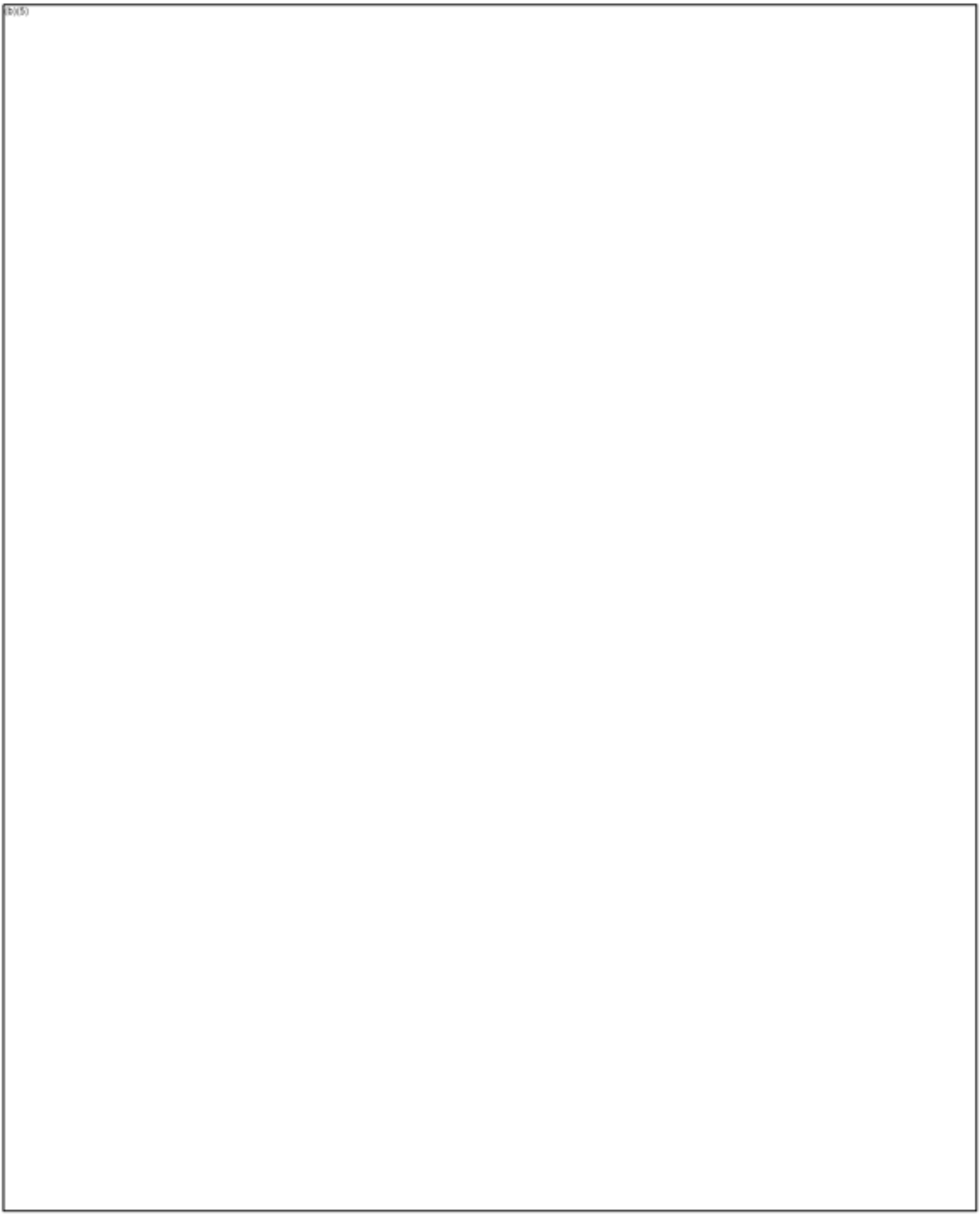
Response to Reviewers



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Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

Comments from Peter Kilmarx – January 23, 2017

Safety and Efficacy of the PrePex™ Device among HIV-positive men in Zimbabwe

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Background

Zimbabwe has reached ~~about~~ approximately 50% of ~~its~~ the national 1.3 million voluntary medical male circumcision (VMMC) target for 2018 [1] with a national VMMC program adverse event (AE) rate of 0.35% [2]. Non-surgical male circumcision (MC) devices, such as Pre ex, have the potential to accelerate adult VMMC programme scale up. In pilot studies and controlled trials in sub-Saharan Africa, moderate and severe AE rates from device-based MC range from 0-5.9% [3-9] with few severe AEs resulting in permanent impairment.

Pre ex ~~may be~~has been shown to be faster, ~~simpler~~more simple to implement, and more cost effective ~~as~~ when compared to surgical ~~circumcision~~ MC [10-12] and may be safely applied by less highly trained~~lower~~ cadres of nurses and clinicians [7, 13, 14]. In some contexts, ~~D~~devices, such as PrePex, ~~also~~ appear more acceptable than surgical MC as they do not cause prolonged pain [6] nor interrupt activities of daily living for most clients [5]. Pre ex has also proven safe and effective [3-5]. For these reasons, PrePex offers an important tool to accelerate VMMC programs to meet targets especially in men over age 15 years. Zimbabwe piloted the Pre ex device in a series of clinical trials from October 2011 to establish its safety and efficacy for VMMC among HIV-negative adults [15] and adolescents [16]. To date, WHO pre-qualification supports PrePex for circumcision of HIV negative adult men [17].

Stigma associated with identification as HIV-positive is a major barrier to the scale up of VMMC ~~in Zimbabwe~~, including the use of PrePex. While HIV testing is usually not a precondition to being circumcised in national VMMC policies, in practice virtually all men are HIV tested prior to circumcision, and some men report~~may~~ avoiding VMMC because they do not want to be HIV tested~~of the strong suggestion to~~perception that ~~HIV testing as part of VMMC counseling by both MC clients and providers~~ [18, 19]. If PrePex is shown to be safe among HIV-positive men, ~~promotion of~~provider initiated HIV testing would continue, but messaging about the perceived mandate for HIV testing before the procedure would be adapted, and the importance of this practice would diminish. Moreover, as VMMC scales up, excluding HIV-positive men in VMMC programs could increase stigmatization. To avoid indirect identification, HIV-positive men might seek MC surgery from potentially unsafe sources to mask their sero-status. ~~Similarly, cHIV-uninfected men might use their circumcision status to negotiate unsafe sex.~~ Therefore, establishment of the safety of use of PrePex for VMMC of HIV-positive men would be advantageous ~~in Zimbabwe and the region~~.

There is some evidence to support the safety of surgical VMMC in healthy, HIV-positive men [20-22], but ~~MC~~ research on the safety of MC among HIV-positive adults is limited, especially in the context of MC devices. This lack of evidence is most acute in countries in the African region where rapid expansion of male circumcision programmes is most urgent. Therefore, we conducted a one-arm, open-label, prospective, cohort field study to assess the safety, acceptability and feasibility of the PrePex device among HIV-positive adult men. The primary objective was to assess the safety of the PrePex device as measured through moderate or severe AEs among HIV-positive men in order to. ~~The results will~~ inform policy and clinical practice pertaining to HIV testing among men seeking circumcision.

Methods

(b)(5)

(b)(5)

Sample Size:

A sample size of 303 provided 80% power at the 0. 5% significance level to determine if the AE rate among the study population, composed of HIV-positive men who receive Pre ex MC, is non-inferior to that of surgical circumcision. Historically, the AE rate among HIV-negative adult PrePex clients was 2%; "nNon-inferior" was defined as not more than 2% greater than the historic AE rate ~~associated with surgical MC of 2%,~~ or, in other words, ~~a~~ 4% AE rate. The AE rate of 2% was selected as it is the lower bound of AE rates reported by previous rigorous studies {Bailey, 2007 #13;Auvert, 2005 #347;Gray, 2007 #99;} and because an AE rate of ≤2% is regarded as a global standard of VMMC safety [23, 24], including in Zimbabwe [2]. We anticipated a loss to follow-up of 20% and rounded up to 400 participants.

This study has 1 arm: HIV+ men using PrePex. It will compare HIV+ men with PrePex MC to the low historical pro-portion of men who experience any (mild, moderate or severe) AE with surgical MC of 2.0% in Kenya [22] and not to the higher rates of AEs of around 3% as seen in both Uganda [23] and South Africa [24] .

A sample size of 303 was calculated at 5% significance level and 80% power to test to see if the AE proportion among the study population is no more than 2% higher than the 2% from previous studies. We anticipated a loss to follow-up of 20% therefore we should recruit 303/0.8=379 participants. The sample size was rounded up to 400 evaluable partici-pants from whom data will be obtained for the study primary endpoints analysis.

Null hypothesis: PrePex has a higher AE rate than 2.0% (the assumed AE rate for forceps-guided MC), plus a non-inferiority margin of 2%. Thus, we fail to reject the hypothesis if our sample of HIV+ men with PrePex MC has an AE rate whose confidence interval crosses 4% (2% historical rate+2% non-inferiority margin).

Alternative hypothesis: PrePex MC does not have an inferior AE rate than forceps-guided MC, defining "not inferi-or" as not being more than 2% greater than the historic AE rate for forceps-guided MC of 2%.

Table 1: Sample size requirements for 80% power

Non-Inferiority Margin	AE proportion cutoff for Prepex Non-Inferiority	Sample Size (1 arm)
1%	3% AEs or less	1212
2%	4% AEs or less	303
3%	5% AEs or less	135

Based on: http://www.cct.cuhk.edu.hk/stat/proportion/OSp_sup.htm

This power calculation was not done for a specific number of historical controls, but rather as a one sample test, using the rate of AEs that we expect based on previous research (2%). This study design compares the AE propor-tion among a study population composed of HIV+ men who receive PrePex MC and tests to see if that proportion is non-inferior to the 2% from previous studies.. Because our comparison group in this study design is a number (2%), rather than a sample of individuals with its own uncertainty and confidence intervals, the sample size needed is much smaller. However, because there is no actual control group, this design has less utility in comparing PrePex MC to forceps guided, since it requires the assumption that forceps-guided MC AEs would have been exactly 2.0% in the study population.

Study site and recruitment

The study was implemented in a large urban area outside of Harare. The study team included

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PrePex master trainers: one surgeon, one urologist and three trained nurses. Males ages 18 and above who voluntarily presented at the study site for circumcision and accepted to be HIV tested could participate. Those who agreed to PrePex circumcision signed the Medical Research Council of Zimbabwe's approved Informed Consent Form before further counseling and assessment for eligibility. Prior to actual PrePex circumcision procedure, all eligible men had an HIV test to confirm their HIV status.

Recruitment from opportunistic infection treatment sites was conducted from October 2015 to May 2016. A total of 1094 clients were screened over a period of 160 working days. Additional inclusion criteria included: confirmed HIV-positive status; WHO HIV clinical stage 1 or 2; agreed to be circumcised by PrePex; ability to give informed consent; agreed to return to the health care facility for follow-up visits until complete healing 7 weeks from device application or until cleared by a clinician; and agreement to anonymous photographs. Exclusion criteria included: known bleeding or coagulation abnormality; uncontrolled diabetes; active genital infection, anatomic abnormality; WHO HIV stage 3 and above; or do not agree to PrePex. Potential participants who did not meet the inclusion criteria were offered surgical circumcision. Study flow is presented in figure 1. The number and reasons for such exclusions were recorded and noted in Table 1.

Follow-up

Client Reporting Forms (CRFs) were completed during each visit by a clinician. The visit schedule is shown in Table 2. All participants received the minimum package of VMMC services ~~which~~ that included ~~:~~ information about the risks and benefits of the MC procedure, ~~counselling about the need to adopt and maintain safer sexual practices,~~ access to HIV testing, and management of sexually transmitted infections (STIs) before the procedure as well as , counselling about the need to adopt and maintain safer sexual practices and condom promotion during post-procedure follow-up visits, ~~and provision and the management of sexually transmitted infections (STIs).~~ Participants were also reminded about the added risk of HIV infection to their partners. CD4 data from participants were collected using a small finger prick to obtain blood sample and analyzed using PIMA Point of care CD4 machine. In addition, participants were instructed to return to the clinic for an unscheduled visit if they experienced any AEs or complications with the device. Weekly visits stopped when the wound was assessed as healed. All men were asked to return for a Day 90 visit for a final physical exam.

If a participant failed to attend the scheduled weekly visit, up to three contact attempts were made by phone and SMS. For a missed Day 7 device removal visit, the study nurse also attempted at least two home visits. All attempts to contact the client were recorded on a contact log in the client's file. All data including AEs ~~was were~~ documented at each visit using CRFs.

Data management and analysis

CRF-based information on safety, efficacy, pain and acceptability of the device was collected and analyzed. ~~CD4 data from participants was were collected using a small finger prick to obtain blood sample and analyzed using PIMA Point of care CD4 machine.~~ Safety of the PrePex™ device was assessed by documenting the incidence of moderate and serious clinical AEs {Population Services International, 2016 #529}. Expected procedure side effects such as localized edema, oozing, clear exudates were not included in the primary safety endpoint but were reported separately.

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Double data entry enabled verification of was performed for all quantitative data. Baseline demographics and patient characteristics are summarized, including inter-quartile ranges (IQR) and presented in tabular format using descriptive statistics. AEs are described and AE rates compared descriptively with the reported rates of similar device treatments; 95%, confidence intervals (CI) were calculated using the Wilson exact test for proportions.

Ethical conduct of the study

The Medical Research Council of Zimbabwe (MRCZ) Harare, Zimbabwe, the University of Washington Human Subjects Division , Seattle, Washington, USA; and the Centers for Disease Control and Prevention, USA, approved this study. In addition, a Data Safety Monitoring Board was established to provide oversight in all phases of the trial.

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Results

Demographic characteristics

Of the 400 participants, tThe median age of participants enrolled in the study was 40 years (IQR:34, 46); the youngest participant was 18 years and the oldest was 73 years (Table 3). Most (75.2%) participants came from Harare area. The majority of participants were observed to be in WHO stage 2 (79.5%). Median CD4 was 336.5c/µl (IQR:232,459), with a range of 8 to 1050 c/µl.

Adherence to study visits

Participants were expected to attend all scheduled visits according to the study schedule until complete healing was assessed. ~~All participants were expected to attend the Day 90 visit.~~ Adherence to visits was high (Table 4). Visit adherence through Day 42, the final day of assessment for routine Prepex VMMC, was ~~over~~ 92% or greater at each time point. Visit adherence to the final study visit at Day 90 was ~~over~~ 94.2%.

Device Removal

The vast majority (394) of devices were successfully removed on-site on Dday 7 following placement. For the six other participants, one removed their device within hours of placement and no further action was required. One participant reported removal on day 7 at another site. These were not considered AEs. Details of the other cases are explained in AE section below.

Adverse Events

AEs were assessed and recorded using the PrePex MC Classification of Adverse Events and Device Hazards (Annex 1). ~~The study-related, severe AE rate was 1.0%.~~ There were four cases of mild AEs: all four were cases of localized edema managed by penile elevation. No moderate AEs were reported.

A total of four study-related severe AEs were reported ~~during the course of the study. The study-related,~~ resulting in a severe AE rate wasof 1.0% (95% CI: 1.39, 3.54) (p=0.0003). ~~A total of four study-related severe AEs were reported during the course of the study.~~ Four d-evice displacements, when the PrePex device is intentionally or accidentally dislodged during the 7-day placement period, were reported with the device in situ: one on day 1; two on day 3; and one on day 5. These are considered severe because a surgical MC procedure is required as part of clinical management. All device displacements were resolved with surgical circumcision. All four men healed completely. Additionally, two non-study related severe AEs were reported. One

urethral stricture was detected on day 37 and determined to be related to prior conditions previously not reported. This man healed completely. Lastly, one study participant death was reported due to car accident; this was unrelated to the study. All AEs were reported to MRCZ as required by the protocol. As noted, four of the six were consistent with the MRCZ classification of device-related AEs. Details of these six cases are included in the appendix (XX).

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Discussion

This study demonstrated that Pre ex is acceptable and safe for HIV-positive men. With an AE rate of 1.0%, the risk of serious AEs is below the rate from previous PrePex [3] and other VMMC device-based [9] studies among HIV-negative men and similar to the AE rate from previous PrePex trials in Zimbabwe [16, 25]. The AE rate is also below the accepted AE risk (≤2%) of the global VMMC community [2, 23, 24]. As adherence to follow-up visits was quite high, it is unlikely that additional severe or moderate AEs would have been missed in this study. This low rate of AEs among HIV-positive men using the Pre ex VMMC device demonstrates that Pre ex is safe for use among HIV-positive men. Therefore, without any additional risk of AEs among these men, all men should be allowed to access VMMC without mandatory HIV testing.

HIV-positive men have been largely ignored in the roll-out of VMMC services, including Pre ex [26]. The UNAIDS/WHO Joint Strategic Action Framework 2012-2016 set a target of 80% coverage among HIV-negative men 15-49 years old in 14 priority countries by 2016, requiring approximately 20 million VMMCs [27]. Therefore, VMMC is promoted for sexually-active, HIV-negative men in sub-Saharan Africa. HIV testing is a common component of VMMC programs to ensure successful targeting of this focal group. However, HIV/AIDS-related stigma is still a major barrier to HIV testing update [28], and inclusion of HIV testing alongside VMMC service delivery may be a barrier to VMMC uptake in the sub-Saharan African region [29] where HIV prevention efforts are most needed.

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Although there is some hesitation to circumcise HIV-positive men due to a perceived higher risk of HIV transmission to partners during the healing process, in our study, only four men ~~admitted~~ reported ~~to~~ having sex the week before they were fully healed. It appears that most men abstained from sex until complete healing as instructed, reducing risk to partners. Although this may underestimate true sexual activity, the overall risks to female partners, especially during the healing process, are difficult to quantify. In a surgical MC cohort study, the main risk for partners appears to occurs during the first 6 weeks after MC as viral shedding increased during that time, then decreas~~ed~~ing after that period [30]. ~~Another~~ randomized controlled trial attempted to assess whether surgical circumcision in HIV-positive men would reduce transmission of the virus to female sexual partners; the study was stopped early as 18% of women in the intervention arm (MC) and 12% of women in the control arm (non-MC) acquired HIV during follow-up, giving an adjusted HR was 1.49 (0.62-3.57) [31]. Although these studies suggest that there may be some additional risk to female partners associated with surgical MC among HIV-positive men in the post-op period, a meta-analysis of six longitudinal cohort studies found little evidence that male circumcision increases~~directly reduces~~ overall risk of transmission to women (RR = 0.80, 95% CI 0.53-1.36)[32]~~, suggesting further confirmation that the HIV prevention benefits of MC are primarily aimed at protecting HIV-naive men.~~

It is critical to note that the benefits of VMMC extend beyond HIV: VMMC also protects males from cancers of the penis, urinary tract infections and ulcerative sexually transmitted diseases , [33] diseases that also affect HIV-positive men. VMMC may reduce the prevalence and incidence of HPV infections in female partners [31, 34-36], including among partners of HIV-infected men [35], decreasing the risk of cervical cancer among these women. With consideration of these additional potential benefits to female partners, it appears that the risk of HIV transmission to female partners is not a strong argument against circumcising HIV-positive men.

This study has several limitations. First, this study compared the AE rate to historical controls and the global acceptable standard of AEs of ≤2%; there is no comparison group for this study. However, because AE rates among HIV-negative men in VMMC programs, including in Zimbabwe, are known, we believe this one-arm study overcomes this weakness. Also, because only HIV-positive men participated in this study, they were older than the average age of men who undergo circumcision in Zimbabwe. This is unlikely to affect the AE rate or bias the results. Lastly, this study did not enroll female partners or investigate HIV transmission to study partners over time. As the study focused on the safety of PrePex among this cohort of HIV-positive men, this was outside the scope of budget of this small study.

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Conclusion

Male circumcision among HIV-positive using the Pre ex device is safe. The risk of adverse events is lower than the ≤2% rate used as a standard of quality care for MC practice. Therefore, to improve uptake of VMMC, we recommend removing the barrier of perceived mandatory HIV testing as part of routine VMMC. In order to promote uptake and reduce barriers to VMMC due to stigma, we recommend that HIV testing be advertised to potential clients as, "recommended not mandatory". In concert with continued promotion of safer sex practices in accordance with VMMC guidelines, we expect that MC service provision could be made more efficient and uptake increase as a result of this suggested policy change, increasing the positive effects of VMMC in the region.

Table 1 Reasons for non-eligibility of participants

Reason:	Frequency	Percentage
Urethral discharge syndrome	1	0.3%
Epistaxis	1	0.3%
Hypospadias	1	0.3%
Hydrocele	2	0.6%
Enlarged prostate	2	0.6%
Refused HIV testing	2	0.6%
Genital sores	3	0.8%
Uncontrolled diabetes	3	0.8%
WHO Stage 3 or 4	3	0.8%
Already circumcised	3	0.8%
Keloids	4	1.1%
Unable to come for reviews	4	1.1%
Opted for surgical	4	1.1%
Phimosis	5	1.4%
Hypertensive	5	1.4%
Genital ulcer	6	1.7%
Adhesions	6	1.7%
Genital warts	10	2.8%
HIV negative	292	81.8%
Total	**357**	

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Table 2: Study follow-up activities and schedule

	Screening, and Device Application	Removal Visit	Physical Examination	Physical Examination	Physical Examination	Physical Examination	Physical Examination
Visit #	1	2	3	4	5	6	7, 8, 9, 10, 11, 12
Day (D)/week (w)	D0	D7	D9	D14	D21	D28	D35, 42, 49, 56, 63, 90
Informed consent	X						
Screen for inclusion/exclusion	X						
Participant specimen collection for CD4 count	X						
Medical history & demography	X						
Current medications	X	X	X	X	X	X	X
Psychosocial interview (n=200)	X			X			X (D90)
Genital examination and potential pictures	X	X	X	X	X	X	X
Device application	X						
Foreskin removal		X					
Device removal		X					
Subject's subjective pain, tingling and discomfort evaluation	X	X	X	X	X	X	X
Evaluate side effects and AEs	X	X	X	X	X	X	X
MC-related attitudes, satisfaction, and return to sexual activity	X	X	X	X	X	X	X

Table 3. Demographics of the Study Participants (n=400)

Characteristic	Frequency	DescriptionProportion (%)
Age		
<25	18	4.5%
25-34	87	(21.8)
35-44	173	(43.3)
45+	122	(30.5)
CD4		
0-250 c/µl	124	31.0%
251-500 c/µl	202	50.5%
501-750 c/µl	65	16.3%
751-1000c/ µl	8	2.0%
Above 1000c/ µl	1	0.3%
WHO clinical stage		
Stage 1	82	20.5%
Stage 2	318	79.5%
ARV regimen		
1st line	322	80.5%
2nd line	15	3.8%
None	53	13.5
Marital Status		
Married	306	76.5%
Single	44	11.0%
Separated / Divorced	29	7.3%
Widowed	21	5.3%
Type of employment		
Informal	210	52.5%
Formal	118	29.5%
Unemployed	65	16.3%
Student	7	1.88%
Residence		
Harare area	301	75.2
Other	99	24.8

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Table 4: Visit adherence

Visit date	Attended/expected*	% Attendance
Day 7	394/395	99.8
Day 9	392/395	99.2
Day 14	381/395	96.4
Day 21	374/395	94.7
Day 28	372/395	94.2
Day 35	341/365	93.4
Day 42	237/255	92.9
Day 49	121/137	88.3
Day 56	41/53	77.4
Day 63	10/21	47.6
Day 90	372/395	94.2

*Participants attended visits until complete healing. Day 90 visit was required.

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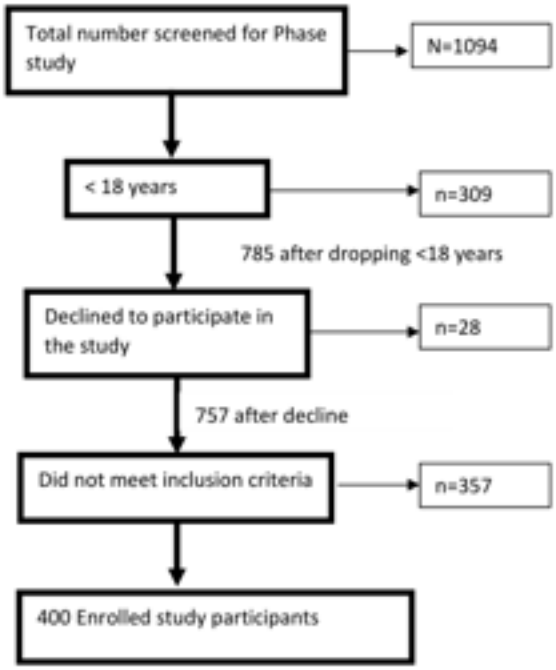
Figure 1. Flow Chart from screening to enrollment



(b)(5)

1. Zimbabwe Ministry of Health and Child Care. *National Overview*. in *VMMC Review and Planning Meeting*. 2016. Kadoma, Zimbabwe.
2. Zimbabwe Ministry of Health and Child Care, *Accelerated Strategic and Operational Plan 2014 – 2018*. 2014: Harare- Zimbabwe.
3. Bitega, J.P., et al., *Safety and efficacy of the PrePex device for rapid scale-up of male circumcision for HIV prevention in resource-limited settings.* J Acquir Immune Defic Syndr, 2011. **58**(5): p. e127-34.
4. Feldblum, P.J., et al., *Safety, effectiveness and acceptability of the PrePex device for adult male circumcision in Kenya.* PLoS One, 2014. **9**(5): p. e95357.
5. Kigozi, G., et al., *The safety and acceptance of the PrePex device for non-surgical adult male circumcision in Rakai, Uganda. A non-randomized observational study.* PLoS One, 2014. **9**(8): p. e100008.
6. Lebina, L., et al., *Piloting PrePex for Adult and Adolescent Male Circumcision in South Africa - Pain Is an Issue.* PLoS One, 2015. **10**(9): p. e0138755.
7. Mutabazi, V., et al., *One-arm, open-label, prospective, cohort field study to assess the safety and efficacy of the PrePex device for scale-up of nonsurgical circumcision when performed by nurses in resource-limited settings for HIV prevention.* J Acquir Immune Defic Syndr, 2013. **63**(3): p. 315-22.
8. Galukande, M., et al., *Adverse events profile of PrePex a non-surgical device for adult male circumcision in a Ugandan urban setting.* PloS one, 2014. **9**(1): p. e86631.
9. Sokal, D.C., et al., *Randomized controlled trial of the shang ring versus conventional surgical techniques for adult male circumcision: safety and acceptability.* J Acquir Immune Defic Syndr, 2014. **65**(4): p. 447-55.
10. Tshimanga, M., et al., *A Phase II Randomized Controlled Trial Comparing Safety, Procedure Time, and Cost of the PrePex™ Device to Forceps Guided Surgical Circumcision in Zimbabwe.* PloS one, 2016. **11**(5): p. e0156220.
11. Mutabazi, V., et al., *Cost Analysis of Adult Male Circumcision with the PrePex Device versus Surgery in Rwanda.* Urol Nurs, 2014. **34**(6): p. 303-11.
12. Kim, H.Y., et al., *Evaluating the cost of adult voluntary medical male circumcision in a mixed (surgical and PrePex) site compared to a hypothetical PrePex-only site in South Africa.* Glob Health Action, 2015. **8**: p. 29116.
13. Galukande, M., et al., *Skills training of health workers in the use of a non surgical device (PrePex) for adult Safe Male Circumcision.* PLoS One, 2014. **9**(8): p. e104893.
14. Mutabazi, V., et al., *Non-surgical adult male circumcision using the PrePex device: task-shifting from physicians to nurses.* Afr J Reprod Health, 2014. **18**(1): p. 61-70.
15. Tshimanga, M., et al., *A Phase II Randomized Controlled Trial Comparing Safety, Procedure Time, and Cost of the PrePex™ Device to Forceps Guided Surgical Circumcision in Zimbabwe.* PLoS ONE, 2016. **11**(5): p. e0156220.
16. Tshimanga, M., et al., *Safety Profile of PrePex Male Circumcision Device and Client Satisfaction With Adolescent Males Aged 13–17 Years in Zimbabwe.* Journal of Acquired Immune Deficiency Syndromes (1999), 2016. **72**(Suppl 1): p. S36.
17. World Health Organization, *WHO Technical Advisory Group on Innovations in Male Circumcision: Evaluation of Two Adult Devices*. 2013, WHO: Geneva, Switzerland.
18. Moyo, S., et al., *Men's attitudes: A hindrance to the demand for voluntary medical male circumcision–A qualitative study in rural Mhondoro-Ngezi, Zimbabwe.* Global public health,

2015(ahead-of-print): p. 1-13.
19. Hatzold, K., et al., *Barriers and motivators to voluntary medical male circumcision uptake among different age groups of men in Zimbabwe: results from a mixed methods study.* PloS one, 2014. **9**(5): p. e85051.
20. Kigozi, G., et al., *The safety of adult male circumcision in HIV-infected and uninfected men in Rakai, Uganda.* PLoS Med, 2008. **5**(6): p. e116.
21. Godfrey, K., et al., *Male Circumcision Wound Healing in HIV-negative and HIV-positive men in Rakai, Uganda.* BJU Int, 2013.
22. Kigozi, G., et al., *Safety of medical male circumcision in human immunodeficiency virus-infected men in Rakai, Uganda.* Urology, 2014. **83**(2): p. 294-7.
23. World Health Organization, *WHO Technical Advisory Group on Innovations in Male Circumcision: Evaluation of two adult devices: Meeting report*. January, 2013 WHO: Geneva, Switzerland.
24. Byabagambi J, et al. *A Guide to Improving the Quality of Safe Male Circumcision in Uganda*. 2015.
25. Tshimanga, M., G. Gwinji, and O. Mugurungi, *Evaluation of Safety and Efficacy of PrePex Device for Male Circumcision in Zimbabwe.* Phase I: Device Safety Trial Report. Harare, Zimbabwe: Ministry of Health and Child Welfare, 2013.
26. Mahomed, M., et al., *HIV Is the Primary Exclusion Criterion in a PrePex™ Male Circumcision Device Introductory Study in Mozambique.* AIDS research and human retroviruses, 2014. **30**(S1): p. A198-A198.
27. WHO, U., *Joint Strategic Action Framework to Accelerate the Scale-Up of Voluntary Medical Male Circumcision for HIV Prevention in Eastern and Southern Africa (2012–2016).* Geneva: UNAIDS, 2011.
28. Mahajan, A.P., et al., *Stigma in the HIV/AIDS epidemic: a review of the literature and recommendations for the way forward.* AIDS (London, England), 2008. **22**(Suppl 2): p. S67.
29. Lissouba, P., et al., *A model for the roll-out of comprehensive adult male circumcision services in African low-income settings of high HIV incidence: the ANRS 12126 Bophelo Pele Project.* PLoS medicine, 2010. **7**(7): p. e1000309.
30. Odoyo-June, E., et al., *Changes in plasma viral load and penile viral shedding after circumcision among HIV-positive men in Kisumu, Kenya.* J Acquir Immune Defic Syndr, 2013.
31. Wawer, M.J., et al., *Circumcision in HIV-infected men and its effect on HIV transmission to female partners in Rakai, Uganda: a randomised controlled trial.* Lancet, 2009. **374**(9685): p. 229-37.
32. Weiss, H.A., C.A. Hankins, and K. Dickson, *Male circumcision and risk of HIV infection in women: a systematic review and meta-analysis.* Lancet Infect Dis, 2009. **9**(11): p. 669-77.
33. Moses, S., R.C. Bailey, and A.R. Ronald, *Male circumcision: assessment of health benefits and risks.* Sexually transmitted infections, 1998. **74**(5): p. 368-373.
34. Larke, N., et al., *Male circumcision and human papillomavirus infection in men: a systematic review and meta-analysis.* J Infect Dis, 2011. **204**(9): p. 1375-90.
35. Serwadda, D., et al., *Circumcision of HIV-infected men: effects on high-risk human papillomavirus infections in a randomized trial in Rakai, Uganda.* J Infect Dis, 2010. **201**(10): p. 1463-9.
36. Auvert, B., et al., *Effect of male circumcision on the prevalence of high-risk human papillomavirus in young men: results of a randomized controlled trial conducted in Orange Farm, South Africa.* J Infect Dis, 2009. **199**(1): p. 14-9.

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Brian Morris <brian.morris@sydney.edu.au>
Subject:	RE: Male circ pubs: Highly virulent HIV variant discovered in Netherlands; Sexual pleasure technical guide; VMMC has big impact in youth in S. Afr; Greater social engagement for unscientific articles; Occlusion and micro-incontinence in l...
Date:	2022/02/08 12:55:00
Priority:	Normal
Type:	Note

Hi Brian,
Thanks for sending these updates.

Note from the text of Johnson et al.: "The prevention benefits of VMMC in South Africa are expected to grow substantially over the next decade as these young men reach their peak ages of sexual risk behaviour, and as the secondary benefits of reduced transmission to female partners become more substantial."

Cheers,
PK

From: Brian Morris via Caa1 <caa1@lists.circumcisionaustralia.org>
Sent: Tuesday, February 8, 2022 11:51 AM
To: caa1@lists.circumcisionaustralia.org
Subject: [EXTERNAL] [Caa1] Male circ pubs: Highly virulent HIV variant discovered in Netherlands; Sexual pleasure technical guide; VMMC has big impact in youth in S. Afr; Greater social engagement for unscientific articles; Occlusion and micro-incontinence in l...

Male circumcision publications this week: Highly virulent HIV variant discovered in Netherlands; Sexual pleasure technical guide; VMMC has big impact in youth in S. Afr; Greater social engagement for unscientific articles; Occlusion and micro-incontinence in lichen sclerosus; Megameatus intact prepuce repair; Tablet-based interactive distraction for pain and anxiety during circumcision of boys; Devices and techniques in adolescent and adult males {German]; Polypoid penile tumor; Acquired lyphangioma circumscriptum.

https://www.science.org/doi/full/10.1126/science.abk1688?et_rid=17217576&utm_campaign=SCIeToc&af=R&et_cid=4098831&utm_medium=email&utm_content=alert&utm_source=sfmc

A highly virulent variant of HIV-1 circulating in the Netherlands

CHRIS WYMANT ____ DANIELA BEZEMER ____ FRANÇOIS BLANQUART ____ LUCA FERRETTI ____ ASTRID GALL ____ MATTHEW HALL ____ TANYA GOLUBCHIK ____ MARGREET BAKKERSWEE HOE ONG ____ [...] THE BEEHIVE COLLABORATION† +25 AUTHORS AUTHORS INFO & AFFILIATIONS

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Evolving virulence in HIV

Changes in viral load and $CD4^+$ T cell decline are expected signals of HIV evolution. By examining data from well-characterized European cohorts, Wymant *et al*. report an exceptionally virulent subtype of HIV that has been circulating in the Netherlands for several years (see the Perspective by Wertheim). More than one hundred individuals infected with a characteristic subtype B lineage of HIV-1 were found who experienced double the rate of $CD4^+$ cell count declines than expected. By the time they were diagnosed, these individuals were vulnerable to developing AIDS within 2 to 3 years. This virus lineage, which has apparently arisen de novo since around the millennium, shows extensive change across the genome affecting almost 300 amino acids, which makes it hard to discern the mechanism for elevated virulence. —CA

Abstract

We discovered a highly virulent variant of subtype-B HIV-1 in the Netherlands. One hundred nine individuals with this variant had a 0.54 to 0.74 $\log_{10}$ increase (i.e., a ~3.5-fold to 5.5-fold increase) in viral load compared with, and exhibited CD4 cell decline twice as fast as, 6604 individuals with other subtype-B strains. Without treatment, advanced HIV—CD4 cell counts below 350 cells per cubic millimeter, with long-term clinical consequences—is expected to be reached, on average, 9 months after diagnosis for individuals in their thirties with this variant. Age, sex, suspected mode of transmission, and place of birth for the aforementioned 109 individuals were typical for HIV-positive people in the Netherlands, which suggests that the increased virulence is attributable to the viral strain. Genetic sequence analysis suggests that this variant arose in the 1990s from de novo mutation, not recombination, with increased transmissibility and an unfamiliar molecular mechanism of virulence.

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JOEL O. WERTHEIM

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See also:

https://www.technologynetworks.com/genomics/news/how-a-new-highly-virulent-hiv-strain-was-discovered-in-the-netherlands-358154?utm_campaign=NEWSLETTER_TN_Breaking%20Science%20News&utm_medium=email&_hsmi=202935160&_hsenc=p2ANqtz--3N_PZOdgkIcURcJwTu9Aygofa6E2Rz4JEAH7WDAs_L7sYWG_-FSExD3-IQAtYIwA5AkzdAARqMJkYsFa-fURWOtW9_gx5QdljTis1j64cp0zsIHk&utm_content=202935160&utm_source=hs_email

News

How a New, Highly Virulent HIV Strain Was Discovered in the Netherlands

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International Journal of Sexual Health

The World Association for Sexual Health's Declaration on Sexual Pleasure: A Technical Guide

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Abstract

This article provides technical guidance on the content, meaning, and application of the World Association of Sexual Health (WAS) Declaration on Sexual Pleasure to various stakeholders and practitioners working in the area of sexuality, sexual health, and sexual rights. A growing body of work shows that sexual pleasure is integral to broader health, mental health, sexual health, well-being and rights and indeed can lead to improvements in health. Yet, more research is needed to identify the best ways to incorporate sexual pleasure to achieve sexual health for different outcomes and populations. In the first part of this article, we deconstruct each statement from the WAS Declaration on Sexual Pleasure and provide key evidence from the literature supporting these statements. In the latter part of the article, we provide guidance on how to include sexual pleasure as a fundamental part of sexual health and sexual rights work. We include a series of case studies and highlight key actions and principles for advocacy, implementation, and quality assurance in terms of law and policy, comprehensive sexuality education, health care services and dissemination of knowledge. This technical document seeks to inspire our partners and collaborators to embark on a journey toward a pleasure-based approach to sexual health and sexual rights. Our hope is that the literature, guidance and case studies provided here can ignite ongoing advocacy and collaboration to embrace sexual pleasure in all settings.

https://pubmed.ncbi.nlm.nih.gov/35125471/
J Acquir Immune Defic Syndr. 2022 Feb 3.
doi: 10.1097/QAI.0000000000002927.Online ahead of print.

The effect of HIV programmes in South Africa on national HIV incidence trends, 2000-2019

Leigh F Johnson[1], Gesine Meyer-Rath, Rob E Dorrington, Adrian Puren, Thapelo Seathlodi, Khangelani Zuma, Ali Feizzadeh

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PMID: 35125471 DOI: 10.1097/QAI.0000000000002927

Abstract

Background: Recent studies have shown HIV incidence declines at a population level in several African countries. However, these studies have not directly quantified the extent to which incidence declines are attributable to different HIV programmes.

Methods: We calibrated a mathematical model of the South African HIV epidemic to age- and sex-specific data from antenatal surveys, household surveys and death registration, using a Bayesian approach. The model was also parameterized using data on self-reported condom use, voluntary medical male circumcision (VMMC), HIV testing and antiretroviral treatment (ART). Model estimates of HIV incidence were compared against the incidence rates that would have been expected had each programme not been implemented.

Results: The model estimated incidence in 15-49 year olds of 0.84% (95% CI: 0.75-0.96%) at the start of 2019. This represents a 62% reduction (95% CI: 55-66%) relative to 2000, a 47% reduction (95% CI: 42-51%) relative to 2010, and a 73% reduction (95% CI: 68-77%) relative to the incidence that would have been expected in 2019 in the absence of any interventions. The reduction in incidence in 2019 due to interventions was greatest for ART and condom promotion, with VMMC and behaviour change after HIV testing having relatively modest impacts. HIV programme impacts differed significantly by age and sex, with condoms and VMMC having greatest impact in youth, and overall incidence reductions being greater in men than in women.

Conclusions: HIV incidence in South Africa has declined substantially since 2000, with ART and condom promotion contributing most significantly to this decline.

https://pubmed.ncbi.nlm.nih.gov/35125286/

J Pediatr Urol. 2021 Dec 11;S1477-5131(21)00586-6.

doi: 10.1016/j.jpurol.2021.12.003.Online ahead of print.

Engagement of common pediatric urologic conditions on social media

Julie W Cheng[1], Nicolas Fernandez[2], Margarett Shnorhavorian[2], Paul A Merguerian[2], Kathleen Kieran[2]

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PMID: 35125286 DOI: 10.1016/j.jpurol.2021.12.003

Abstract

Introduction: As social media use continues to increase, parents and caregivers report using social media platforms as a source of health information. However, there are minimal regulations for social media content and health misinformation has been shared for various medical issues and urologic conditions. While internet content related to pediatric urology has been previously described, social media engagement for various pediatric urologic conditions have yet to be described.

Objective: To evaluate the evidence supporting articles engaged on social media that are related to common pediatric urologic conditions.
Study design: A social media analysis tool was used to identify articles engaged through Facebook, Reddit, Twitter, and Pinterest between July 2020-2021. The top 5 articles related to toilet training, circumcision, cryptorchidism, testicular torsion, and hypospadias were identified. Article citations were reviewed and classified by Oxford levels of evidence. The content of each article was then reviewed and compared against supporting evidence on an independent literature search. Statistical analysis was completed with descriptive statistics, Mann-Whitney U, Wilcoxon signed rank, and bivariate correlation.
Results: Of the 25 articles reviewed, 8 (32%) were affiliated with medical journals, hospitals, or academic institutions and 17 (68%) were on non-affiliated websites with advertisements. There was greater social media engagement for articles related to toilet training and circumcision than testicular torsion, hypospadias, and cryptorchidism. No articles cited level 1 evidence and 32% of articles cited no evidence. Literature search for article content demonstrated a discrepancy between the level of evidence cited by articles compared to the evidence available in the literature to support article content. There was greater social media engagement for articles with no cited or supporting evidence and those not affiliated with medical journals, hospitals, or academic institutions.
Discussion: The findings in this study are consistent with trends reported for other urologic conditions, including genitourinary malignancy, female pelvic medicine and reconstructive surgery, nephrolithiasis, and sexual function. Parents without a medical background may have difficulty identifying whether articles shared on social media can be a reliable resource for health information. It is important to understand how information related to pediatric urologic conditions is engaged on social media so that misinformation can be addressed in clinical, online, and regulatory settings.
Conclusion: There was greater social media engagement for articles with no cited or supporting evidence and those not affiliated with medical journals, hospitals, or academic institutions.

https://pubmed.ncbi.nlm.nih.gov/35103930/
Int Urol Nephrol. 2022 Feb 1.
doi: 10.1007/s11255-022-03130-7. Online ahead of print.

The role of occlusion and micro-incontinence in the pathogenesis of penile lichen sclerosus: an observational study of pro-inflammatory cytokines' gene expression

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[6]Greater Poland Cancer Center, Poznan University of Medical Sciences, Poznań, Poland.
[7]Molecular Laboratory, Invicta Fertility and Reproductive Center, Sopot, Poland.
PMID: 35103930 DOI: 10.1007/s11255-022-03130-7

Abstract

Purpose: To assess the expression of selected cytokines in penile lichen sclerosus (PLS) and associate them with the occurrence of micro-incontinence (MI) in different stages of PLS.

Methods: The skin biopsies from 49 PLS affected, and 13 from nonlesional foreskins (healthy control adult males undergoing circumcision due to phimosis caused by short frenulum) were obtained. All specimens were used for RNA extraction and RT-qPCR. Quantitative assessment of the gene expression of interleukin 1-A (IL-1A), interleukin 1-B (IL-1B), interleukin 1 receptor antagonist (IL-1RN), interleukin 6 (IL-6), transforming growth factor β1 (TGF-β1), and interferon-gamma (INF-γ) was performed. To determinate the presence of MI, the patients were asked about voiding patterns, especially leaking tiny drops of urine from the urethral meatus after urination.

Results: IL-1A, IL-6, and INF-γ mRNA levels were approximately 150, 16, and 59 times higher in PLS than in control samples, respectively. The highest IL-1A mRNA levels were observed in early PLS (n = 13), INF-γ in moderate PLS (n = 32), while IL-6 in severe PLS (n = 4). MI was noted in 45 PLS patients vs. 0 in control ($p < 0.0001$). IL-1A and IL-6 vs control ratios were concentration (ca.) 400 and 30 times higher, respectively, in MI PLS samples than in PLS without MI.

Conclusion: Occlusion and irritating urine effect are associated with the clinical progression of penile LS with increased mRNA expression of IL-1A, INF-γ, and IL-6 pro-inflammatory cytokines in the foreskin.

https://pubmed.ncbi.nlm.nih.gov/35118992/
Turk J Urol. 2022 Jan;48(1):74-81.
doi: 10.5152/tud.2022.20526.

Mathieu vs urethral plate tubularization in circumcised Megameatus intact prepuce repair: A prospective randomized comparative study

Mohamed Abdalla[1], Ahmed Sakr[1], Hazem Elgalaly[1], Ehab Elsayed[1], Mohamed Omran[1]
[1]Department of Urology, Zagazig University Faculty of Medicine, Zagazig City, Egypt.
PMID: 35118992 DOI: 10.5152/tud.2022.20526

Abstract

Objective: The objective of this study is to evaluate and compare urethral plate tubularization vs Mathieu in circumcised Megameatus intact prepuce (MIP) repair. Many

techniques were described for MIP, which account for 5% of hypospadias cases and usually diagnosed at time of, or even after circumcision.

Material and methods: Forty-six circumcised MIP cases were prospectively enrolled in this prospective study, which was carried out in April 2017 and March 2020. Patients were randomly allocated into two groups. Group one operated by simple urethral plate tubularization and group two by the Mathieu technique. Hypospadias objective scoring evaluation (HOSE) scores, success rate, operative time, and the need for relaxing incision or scrotal flaps for skin closure were compared.

Results: Forty-three circumcised cases (22 in group one and 21 in group two) completed at least 6 months of follow-up. Ages ranged from 12 to 39 months (mean 18.06 6 6.35) in group one and from 10 to 32 months (mean 19.5 6 7.14) in group two. There was no significant difference between cases with accepted outcome based on HOSE scores (14) of the two groups (P value ¼ .942). Three fistulae and one meatal stenosis were the complications in group one (18.2%). In group two, two patients complicated with fistula (9.5%) (P value ¼ .674). Significant differences were present only in the operative time (P ¼ .001) and in the need of relaxing incision or scrotal skin flaps (P ¼ .012) both were more in group two.

Conclusion: Mathieu and tubularized incised plate urethroplasty both are good options for circumcised MIP repair.

https://pubmed.ncbi.nlm.nih.gov/35118971/
Turk J Urol. 2021 Nov;47(6):518-525.
doi: 10.5152/tud.2021.21228.

Is tablet-based interactive distraction effective on pain and anxiety during circumcision in children? A randomized controlled trial

Elif Gezginci[1], Derya Suluhan[2], Mehmet Bahadir Caliskan[3]
Affiliations collapse
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- PMID: 35118971
- DOI: 10.5152/tud.2021.21228

Abstract

Objective: Distraction is a nonpharmacological method commonly used during painful procedures in children. However, there are a few studies investigating the effectiveness of active distraction on pain and anxiety in children during circumcision. The purpose of

this study was to evaluate the effectiveness of tablet-based interactive distraction on pain and anxiety in children during circumcision.

Material and methods: To evaluate how tablet distraction could improve children's outcomes during circumcision, a single-center, nonblinded, randomized controlled, parallel group trial research design was employed. In this study, 35 children were included in tablet distraction group, which have a control group (n ¼ 35). The primary outcome measure was the Numeric Rating Scale for pain. Secondary outcome measure was the State- Trait Anxiety Scale for Children, and other outcome variables were physiological parameters and satisfaction levels.

Results: During and after the surgical procedure, pain scores (P <.001, P <.001, respectively) and pulse rates (P <.001, P <.001, respectively) were significantly lower in the tablet distraction group, whereas O2 saturation was higher than the control group (P <.001, P <.001, respectively). After the procedure, the anxiety scores were significantly lower in the tablet distraction group (P <.001), whereas the satisfaction scores were higher than control group (P <.001).

Conclusion: This study concluded that the use of tablet distraction during circumcision has a positive effect on children's pain, anxiety, satisfaction levels, and physiological parameters.

https://pubmed.ncbi.nlm.nih.gov/35113172/
Urologe A. 2022 Feb 3.
doi: 10.1007/s00120-021-01755-7. Online ahead of print.

[Comparison of circumcision devices and surgical techniques in adolescent and adult males]

[Article in German]

Sebastian Graf[1,2]
[1]Klinik für Urologie und Andrologie, Kepler Universitätsklinikum Linz, Linz, Österreich. uroevidence@dgu.de.
[2]UroEvidence@Deutsche Gesellschaft für Urologie, Martin-Buber-Str. 10, 14163, Berlin, Deutschland. uroevidence@dgu.de.
PMID: 35113172 DOI: 10.1007/s00120-021-01755-7

No abstract available

https://pubmed.ncbi.nlm.nih.gov/35106820/
Pediatr Dermatol. 2022 Jan;39(1):e3-e4.
doi: 10.1111/pde.14863.

Polypoid tumor of penis in an adolescent boy

Mariana Maza-Morales[1], Celso Tomás Corcuera-Delgado[2], Laura Becerril-Cholula[2], María Teresa García-Romero[1]
[1]Department of Dermatology, National Institute of Pediatrics, Mexico City, Mexico.
[2]Department of Pathology, National Institute of Pediatrics, Mexico City, Mexico.
PMID: 35106820 DOI: 10.1111/pde.14863

No abstract available

https://pubmed.ncbi.nlm.nih.gov/35110129/
Turk Arch Pediatr. 2021 Sep;56(5):539-540.
doi: 10.5152/TurkArchPediatr.2021.21066.

Acquired Lymphangioma Circumscriptum Post-neonatal Circumcision

Jad A Degheili[1], Tag Keun Yoo[2], Sara Trincao-Batra[3], Jun Ho Lee[2]
[1]Division of Urology, Department of Surgery, Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada.
[2]Department of Urology, Nowon Eulji Medical Center, Eulji University School of Medicine, Seoul, Republic of Korea.
[3]Faculty of Medicine, University of Ottawa, Ontario, Canada.
PMID: 35110129 DOI: 10.5152/TurkArchPediatr.2021.21066

No abstract available

Circumcision Academy of Australia: https://www.circumcisionaustralia.info
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Brian J. Morris, AM DSc PhD FAHA ISHF
Professor Emeritus
School of Medical Sciences
Anderson Stuart Building (F13)
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To:	Journal of Men's Health <jomh-editor@jomh.net>
Subject:	RE: Review Invitation for JOMH2021112201
Date:	2021/12/30 08:15:00
Priority:	Normal
Type:	Note

Apologies, I am not able to do this.

From: Journal of Men's Health <jomh-editor@jomh.net>
Sent: Thursday, December 30, 2021 12:14 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: [EXTERNAL] Review Invitation for JOMH2021112201
Importance: High

Manuscript ID: JOMH2021112201
Title: Evidence-based circumcision policy for Australia

Dear Dr. Peter Kilmarx,

We would appreciate if you could provide comments on the above paper as you are an expert in this area. The abstract for this manuscript appears below.

Title: Evidence-based circumcision policy for Australia
Abstract: The aim was (1) to perform an up-to-date systematic review of the male circumcision (MC) literature and (2) to determine the number of adverse medical conditions prevented by early MC in Australia. Searches of PubMed using "circumcision" with 39 keywords and bibliography searches yielded 278 publications meeting our inclusion criteria. Early MC provides immediate and lifetime benefits, including protection against: urinary tract infections, phimosis, inflammatory skin conditions, inferior penile hygiene, candidiasis, various STIs, and penile and prostate cancer. In female partners MC reduces risk of STIs and cervical cancer. A risk-benefit analysis found benefits exceeded procedural risks, which are predominantly minor, by approximately 200 to 1. It was estimated that more than 1 in 2 uncircumcised males will experience an adverse foreskin-related medical condition over their lifetime.

An increase in early MC in Australia to mid-1950s prevalence of 85% from the current le vel of 18.75% would avoid 77,000 cases of infections and other adverse medical conditions over the lifetime for each annual birth cohort. Survey data, physiological measurements, and the anatomical location of penile sensory receptors responsible for sexual sensation indicate that MC has no detrimental effect on sexual function, sensitivity or pleasure. US studies found that early infant MC is cost saving. Evidence-based reviews by the AAP and CDC support early MC as a desirable public health measure. Although MC can be performed at any age, early MC maximizes benefits and reduces procedural risks. Parents should routinely be provided with accurate, up-to-date evidence-based information in an unbiased manner early in a pregnancy so that they have time to weigh benefits and risks of early MC and make an informed decision should they have a son. Parental choice should be respected. A well-trained competent practitioner is essential and local anaesthesia should routinely used. Third pa rty coverage of costs is advocated.

If you accept this invitation, we hope to receive your comments by January 10,2022. You may submit your comments online at the URL given below. If you are unable to act as a reviewer at this time, your suggestions for alternate reviewers would be greatly appreciated.

To accept this invitation, please go here:
http://info.jomh.org/ch/arm.aspx?id=b0baabc0acaab600a

or you may select the following link and log into our System.

Login address: http://info.jomh.org/ch/auditor/login.aspx
User name: peter.kilmarx@nih.gov
Password: ChrU54In

Thank you for your support of Journal of Men's Health. We look forward to your positive response.

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Best wishes,
The Editorial Office

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Subject:	RE: Clearance for AHISA Scoping Review
Date:	2021/12/18 18:04:00
Priority:	Normal
Type:	Note

Hi,
This is cleared – attached. Congratulations on a lot of work and a very nice paper.

I'm was surprised there are only 44 papers in total about HIV in SSA including adolescents with an IS outcome. You might want to clarify in the methods on how strictly the age limit was applied – any 9 or 25 y.o.s and the paper was out. Also should clarify in the methods that it wasn't enough to have "consideration and/or measurement" one or more of "acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, sustainability, and scale-up"; the paper had to specifically use the words implementation science/research etc. These weren't clear until I got to the limitations. I think this also makes it hard to conclude that more IR is needed when so much of it is not labeled as such. Perhaps could expand on the challenges of bibliometric research on IR?

I'm unclear about male circumcision. There has been a lot of implementation research. Did studies have to include both males and females to be included? This would also be an issue for studies of pregnant adolescents.

Good luck with submission!

PK

From: Vorkoper, Susan (NIH/FIC) [E] <susan.vorkoper@nih.gov>
Sent: Friday, December 17, 2021 12:57 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Cc: Sturke, Rachel (NIH/FIC) [E] <sturkerachel@mail.nih.gov>; Anand, Nalini (NIH/FIC) [E] <anandn@mail.nih.gov>; Kadam, Arina (NIH/FIC) [C] <arina.kadam@nih.gov>
Subject: FW: Clearance for AHISA Scoping Review

Hi Peter and Ann,

Could you please review and clear the scoping review on adolescent HIV and implementation science Rachel and I have developed? We're planning to submit to AIDS &Behavior as part of an AHISA-focused special issue.

Best,
Susan

From: Anand, Nalini (NIH/FIC) [E] <anandn@mail.nih.gov>
Sent: Thursday, December 16, 2021 7:25 PM
To: Vorkoper, Susan (NIH/FIC) [E] <susan.vorkoper@nih.gov>
Cc: Sturke, Rachel (NIH/FIC) [E] <sturkerachel@mail.nih.gov>; Kadam, Arina (NIH/FIC) [C] <arina.kadam@nih.gov>
Subject: RE: Clearance for AHISA Scoping Review

Fantastic you guys – reflects a huge amount of work and significant contribution to the literature.

Arina can add my esig and forward to Peter and Ann.

Nalini

From: Vorkoper, Susan (NIH/FIC) [E] <susan.vorkoper@nih.gov>
Sent: Wednesday, December 15, 2021 11:43 AM
To: Anand, Nalini (NIH/FIC) [E] <anandn@mail.nih.gov>
Cc: Sturke, Rachel (NIH/FIC) [E] <sturkerachel@mail.nih.gov>
Subject: Clearance for AHISA Scoping Review

Nalini,

We're about ready to submit the adolescent HIV and IS scoping review. Can you please review and clear?

Thank you!
Susan

Susan Vorkoper, MPH, MSW
Global Health Research and Policy Analyst
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June 24, 2016

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Overview: Scientific staff are asked to follow these simple guidelines when producing scientific products for publication. Prior to submitting, publishing, or distributing materials, FIC staff should receive *final clearance* according to this clearance policy. This process is intended to be quick and efficient for all concerned. Divisions and offices are also asked to maintain records of cleared and disseminated scientific products.

Relevant NIH Policy: *1184 - Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH*. This chapter provides guidelines products that carries the agency's trademark (i.e., name and logo). "Scholarly works" are explicitly exempted from the NIH-wide policy, however, it is noted that "ICs should have in place—in writing—their own internal review procedures for scientific publications completed in the normal course of professional responsibilities."

Applicability: This FIC policy applies to those using the FIC/NIH affiliation who write or contribute to an original, scholarly abstract, article, report, editorial, review, book, book chapter, monograph, proceedings or statistical compendium, or who otherwise contribute to a technical and scientific product. Also included are letters to the editor, opinion pieces, broadcast scripts, audio and videotapes. Routine presentations are exempt, including traditional scientific presentations; routine presentations developed for informational purposes; training materials and presentations; and presentations describing grant application procedures and management procedures. However, presentations that discuss Federal policies or legislation or that may have policy or legislative implications require IC clearance. Additionally, employees should consult their supervisor and/or ethics officer for guidance on clearance of any speech or presentation which may imply agency endorsement.

Review and approval:

1. Initial approval:

- Office/Division Director—this review will take a comprehensive approach and consider:
    - evaluation of science/quality of research and appropriateness of subject matter

- overall quality and content

Approval at this level should indicate that there is high potential of the document being cleared with only minor changes from subsequent reviewers.

2. Communications review and Final Approval:

- Document will be sent to the FIC Deputy Director or his designee and the Communication Director in parallel
- Communication Director will review, make recommendations and provide appropriate support as relevant regarding:
  - media or other public interest
  - sensitive/controversial issues
  - visual and graphical elements; compliance with design guidelines (such as logo)
  - appropriate attributions
  - minor edits needed (spelling and grammar), readability for the intended audience, and use of plain language
- FIC Deputy Director gives final approval

Note: Op-eds in major media and/or papers that are considered controversial, propose policy change or that express potentially controversial opinions should also be cleared with the Fogarty Director, Building One Communications, and the NIH Director, if deemed necessary by the CD and Deputy Director.

Timeline: The review process at each level should take no longer than one week for abstracts and two weeks for manuscripts and other materials.

Submission: The appended form should be used for submission.

Record keeping: FIC Divisions and Offices should maintain records of products covered by this policy as they are submitted for clearance and subsequently disseminated.

FIC SCIENTIFIC PRODUCT CLEARANCE FORM Date **6/19/2020**

Implementation Science for the Prevention and Treatment of HIV among Adolescents and Young Adults in sub-Saharan Africa: A Scoping Review_
TITLE

Rachel Sturke, DISPPE
Susan Vorkoper, DISPPE

AUTHOR'S NAME AND DIVISION/OFFICE

Lead authors on the manuscript including conceptualizing and drafting the article

AUTHOR'S ROLE IN THE WORK

Submission to AIDS & Behavior

PROPOSED USE (i.e., submission to *Nature*, book chapter, etc.)

POLICY IMPLICATIONS (Check one □Yes X □No; if Yes, describe briefly)

Spring/Summer 2022

PROPOSED PUBLICATION DATE

Susan Vorkoper[1], Kadija M. Tahlil[2], Nadia A. Sam-Agudu[3,4], Joseph D. Tucker[5,6], Alicia A. Livinski[7], Frances Fernando[8], Rachel Sturke[1]

[1]Fogarty International Center, National Institutes of Health, Bethesda, MD, USA.
[2]Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.
[3]Pediatric &Adolescent HIV Unit and International Research Center of Excellence, Institute of Human Virology Nigeria, Abuja, Nigeria.
[4]Institute of Human Virology and Department of Pediatrics, University of Maryland School of Medicine, Baltimore, MD, USA.
[5]Institute of Global Health and Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.
[6]Faculty of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London, UK.
[7]National Institutes of Health (NIH) Library, Office of Research Services, OD, NIH, Bethesda, MD, USA
[8]Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD, USA.

LIST OF AUTHORS AND AFFILIATIONS

Author certifies that all other authors have agreed to this submission ___SCV___ (initial)

	Printed name	Signature	Date	Comments
DIVISION/OFFICE DIRECTOR	Nalini Anand	Redacted by agreement	12/17/2021	Approved
COMMUNICATIONS DIRECTOR				
DEPUTY DIRECTOR	Peter Kilmarx	[signed] PK	12/18/2021	See email

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	RE: Male circ pubs this week: Poor health-related quality of life among patients operated on for penile cancer; Final form of: Effectiveness of VMMC for HIV prevention in Rakai, Uganda.
Date:	2021/10/12 16:42:00
Priority:	Normal
Type:	Note

She gets more than her share of criticism, which I imagine has elements of misogyny and racism.

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Tuesday, October 12, 2021 4:37 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Male circ pubs this week: Poor health-related quality of life among patients operated on for penile cancer; Final form of: Effectiveness of VMMC for HIV prevention in Rakai, Uganda.

She still learning

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Tuesday, October 12, 2021 4:36 PM
To: Timothy Mastro <TMastro@fhi360.org>
Subject: RE: Male circ pubs this week: Poor health-related quality of life among patients operated on for penile cancer; Final form of: Effectiveness of VMMC for HIV prevention in Rakai, Uganda.

Hi and thanks Tim. Nice to see. Took them 5 years to publish?

There's an occasional like or retweet from past Twitter discussions, but no new disinformation for me to respond to. I did correct NY Times' Apoorva Mandavilli on Twitter last month when she wrote that VMMC was "thought to" prevent HIV transmission ☺

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Tuesday, October 12, 2021 1:05 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: Male circ pubs this week: Poor health-related quality of life among patients operated on for penile cancer; Final form of: Effectiveness of VMMC for HIV prevention in Rakai, Uganda.

Good to see the Rakai paper:

Are you still getting slammed in this arena?

From: Brian Morris via Caa2 <caa2@lists.circumcisionaustralia.org>
Sent: Tuesday, October 12, 2021 12:47 PM
To: caa2@lists.circumcisionaustralia.org

Subject: [Caa2] Male circ pubs this week: Poor health-related quality of life among patients operated on for penile cancer; Final form of: Effectiveness of VMMC for HIV prevention in Rakai, Uganda.

Male circumcision publications this week: Poor health-related quality of life among patients operated on for penile cancer; Final form of: Effectiveness of VMMC for HIV prevention in Rakai, Uganda.

Now published in final form:
https://pubmed.ncbi.nlm.nih.gov/33043978/
Clin Infect Dis. 2021 Oct 5;73(7):e1946-e1953.
doi: 10.1093/cid/ciaa1533.

Effectiveness of Voluntary Medical Male Circumcision for Human Immunodeficiency Virus Prevention in Rakai, Uganda

Gideon Loevinsohn[1,2], Godfrey Kigozi[3], Joseph Kagaayi[3], Maria J Wawer[1,3,4], Fred Nalugoda[3], Larry W Chang[1,3,5], Thomas C Quinn[1,3,6], David Serwadda[3,7], Steven J Reynolds[1,3,5,6], Lisa Nelson[8], Lisa Mills[8], Stella Alamo[8], Gertrude Nakigozi[3], Geoffrey Kabuye[8], Robert Ssekubugu[3], Aaron A R Tobian[1,3,9], Ronald H Gray[1,3], M Kathryn Grabowski[1,3,9], Rakai Health Sciences Program

Rakai Health Sciences Program: Dorean Nabukalu, Anthony Ndyanabo, Joseph Ssekasanvu, Hadijja Nakawooya, Jessica Nakukumba, Grace N Kigozi, Betty S Nantume, Nampijja Resty, Jedidah Kambasu, Margaret Nalugemwa, Regina Nakabuye, Lawrence Ssebanobe, Justine Nankinga, Adrian Kayiira, Gorreth Nanfuka, Ruth Ahimbisibwe, Stephen Tomusange, Ronald M Galiwango, Sarah Kalibbali, Margaret Nakalanzi, Joseph Ouma Otobi, Denis Ankunda, Joseph Lister Ssembatya, John Baptist Ssemanda, Robert Kairania, Emmanuel Kato, Alice Kisakye, James Batte, James Ludigo, Abisagi Nampijja, Steven Watya, Kighoma Nehemia, Sr Margaret Anyokot, Joshua Mwinike, George Kibumba, Paschal Ssebowa, George Mondo, Francis Wasswa, Agnes Nantongo, Rebecca Kakembo, Josephine Galiwango, Geoffrey Ssemango, Andrew D Redd, John Santelli, Caitlin E Kennedy, Jennifer Wagman, Tom Lutalo, Fred Makumbi, Nelson K Sewankambo, Oliver Laeyendecker

[1]Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland, USA.
[2]Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.
[3]Rakai Health Sciences Program, Kalisizo, Uganda.
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[5]Division of Infectious Diseases, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.
[6]Laboratory of Immunoregulation, Division of Intramural Research, National Institute for Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland, USA.
[7]School of Public Health, Makerere University, Kampala, Uganda.
[8]US Centers for Disease Control and Prevention Uganda, Kampala, Uganda.
[9]Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.
PMID: 33043978 PMCID: PMC8492113 DOI: 10.1093/cid/ciaa1533

Abstract

Background: The efficacy of voluntary male medical circumcision (VMMC) for human immunodeficiency virus (HIV) prevention in men was demonstrated in 3 randomized trials. This led to the adoption of VMMC as an integral component of the United States President's Emergency Plan for AIDS Relief (PEPFAR) combination HIV prevention program in sub-Saharan Africa. However, evidence on the individual-level effectiveness of VMMC programs in real-world, programmatic settings is limited.

Methods: A cohort of initially uncircumcised, non-Muslim, HIV-uninfected men in the Rakai Community Cohort Study in Uganda was followed between 2009 and 2016 during VMMC scale-up. Self-reported VMMC status was collected and HIV tests performed at surveys conducted every 18 months. Multivariable Poisson regression was used to estimate the incidence rate ratio (IRR) of HIV acquisition in newly circumcised vs uncircumcised men.

Results: A total of 3916 non-Muslim men were followed for 17 088 person-years (PY). There were 1338 newly reported VMMCs (9.8/100 PY). Over the study period, the median age of men adopting VMMC declined from 28 years (interquartile range [IQR], 21-35 years) to 22 years (IQR, 18-29 years) (P for trend <.001). HIV incidence was 0.40/100 PY (20/4992.8 PY) among newly circumcised men and 0.98/100 PY (118/12 095.1 PY) among uncircumcised men with an adjusted IRR of 0.47 (95% confidence interval, .28-.78). The effectiveness of VMMC was sustained with increasing time from surgery and was similar across age groups and calendar time.

Conclusions: VMMC programs are highly effective in preventing HIV acquisition in men. The observed effectiveness is consistent with efficacy in clinical trials and supports current recommendations that VMMC is a key component of programs to reduce HIV incidence.

Keywords: Africa; PEPFAR; VMMC; circumcision; combination HIV prevention.

CIRCUMCISION: An Evidence-Based Appraisal
MEDICAL, HEALTH &SEXUAL
https://circinfo.net
(This website also has free brochures in English, French, German, Spanish, Dutch, Hungarian &Chinese)

Brian J. Morris, AM DSc PhD FAHA ISHF
Professor Emeritus
School of Medical Sciences
Anderson Stuart Building (F13)
The University of Sydney
Sydney NSW 2006
Australia

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2021/10/12 16:42:30
Delivered Date:	2021/10/12 16:42:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Malekzadeh, Arianne (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f17c6466d8244ae94a49fa8c6041aec-malekzadeha <arianne.malekzadeh@nih.gov>
CC:	Kupfer, Linda (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc018682e08f417faffb7f103d8dbaf4-kupferl <kupferl@mail.nih.gov>
Subject:	RE: Your Input: Global Health Knowledge Exchange proposal
Date:	2021/03/29 17:09:00
Priority:	Normal
Type:	Note

Hi Arianne and Linda,
Thanks for your work on this and congratulations with your progress.

I have reviewed and would recommend bringing back the focus on interventions that were developed in LMIC and then adapted and implemented in the United States. Otherwise, it seems like it becomes very diffuse, hard to define, and very challenging to do it justice. Most interventions are developed in a limited number of countries and then implemented more broadly. This is everything – medicines, vaccines, surgical techniques, use of checklists, devices, diagnostics, behavioral interventions, etc. They start somewhere and then are implemented elsewhere. What will be novel and add value will be to highlight those developed in LMIC and then adapted in the U.S. or HIC generally. Alternatively, you could have LMIC to HIC and HIC to LMIC (and LMIC to LMIC and HIC to HIC), but explicitly seek to have a large category for LMIC to HIC.

Other comments:

1. • I would keep a more descriptive (and restrictive) title like "reciprocal innovation." It can be descriptive without being pejorative. Again, "global knowledge exchange" sounds overly broad.
2. • Would highlight the importance of guidelines, either national (like IDSA, ACIP, or USPSTF) or global (WHO). This is how many interventions get put into practice. To what extent are interventions developed in LMIC part of the evidence base in guidelines for HIC or global? This could be an analysis of reference lists of guidelines documents.
3. • Need to carefully define where an innovation comes from. If NIH-funded U.S. researchers study an PMTCT intervention in LMIC that subsequently gets used in the U.S., is that reciprocal innovation? Male circumcision for HIV prevention another example. Isoniazid for TB prevention is another.
4. • Another way to focus this would be to limit it to NIH-funded research. This will make it more relevant to the other ICs and a more effective communication and advocacy tool for congress and other ICs to invest in global collaboration. There will be plenty of material. Again, I'm worries about biting off too much to say we are going to characterize all knowledge transfer from any country to any other country funded by anyone. It may be more credible and authoritative to say that NIH is focusing on NIH-funded research. We could be accused of a "Not Invented Here" (NIH) mentality, but I think it makes sense that we are reviewing our own portfolios. If we don't do this explicitly, Wellcome and India and Gates and everyone else could complain that we didn't include their fabulous innovation.

I hope these comments are helpful. You know best where you want to go with this.

Good luck!
PK

P.S. Arianne: https://the1a.org/segments/intersectionality-kimberle-crenshaw/

From: Malekzadeh, Arianne (NIH/FIC) [C] <arianne.malekzadeh@nih.gov>
Sent: Monday, March 29, 2021 1:04 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Cc: Kupfer, Linda (NIH/FIC) [E] <kupferl@mail.nih.gov>
Subject: Your Input: Global Health Knowledge Exchange proposal

Hi Peter,

I hope you had a nice weekend.

Linda and I are moving forward with the global health knowledge exchange project (formerly Global-to-Local) and are hoping to get your feedback on our proposal (attached). The one-pager incorporates feedback from our NIH partners, and we just sent it to our external work group for review. A few notes…

- • **Title:** In light of recent writings and presentations which have highlighted the importance of adding an equity lens to global health research, we have decided to use the term "global health knowledge exchange" rather than "global-to-local" for this project. We feel the term "knowledge exchange" better indicates the importance of equity in global health research.

- • **Project**: During recent discussions with our intra-NIH working group, it was agreed that developing a journal supplement featuring case examples of global health knowledge exchange from one country to another would be the most useful product for the ICs interested in supporting this type of research. Our specific goal would be to highlight the scientific methods and lessons learned through case examples of research in this area. The scientists who participate in the journal supplement will be identified through our two working groups (intra-NIH and extramural) as well as through a landscape analysis and literature review. We will host a workshop with the scientists participating in the supplement to discuss its goals and content. Our colleagues believe this supplement will inform researchers and research funders alike about how to conduct and why to support this type of work.

- • **Activities**: This activity follows the webinar we hosted with our NIH colleagues last year on transferring HIV and Stigma Reduction Interventions from LMICs to the US where researchers discussed lessons learned in this area of global health research. Given the widespread interest in the webinar from the scientific community, our partners decided that peer-reviewed publications would be the most useful way to guide this field forward.

We have asked our external work group to consider the following questions as they review the proposal:

- o • *Given the dialogue around decolonization in global health research and the push for more equity in health research generally, is this an appropriate time to focus on the scientific methods around global health knowledge exchange? And if so, how can we ensure equity comes through in our project?*
- o • *Do you have any feedback on the one-pager?*
- o • *Do you know of examples that could be considered for the supplement? If so, please include the contact information for the project(s).*

At your earliest convenience, can you please review the proposal and send us your thoughts/feedback? We are aiming to move forward with next steps within the next few weeks.

Many thanks for your consideration.

All best,

Arianne

Arianne Malekzadeh, M.A.
Global Health Research and Policy Analyst [C]
Division of International Science Policy, Planning and Evaluation
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Fogarty International Center
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Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Malekzadeh, Arianne (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f17c6466d8244ae94a49fa8c6041aec-malekzadeha <arianne.malekzadeh@nih.gov>; Kupfer, Linda (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc018682e08f417faffb7f103d8dbaf4-kupferl <kupferl@mail.nih.gov>
Sent Date:	2021/03/29 17:09:13
Delivered Date:	2021/03/29 17:09:00

Fogarty International Center at National Institute of Health

REASON FOR NOMINATION

As Director of Zimbabwe's HIV and TB Department since 2000, Dr. Mugurungi is widely recognized as the national leader of the HIV/AIDS response. The national program results are his results. According to the Global Burden of Disease database, HIV/AIDS was the number one cause of death in Zimbabwe in 2000 at 833 deaths per 100,000 population. By 2017, it had fallen to number three at 111 per 100,000, an 87% decline. From UNAIDS data, in 2000 there were an estimated 1.7 million people living with HIV infection (PLHIV), an adult prevalence of 25.1%; 110,000 new HIV infections per year; and 120,000 AIDS-related deaths. By 2018, the annual number of new HIV infections had declined to 38,000, a 65% decrease, and AIDS-related deaths declined to 22,000, an 82% decrease. During that time, the incidence-prevalence ratio declined from 0.07 to 0.03, which is the UNAIDS-defined threshold for "epidemic control." In 2000, programs for HIV testing and treatment were in their infancy. Under Dr. Mugurungi's leadership, by 2018, 90% of PLHIV (1.1 million) had been diagnosed, 98% of them were on antiretroviral treatment (ART), and 85% of those on ART had an undetectable (suppressed) viral load (2016 estimate). This represents outstanding progress towards the UNAIDS "90-90-90" goals for achieving 90% in each of these measurements by the year 2020. In 2017 alone, 160,000 PLHIV initiated HIV treatment and an estimated 56,000 AIDS-related deaths were averted by the national program.

Early in the 2000s, before HIV treatment and biomedical prevention interventions were widely available, Dr. Mugurungi led a one of the few successful national programs for behavioral HIV prevention. Longitudinal studies showed an annual HIV incidence decline from 2.1% in 2000 to 0.63% in 2010, largely due to reduced sexual risk behavior – lower numbers of casual partners and high condom use in non-regular partnerships. Educational messaging continues and condom use, both male and female, remains high in Zimbabwe. With Dr. Mugurungi's hands-on direction, by 2018 the national program for prevention of mother-to-child transmission of NIH (PMTCT) reached 94% coverage of

Additional materials on the page/s to follow

HIV-infected women received antiretroviral drugs, preventing 11,000 new infections among newborns. The annual number of infant infections through MTCT fell from an estimated 26,000 in 2000 to 4,300 in 2017, an 84% decline. Dr. Mugurungi was at the forefront of implementing evidence-based policies, for example, "Option-B+" to provide ART to all HIV-infected pregnant women regardless of CD4 count to benefit the woman's health as well as preventing infant infection. Dr. Mugurungi has also led an evidence-based, data-driven national program of voluntary medical male circumcision (VMMC), which is 60% effective in reducing female-to-male HIV transmission. Under his leadership, by 2018, 1.4 million circumcisions had been carried out nationally, with more than 300,000 procedures in 2018. In summary, Dr. Mugurungi exemplifies the ideal of using health evidence in innovative ways to improve population health. For these accomplishments and impacts, he is truly deserving of the Roux Prize.

USE OF EVIDENCE FOR IMPACT

As Director of the HIV and TB Department in Zimbabwe since 2000, Dr. Mugurungi has led the HIV response in Zimbabwe, which has been very strongly grounded in epidemiologic and programmatic data, and, despite limited resources and occasional national emergencies, very successful. Dr. Mugurungi has been a principal investigator or senior scientist in research, program implementation, and evaluations including HIV surveillance; HIV prevention, including voluntary medical male circumcision (VMMC) and prevention of mother-to-child transmission (PMTCT); and HIV care and treatment. He has taken a population-wide, public health approach, always with evidence and data at the forefront. His department is responsible for HIV surveillance activities and for producing national and regional HIV estimates. He has led the design and implementation of routine HIV surveillance systems and surveys and in interpreting and disseminating the results. As one example, he led studies to transition from use of special periodic antenatal surveys to use of routine PMTCT program records. Dr. Mugurungi is a global leader in conducting research to develop methods for VMMC that are less dependent on clinicians and are more acceptable to men. This research has ranged from studies to identify barriers to uptake of VMMC to development of biomedical tools and procedures for male circumcision. With his direct involvement, the national VMMC program uses a specialized program planning tool. VMMC data were harmonized with nationally representative household-level data and are monitored with weekly data from Ministry dashboards and the national District Health Information System (DHIS2). Quality of program implementation is assessed through biannual national quality reports. He has led the national PMTCT program with extensive use of data and evaluation, including development and implementation of a cell-phone based system to track infant HIV test specimens to centralized laboratories with test results transmitted by SMS back to the clinic and with an SMS notification to the mother. Dr. Mugurungi was a co-principal investigator on the pioneering DART trial ("Development of Antiretroviral Therapy") and co-led research on more feasible approaches to HIV

Additional materials on the page/s to follow

testing, point-of-care equipment for CD4 measurement, and accelerated ART initiation. National surveillance and data systems track HIV testing, test results, initiation and retention in HIV treatment, viral load, and HIV drug resistance at national and provincial and, for some elements, district and clinic level by sex and age group. Dr. Mugurungi has evaluated the population-level impact of national HIV control programs with studies have included in-depth, mixed-method investigations and mathematical models to interpret trends in the HIV epidemic and to evaluate the potential impact of alternative implementation strategies. Ongoing innovations in data use led by Dr. Mugurungi include 1) expanding the national DHIS2 system, which captures all HIV program data, to support scale-up of an electronic health record and include data from other disease programs and 2) implementation of case-based surveillance of new HIV infections with behavioral risk factors as well as bio-markers to design and implement innovative and efficient differentiated models of care, which will be crucial to access increasingly hard-to-reach populations

Additional materials on the page/s to follow

ADDITIONAL MATERIALS (SELECT TITLE TO SKIP TO ATTACHMENT)

- "Towards UNAIDS Fast-Track goals: targeting geographic areas for HIV prevention and care in Zimbabwe", *AIDS*, 2018
- Support letter from Scott Barnhart, MD, MPH, Professor of Medicine and Global Health, University of Washington
- "HIV decline in Zimbabwe due to reductions in risky sex? Evidence from a comprehensive epidemiological review", *International Epidemiological Association*, 2010
- "HIV Population Surveys – Bringing Precision to the Global Response", *The New England Journal of Medicine*, 2018
- Curriculum Vitae, 2018
- "Extended Zimbabwe National HIV and AIDS Strategic Plan", *Government of Zimbabwe*, 2015

Additional materials on the page/s to follow

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject:	RE: (b)(4)
Date:	2020/10/18 09:30:00
Priority:	Normal
Type:	Note

Hi Wolfgang,
It looks like the data are mixed on whether HIV-2 infection confers relative immunity to HIV-1.

Yes: https://science.sciencemag.org/content/268/5217/1612.long
No:
https://journals.lww.com/aidsonline/fulltext/1997/08000/does_hiv_2_infection_provide_cross_protection.15.aspx

(b)(4)

Best,
PK

From: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent: Saturday, October 17, 2020 11:42 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: (b)(4)

Peter – thanks for these excellent thoughts. Your thoughts on VMMC reminds me of a comment by Shirish Balachandra (current country director in Cd'I): (b)(5)

(b)(5)

(b)(5)

Best
Wolfgang Hladik

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Saturday, October 17, 2020 10:05 AM
To: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject: RE: (b)(4)

Thanks Wolfgang and congratulations on this outstanding paper. I appreciate being included and your responses to my comments. Pity my hypotheses did not pan out!

(b)(5)

Good luck with clearance.

PK

From: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent: Thursday, October 15, 2020 10:14 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: (b)(4)

Hi Peter, thanks again for your comments on this paper. I'm only now getting close in securing all author concurrences and country clearances. Attached is the version we'll submit to CDC for clearance. Sending it to you as I re-read that you'd appreciate seeing a new version. No need to spend time on it again but should you have any more comments, they are of course still welcome. The paper has changed quite a bit since you last saw it.

(b)(5)

Thanks!
Wolfgang Hladik

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Friday, August 7, 2020 3:47 PM
To: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject: RE: (b)(4)

(b)(5)

Thanks,
PK

From: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent: Friday, August 7, 2020 3:21 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: (b)(4)

Peter – thanks for your concurrence and I look forward to reading your online comments in detail. I want to make sure I understand your 1st comment below: with (b)(5)

(b)(5)

(b)(5) Thanks also for your 2nd comment – this seems pertinent and worthwhile to add to the discussion.

Wolfgang Hladik

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Friday, August 7, 2020 3:09 PM
To: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject: RE: (b)(4)

Hi again Wolfgang. Thanks for including me in wonderfully data-rich paper! It was fascinating to read.

I made a bunch of comments. Perhaps the two most substantive:

(b)(5)

In any case:

I, Peter Kilmarx, concur with submission of the manuscript entitled (b)(4)

(b)(4) **to CDC for clearance.**

I'm happy to look at subsequent versions if possible.

PK

From: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent: Sunday, July 26, 2020 9:52 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: (b)(4)

Dear Peter, hope all is well. After long last, we completed the (b)(4)
(b)(4)

We hope you will accept co-authorship and review the manuscript. Because of the many authors, I uploaded the draft paper to my Google Drive / Google Docs for collaborative review. Below link leads to the paper. You should not need a Google account but let me know if you have any problems. Use the "Suggesting" mode to make any edits visible (*Editing* drop down menu - look for the pencil like symbol near the upper right corner).

We look forward to your comments within two weeks (Fri, Aug 7) if possible. If you feel comfortable with the text please email me your concurrence stating e.g., "I, *name*, concur with submission of the manuscript entitled (b)(4) to CDC for clearance".

Thanks!

(b)(4)

Wolfgang Hladik, MD, PhD wfh3@cdc.gov | Office: 404.639.8691 | Mobile: Redacted by agreement
Branch Chief | Epidemiology and Surveillance Branch | Division of Global HIV and TB | Centers for Disease Control and Prevention

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent Date:	2020/10/18 09:25:37
Delivered Date:	2020/10/18 09:30:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject:	RE: (b)(4)
Date:	2020/08/07 15:32:00
Priority:	Normal
Type:	Note

Good, thanks!

From: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent: Friday, August 7, 2020 3:24 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: (b)(4)

I see a number comments from you so would hope they all were saved. PS: Yes, Table 1 was originally in landscape, wide enough to include all countries. Google Doc converted it into portrait – we'll undo that again.

Wolfgang Hladik

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Friday, August 7, 2020 3:18 PM
To: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject: RE: (b)(4)

I'm not sure if my ~20 comments are saved. When I try to log out, it says "Changes you made may not have been saved."

I tried sharing with you a couple times and hope that worked.

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Friday, August 7, 2020 3:09 PM
To: Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Subject: RE: (b)(4)

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Sent: Sunday, July 26, 2020 9:52 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: [b)(4)]

Dear Peter, hope all is well. After long last, we completed the [b)(4)]
[b)(4)]

We hope you will accept co-authorship and review the manuscript. Because of the many authors, I uploaded the draft paper to my Google Drive / Google Docs for collaborative review. Below link leads to the paper. You should not need a Google account but let me know if you have any problems. Use the "Suggesting" mode to make any edits visible (*Editing* drop down menu - look for the pencil like symbol near the upper right corner).

We look forward to your comments within two weeks (Fri, Aug 7) if possible. If you feel comfortable with the text please email me your concurrence stating e.g., "I, *name*, concur with submission of the manuscript entitled [b)(4)] to CDC for clearance".

Thanks!

[b)(4)]

Wolfgang Hladik, MD, PhD wfh3@cdc.gov | Office: 404.639.8691 | Mobile: Redacted by agreement
Branch Chief | Epidemiology and Surveillance Branch | Division of Global HIV and TB | Centers for Disease Control and Prevention

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Hladik, Wolfgang (CDC/DDPHSIS/CGH/DGHT) <wfh3@cdc.gov>
Sent Date:	2020/08/07 15:36:10
Delivered Date:	2020/08/07 15:32:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Emmanuel Njeuhmeli [Redacted by agreement]
Subject:	RE: Modelling impact and cost-effectiveness of oral pre-exposure prophylaxis in 13 low-resource countries
Date:	2020/03/02 10:33:00
Priority:	Normal
Type:	Note

Thanks Emmanuel.

(b)(5)

Best,
PK

From: Emmanuel Njeuhmeli [Redacted by agreement]
Sent: Monday, March 2, 2020 10:23 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: Re: Modelling impact and cost-effectiveness of oral pre-exposure prophylaxis in 13 low-resource countries

Hi Peter,

Thanks for the comments, I provide a few clarifications below also.

Best regards,
Emmanuel

On Sun, Mar 1, 2020 at 9:06 AM Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>wrote:
Congratulations Emmanuel.

Two comments:

(b)(5)

b)(5)

Best wishes,
PK

From: Emmanuel Njeuhmeli [Redacted by agreement]
Sent: Saturday, February 29, 2020 5:40 AM
To: Emmanuel Njeuhmeli [Redacted by agreement]
Subject: Modelling impact and cost-effectiveness of oral pre-exposure prophylaxis in 13 low-resource countries

Dear colleagues.

I am sharing with you my last publication. With colleagues, we modeled the impact and cost-effectiveness of oral Pre Exposure prophylaxis (PrEP) in 13 countries in Eastern and Southern Africa.

Below is the abstract of the manuscript.

Abstract

Introduction

Oral pre-exposure prophylaxis (PrEP) provision is a priority intervention for high HIV prevalence settings and populations at substantial risk of HIV acquisition. This mathematical modelling analysis estimated the impact, cost, and cost-effectiveness of scaling up oral PrEP in 13 countries.

Methods

We projected the impact and cost-effectiveness of oral PrEP between 2018 and 2030 using a combination of the Incidence Patterns Model and the Goals model. We created four PrEP rollout scenarios involving three priority populations—female sex workers (FSWs), serodiscordant couples (SDCs) and adolescent girls and young women (AGYW)—both with and without geographic prioritization. We applied the model to 13 countries (Eswatini, Ethiopia, Haiti, Kenya, Lesotho, Mozambique, Namibia, Nigeria, Tanzania, Uganda, Zambia, and Zimbabwe). The base case assumed achievement of the Joint United Nations Programme on HIV/AIDS 90-90-90 antiretroviral therapy targets, 90% male circumcision coverage by 2020 and 90% efficacy and adherence levels for oral PrEP.

Results

In the scenarios we examined, oral PrEP averted 3% to 8% of HIV infections across the 13 countries between 2018 and 2030. For all but three countries, more than 50% of the HIV infections averted by oral PrEP in the scenarios we examined could be obtained by rollout to FSWs and SDCs alone. For several countries, expanding oral PrEP to include medium-risk AGYW in all regions greatly increased the impact. The efficiency and

impact benefits of geographic prioritization of rollout to AGYW varied across countries. Variations in cost-effectiveness across countries reflected differences in HIV incidence and expected variations in unit cost. For most countries, rolling out oral PrEP to FSWs, SDCs, and geographically prioritized AGYW was not projected to have a substantial impact on the supply chain for antiretroviral drugs.

Conclusions
These modelling results can inform prioritization, target-setting and other decisions related to oral PrEP scale-up within combination prevention programmes. We caution against extensive use given limitations in cost data and implementation approaches. This analysis highlights some of the immediate challenges facing countries—for example, trade-offs between overall impact and cost-effectiveness—and emphasizes the need to improve data availability and risk assessment tools to help countries make informed decisions.

Best regards,
Emmanuel

Emmanuel Njeuhmeli, MD, MPH, MBA
email Redacted by agreement
Cell phone: Redacted by agreement

--

Best regards,
Emmanuel

Emmanuel Njeuhmeli, MD, MPH, MBA
email. Redacted by agreement
Cell phone: Redacted by agreement

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Emmanuel Njeuhmeli Redacted by agreement
Sent Date:	2020/03/02 10:33:35
Delivered Date:	2020/03/02 10:33:00

Nomination of Dr. Owen Mugurungi for the Roux Prize

January 15, 2020

Name: Dr. Owen Mugurungi

Title: Director HIV and TB Department

Organization: Ministry of Health and Child Care

Country: Zimbabwe

Email: Redacted by agreement

Phone:

Describe the nominee's accomplishments and use of health evidence.

As Director of Zimbabwe's HIV and TB Department since 2000, Dr. Mugurungi is widely recognized as the national leader of the HIV/AIDS response. The national program results are his results. According to the *Global Burden of Disease* database, HIV/AIDS was the number one cause of death in Zimbabwe in 2000 at 833 deaths per 100,000 population. By 2017, it had fallen to number three at 111/100,000, an 87% decline. From UNAIDS data, in 2000 there were an estimated 1.7 million people living with HIV infection (PLHIV), an adult prevalence of 25.1%; 110,000 new HIV infections per year; and 120,000 AIDS-related deaths. By 2018, the annual number of new HIV infections had declined to 38,000, a 65% decrease, and AIDS-related deaths declined to 22,000, an 82% decrease. During that time, the incidence-prevalence ratio declined from 0.07 to 0.03, which is the UNAIDS-defined threshold for "epidemic control."

In 2000, programs for HIV testing and treatment were in their infancy. Under Dr. Mugurungi's leadership, by 2018, 90% of PLHIV (1.1 million) had been diagnosed, 98% of them were on antiretroviral treatment (ART), and 85% of those on ART had an undetectable (suppressed) viral load (2016 estimate). This represents outstanding progress towards the UNAIDS "90-90-90" goals for achieving 90% in each of these measurements by the year 2020. In 2017 alone, 160,000 PLHIV initiated HIV treatment and an estimated 56,000 AIDS-related deaths were averted by the national program.

Early in the 2000s, before HIV treatment and biomedical prevention interventions were widely available, Dr. Mugurungi led a one of the few successful national programs for behavioral HIV prevention. Longitudinal studies showed an annual HIV incidence decline from 2.1% in 2000 to 0.63% in 2010, largely due to reduced sexual risk behavior – lower numbers of casual partners and high condom use in non-regular partnerships. Educational messaging continues and condom use, both male and female, remains high in Zimbabwe.

With Dr. Mugurungi's hands-on direction, by 2018 the national program for prevention of mother-to-child transmission of NIH (PMTCT) reached 94% coverage of HIV-infected women received antiretroviral drugs, preventing 11,000 new infections among newborns. The annual number of infant infections

through MTCT fell from an estimated 26,000 in 2000 to 4,300 in 2017, an 84% decline. Dr. Mugurungi was at the forefront of implementing evidence-based policies, for example, "Option-B+" to provide ART to all HIV-infected pregnant women regardless of CD4 count to benefit the woman's health as well as preventing infant infection.

Dr. Mugurungi has also led an evidence-based, data-driven national program of voluntary medical male circumcision (VMMC), which is 60% effective in reducing female-to-male HIV transmission. Under his leadership, by 2018, 1.4 million circumcisions had been carried out nationally, with more than 300,000 procedures in 2018.

In summary, Dr. Mugurungi exemplifies the ideal of using health evidence in innovative ways to improve population health. For these accomplishments and impacts, he is truly deserving of the Roux Prize.

How has the nominee used evidence to impact health?

As Director of the HIV and TB Department in Zimbabwe since 2000, Dr. Mugurungi has led the HIV response in Zimbabwe, which has been very strongly grounded in epidemiologic and programmatic data, and, despite limited resources and occasional national emergencies, very successful. Dr. Mugurungi has been a principal investigator or senior scientist in research, program implementation, and evaluations including HIV surveillance; HIV prevention, including voluntary medical male circumcision (VMMC) and prevention of mother-to-child transmission (PMTCT); and HIV care and treatment. He has taken a population-wide, public health approach, always with evidence and data at the forefront.

His department is responsible for HIV surveillance activities and for producing national and regional HIV estimates. He has led the design and implemention of routine HIV surveillance systems and surveys and in interpreting and disseminating the results. As one example, he led studies to transition from use of special periodic antenatal surveys to use of routine PMTCT program records.

Dr. Mugurungi is a global leader in conducting research to develop methods for VMMC that are less dependent on clinicians and are more acceptable to men. This research has ranged from studies to identify barriers to uptake of VMMC to development of biomedical tools and procedures for male circumcision. With his direct involvement, the national VMMC program uses a specialized program planning tool. VMMC data were harmonized with nationally representative household-level data and are monitored with weekly data from Ministry dashboards and the national District Health Information System (DHIS2). Quality of program implementation is assessed through biannual national quality reports.

He has led the national PMTCT program with extensive use of data and evaluation, including development and implementation of a cell-phone based system to track infant HIV test specimens to centralized laboratories with test results transmitted by SMS back to the clinic and with an SMS notification to the mother.

Dr. Mugurungi was a co-principal investigator on the pioneering DART trial ("Development of AntiRetroviral Therapy") and co-led research on more feasible approaches to HIV testing, point-of-care equipment for CD4 measurement, and accelerated ART initiation. National surveillance and data

systems track HIV testing, test results, initiation and retention in HIV treatment, viral load, and HIV drug resistance at national and provincial and, for some elements, district and clinic level by sex and age group.

Dr. Mugurungi has evaluated the population-level impact of national HIV control programs with studies have included in-depth, mixed-method investigations and mathematical models to interpret trends in the HIV epidemic and to evaluate the potential impact of alternative implementation strategies.

Ongoing innovations in data use led by Dr. Mugurungi include 1) expanding the national DHIS2 system, which captures all HIV program data, to support scale-up of an electronic health record and include data from other disease programs and 2) implementation of case-based surveillance of new HIV infections with behavioral risk factors as well as bio-markers to design and implement innovative and efficient differentiated models of care, which will be crucial to access increasingly hard-to-reach populations.

Attachments (limit of five):

1. Dr. Mugurungi's CV.
2. EXTENDED ZIMBABWE NATIONAL HIV AND AIDS STRATEGIC PLAN (ZNASP) 2015 – 2020 http://procurement-notices.undp.org/view_file.cfm?doc_id=114051
3. Publication: Justman JE, Mugurungi O, El-Sadr WM. HIV Population Surveys - Bringing Precision to the Global Response. N Engl J Med. 2018 May 17;378(20):1859-1861.
4. Publication: Gregson S, Gonese E, Hallett TB, Taruberekera N, Hargrove JW, Lopman B, Corbett EL, Dorrington R, Dube S, Dehne K, Mugurungi O. HIV decline in Zimbabwe due to reductions in risky sex? Evidence from a comprehensive epidemiological review. Int J Epidemiol. 2010 Oct;39(5):1311-23.
5. Publication: Cuadros DF, Li J, Mukandavire Z, Musuka GN, Branscum AJ, Sartorius B, Mugurungi O, Tanser F. Towards UNAIDS Fast-Track goals: targeting priority geographic areas for HIV prevention and care in Zimbabwe. AIDS. 2019 Feb 1;33(2):305-314.

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Catherine Hankins /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26ce65daf4844079b87db7f2e1200af5-CUSTOM_hank <c.hankins@aighd.org>
Subject:	FW: 2020 INTEREST Scientific Programme brainstorm - VMMC
Date:	2019/12/19 14:11:00
Priority:	Normal
Type:	Note

Hi Cate,
I asked Emmanuel Njeuhmeli, Carlos Toledo (VMMC lead at CDC), and Amy Herman-Roloff (CDC Director, South Africa) for suggestions on VMMC speakers.

1. • Emmanuel may be coming to Windhoek and could speak again, especially if we have more than one speaker.
2. • I'm told either of these two would be great. Dr. June is more scientific. Tigi is a better speaker and more applied.
    a. • Elijah Odoyo-June (CDC-Kenya office)
    b. • Tigistu "Tigi" Adamu Ashengo (formerly JHPIEGO, now working in Ethiopia)

Note: The attached poster from the PHIAs shows that traditional circumcision and VMMC in older men were NOT protective. I was told: "Regarding non-medical MC, it's probably because it's many different things. In some places it's basically a slit, in others a semi circumcision, and in others a full circumcision. It really varies country to country and even within one country. For older men, we think there just wasn't enough power in the analysis as the findings were not significant. Incidence is just a very rare event to capture in these cross sectional surveys. And we know that MC coverage in men >35 is fairly low in most countries." Still some interesting science! BTW - I've been "debating" with some intactivists on Twitter.

Please let me know if you want to proceed and whether to think about one, two, or three speakers.

Thanks,
PK

From: Cate Hankins <c.hankins@aighd.org>
Sent: Wednesday, December 4, 2019 8:32 PM
Cc: Marloes Nijboer <m.nijboer@aighd.org>
Subject: Save the time: Friday December 13 from 1300-1400 Amsterdam time 2020 INTEREST Scientific Programme brainstorm

Hi everyone,
Thank you for your quick replies and for the excellent ideas that have been coming in for the scientific programme and potential peer reviewers. Please mark this time in your calendars now: Friday December 13 from 1300-1400 Amsterdam time.

We will likely have the call by Zoom – Marloes will send the details.

If you haven't sent in ideas yet, please send in some priority subjects this week to add to the compilation that we will send out before the call. If you are unable to join the call, it would be good to get your ideas to share with others on the call, even if you can't join.

All the best,
Cate

From: Catherine Hankins <c.hankins@aighd.org>
Date: Sunday, December 1, 2019 at 11:07 PM
Cc: Marloes Nijboer <m.nijboer@aighd.org>
Subject: 2020 INTEREST Scientific Programme brainstorm

Hi everyone,
Hope that this finds you all well on World AIDS Day! Thank you for expressing your interest in continuing as an active member of the International Conference Committee (ICC) for INTEREST 2020! Your suggestions for new peer reviewers have been welcome – please do keep sending more along with contact info.

It is time for us to brainstorm on potential topics for the scientific programme for INTEREST 2020. We have received some ideas so far (thank you!) and we have had some initial calls with sponsors about their topics.

Please answer the doodle poll and select all times (Dec 6-13) that are currently available for you. The poll will close this Wednesday night December 4th so that you can free up the other times.
https://doodle.com/poll/c6miqpc2ubey8hgk

Please send your ideas for burning issues that you think INTEREST 2020 should cover and we will compile them for our discussion.

Looking forward to our first call!
All the best,
Cate

From: Catherine Hankins <c.hankins@aighd.org>
Date: Wednesday, October 23, 2019 at 6:59 PM
Subject: Looking forward to INTEREST 2020

Dear Members of the INTEREST 2019 International Conference Committee (ICC),

How are you? I hope this finds you well as we edge toward November. We are beginning work now on INTEREST 2020 which will be held May 5-8th 2020 in Windhoek, Namibia. This location edged out the three top choices that we considered at the ICC/EG/Sponsor lunch meeting in May during the 2019 INTEREST conference in Accra, Ghana.

In what we hope will become a tradition, following the attention that has been building before and after the February 9 Lancet theme issue on advancing women in science, medicine, and global health (https://www.thelancet.com/journals/lancet/issue/vol393no10171/PIIS0140-6736(19)X0006-9), we have two Local Co-Chairs for INTEREST 2020. We warmly welcome Anne-Marie Nitscke, who is Director of Special Programmes (HIV, TB, Leprosy, Malaria, and Research Development) at the Ministry of Health and Social Services, and Ismael Katjitae, an internist who is Chair of the Ministry's HIV Technical Advisory Committee.

They will work with Professor Elly Katabira, who has agreed to stay on as a Co-Chair for another year, and myself as Scientific Chair. An invitation to the First Lady of Namibia, UNAIDS Special Advocate for young women and adolescent girls, to open the conference has been accepted. https://www.unaids.org/en/aboutunaids/unaidsambassadors/MonicaGeingos
After the 2018 INTEREST conference in Kigali, we formed the active International Conference Committee and the Emeritus Group composed of those who wanted to remain linked to INTEREST in a less active but nonetheless supportive role. Emeritus Group members are natural ambassadors for INTEREST, keeping an eye open for synergies and funding opportunities while continuing to promote INTEREST's early-career capacity building objectives in Africa. Some Emeritus Group members reviewed scientific abstracts, which was very much appreciated given the huge volume of abstracts submitted for INTEREST 2019. We accepted 435 abstracts from among the 613 that we received.

So today, there are two requests for you to consider:

1. • Will you stay on the active ICC or join the Emeritus Group? Being an active ICC member means reviewing 60-100 abstracts on average, participating in email exchanges and conference calls about the scientific programme, taking on responsibility for organising one or more specific elements of the programme, and seeking out funding to participate actively in the actual meeting. INTEREST can help you with some costs but if you attend INTEREST 2019 you will likely need to co-fund your participation to a certain level.

2. • Whether you remain an ICC member or not, we need help to identify early and mid-career researchers to begin to engage with the INTEREST process. This year I would propose that we start first by asking all 4 Joep Lange award recipients (2016-2019) to review abstracts for us in their chosen fields. In addition, could you please consider nominating someone as a reviewer? It could also be someone you would like to be considered already for the ICC should you be moving to the Emeritus Group or someone

we should keep on our radar for the future. In any case, we need more scientific peer reviewers!

Please get back to me should you have any questions or concerns. Please indicate the role that most suits you at this time, along with any comments that can help us in the final composition of the Emeritus Group and the active committee.

ICC Active committee
Yes: ____
No: ____
Comments: _____
_____
_____
_____

Emeritus Group:
Yes: ___
No: ___
Comments: _____
_____
_____

Suggestions for additional reviewers:

_____
_____
_____
_____
_____
_____

It would be appreciated if you could reply in the next week or so before we reach November.

Thank you to each and every one of you for making INTEREST what is has become today!
All the best,
Cate

Catherine Hankins MD PhD FRCPC CM
Scientific Chair, INTEREST 2020, May 5-8, Windhoek, Namibia
Deputy Director, Science; Amsterdam Institute for Global Health and Development; Department of Global Health, Academic Medical Center, University of Amsterdam
Professor of Public and Population Health, Department of Epidemiology, Biostatistics, and Occupational Health, Faculty of Medicine, McGill University, Montreal
Honorary Professor, Department of Infectious Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine
c.hankins@aighd.org; catherine.hankins@mcgill.ca; catherine.hankins@lshtm.ac.uk
+1 450 775 0032; +31 20 210 3960

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Catherine Hankins /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26ce65daf4844079b87db7f2e1200af5-CUSTOM_hank <c.hankins@aighd.org>
Sent Date:	2019/12/19 14:11:35
Delivered Date:	2019/12/19 14:11:00

HIV Incidence by Male Circumcision Status in Population-Based HIV Impact Assessment (PHIA) Surveys from Eight Sub-Saharan African Countries, 2015-2017

Jonas Z. Hines[1], Stephanie Davis[1], Carlos Toledo[1], Sherri Pals[1], Dan B. Williams[1], Megan Bronson[1], Bharat Parekh[1], Zandile Mnisi[2], Harriet Nuwagaba-Biribonwoha[3], Tapiwa Tarumbiswa[4], Robert Manda[5], Rose Nyirenda[6], Wezi Msungama[7], Mekondjo A. Aupokolo[8], Brigitte Zemburuka[9], Jeremiah Mushi[10], Kokuhumbya Kazaura[11], George S. Mgomella[11], Wilford L. Kirungi[12], Geoffrey Kabuye[13], Anna Colletar Awor[13], Royd Kamobyi[14], Omega Chituwo[15], Sinokuthemba Xaba[16], John Mandisarisa[17], Maria Carrasco[18], Valerian Kiggundu[19], Anne G. Thomas[19], Karampreet Sachathep[20]

BackgroundMale circumcision (MC) offers men lifelong partial protection from heterosexually-acquired HIV infection. The Population-based HIV Impact Assessments (PHIAs) are national surveys estimating national HIV incidence in the setting of HIV programs. We assessed HIV incidence by MC status in eight countries implementing voluntary medical male circumcision (VMMC) with completed PHIAs.MethodsData pooled from PHIAs in Eswatini, Lesotho, Malawi, Namibia, Tanzania, Uganda, Zambia and Zimbabwe from 2015-2017. HIV incidence measured using a recent infection testing algorithm (Limiting-Antigen Avidity assay [normalized optical density < 1.5s], viral load [VL] >1000 copies/mL and detection of antiretroviral treatment [ART]). Analyzed incidence by self-reported MC status, using MC provider type to distinguish between medical and non-medical MC because the latter may not provide comparable protection if foreskin removal is not complete . Controlled for country, marital status, urban setting, sexual risk behaviors, and mean VL among women at the sub-national unit-level (to account for effects of ART scale-up on transmission), and adjusted for survey weights.Analyses age-stratified (15-34 and 35-59 years) because age was associated with MC status.Annualized incidence rates and 95% confidence intervals of circumcised men (medical and non-medical

ResultsAnnualized HIV incidences were 0.03% (0.00-0.08%), 0.33% (0.04-0.61%), and 0.27% (0.08-0.47%) among men 15-34 years reporting medical MC, non-medical MC, and being uncircumcised, respectively (Table). Among men 35-59 years, HIV incidences were 1.11% (0.26-1.96%), 0.34% (0.00-0.68%), and 0.45% (0.12-0.79%) in the same groupings as above. The incidence difference between medically circumcised and uncircumcised men was statistically significant in men 15-34 years (p<0.01) but not 35-59 years (p=0.14). HIV incidence differences were not statistically significant between non-medically circumcised and uncircumcised men in both age groups (p=0.98 and 0.68). LimitationsFew recent infections in the PHIAs resulted in wide confidence intervals. Self-reported MC status may not be accurate.Cross-sectional, observational data cannot data cannot establish causality.Summary & ConclusionsAs compared to being uncircumcised, medical MC was associated with lower HIV incidence in men aged 15-34 years in nationally-representative surveys in sub-Saharan Africa. Non-medical MC was not associated with reduced incidence. These findings are consistent with the expected ongoing VMMC program impact and highlight the importance of VMMC as part of the HIV response in sub-Saharan Africa.

Table: HIV incidence and incidence difference among men aged 15-34 years and 35-59 years by male circumcision status in Population-Based HIV Impact Assessment surveys, eight countries, 2015-2017

		Number of recent infections	Annualized HIV incidence (unadjusted[β]) (%)	95% CI for incidence (unadjusted[β])	Incidence difference (adjusted[†])	95% CI for incidence difference (adjusted[†])	P-value for incidence difference (adjusted[†])
15-34	Medically circumcised[‡]	3	0.03	0.00-0.08	0.19	0.01-0.36	0.01
	Non-medically circumcised[‡]	9	0.33	0.04-0.61	0.00	-0.22-0.22	0.98
	Uncircumcised	27	0.27	0.08-0.47	N/A	N/A	N/A
35-59	Medically circumcised[‡]	9	1.11	0.26-1.96	-0.28	-0.65-0.09	0.14
	Non-medically circumcised[‡]	8	0.34	0.00-0.68	0.04	-0.16-0.25	0.68
	Uncircumcised	19	0.45	0.12-0.79	N/A	N/A	N/A

* Eswatini, Lesotho, Malawi, Namibia, Tanzania, Uganda, Zambia, and Zimbabwe β Annualized HIV incidence is prior to adjusting for covariables† Adjusted for the following covariables: mean VL among women aged 15-59, sexual risk behavior score (past 12 month: : any sexual intercourse; sexual intercourse with 12 partners; no condom use at last sexual intercourse with a non-regular partner (defined as friend/acquaintance, sex worker, sex worker client, ex wife/ex-partner, stranger, or other); and, any sexual partner with HIV-positive or unknown HIV status), urban/rural setting, marital status, and country‡ Medically circumcised = physician, clinical officer, nurse, or midwife; non-medically circumcised = traditional practitioner/circumciser, religious leader, initiation school personnel, family member/relative, or friend); confidence interval

Author affiliations: [1]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Atlanta, USA; [2]Ministry of Health, Eswatini; [3]ICAP, Columbia University, Eswatini; [4]Ministry of Health, Lesotho; [5]U.S. Agency for International Development, Lesotho; [6]Ministry of Health, Malawi; [7]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Malawi; [8]National HIV/AIDS, STI and Hepatitis Control Program, Ministry of Health and Social Services, Namibia; [9]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Namibia; [10]National AIDS Control Programme (NACP), Ministry of Health, Community Development, Gender, Elderly and Children, Tanzania; [11]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Tanzania; [12]Ministry of Health, Uganda; [13]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Uganda; [14]Ministry of Health, Zambia; [15]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Zambia; [16]Ministry of Health and Child Care, Zimbabwe; [17]Division of Global HIV and Tuberculosis, US Centers for Disease Control and Prevention, Zimbabwe; [18]Office of HIV and AIDS, U.S. Agency for International Development, [19]Ethos Health Agency, U.S. Department of Defense, San Diego, USA; [20]ICAP at Columbia University, Mailman School of Public Health, Columbia University, New York, USA

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From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	RE: Male circ pubs this week: VMMC effective in SAfr; Circ protects against STIs; Lichen sclerosis; UTI; VUR; VMMC; Local anesthesia
Date:	2019/12/11 13:35:00
Priority:	Normal
Type:	Note

First author of Tanser et al.

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Wednesday, December 11, 2019 1:34 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Male circ pubs this week: VMMC effective in SAfr; Circ protects against STIs; Lichen sclerosis; UTI; VUR; VMMC; Local anesthesia

Peter Hotez gave a terrific talk at ASTMH last month. Brilliant.

Who is Vandormael?

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Wednesday, December 11, 2019 1:27 PM
To: Timothy Mastro <TMastro@fhi360.org>
Subject: RE: Male circ pubs this week: VMMC effective in SAfr; Circ protects against STIs; Lichen sclerosis; UTI; VUR; VMMC; Local anesthesia

Thanks Tim. I'm inspired by Peter Hotez. I think it's a pretty small readership, but don't want to let the disinformation go unanswered.

Vandormael et al, tweet leaw! https://twitter.com/PeterKilmarx/status/1204479429260402688?s=20

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Wednesday, December 11, 2019 1:21 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: Male circ pubs this week: VMMC effective in SAfr; Circ protects against STIs; Lichen sclerosis; UTI; VUR; VMMC; Local anesthesia

Thanks Peter for fighting the good fight with Intaction.org. Sorry for you that @PeterKilmarx is now all over the Twitter-verse.
Hope you don't get more sucked into this exchange.

Good to see Brian Morris distribute the good Frank Tanser paper below.
Tim

From: Brian Morris <brian.morris@sydney.edu.au>
Sent: Tuesday, December 10, 2019 2:04 PM
To: Brian Morris <brian.morris@sydney.edu.au>
Subject: Male circ pubs this week: VMMC effective in SAfr; Circ protects against STIs; Lichen sclerosis; UTI; VUR; VMMC; Local anesthesia

https://www.ncbi.nlm.nih.gov/pubmed/31792217
Nat Commun. 2019 Dec 2;10(1):5482. doi: 10.1038/s41467-019-13473-y.

Declines in HIV incidence among men and women in a South African population-based cohort.

Vandormael A[1,2,3,4], Akullian A[5,6], Siedner M[7,8,9], de Oliveira T[10,6,11], Bärnighausen T[7,12,13], Tanser F[7,14,11,15].

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Abstract

Over the past decade, there has been a massive scale-up of primary and secondary prevention services to reduce the population-wide incidence of HIV. However, the impact of these services on HIV incidence has not been demonstrated using a prospectively followed, population-based cohort from South Africa-the country with the world's highest rate of new infections. To quantify HIV incidence trends in a hyperendemic population, we tested a cohort of 22,239 uninfected participants over 92,877 person-years of observation. We report a 43% decline in the overall incidence rate between 2012 and 2017, from 4.0 to 2.3 seroconversion events per 100 person-years. Men experienced an earlier and larger incidence decline than women (59% vs. 37% reduction), which is consistent with male circumcision scale-up and higher levels of female antiretroviral therapy coverage. Additional efforts are needed to get more men onto consistent, suppressive treatment so that new HIV infections can be reduced among women.

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Free PMC Article

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Int J STD AIDS. 2019 Dec;30(14):1408-1416. doi: 10.1177/0956462419874593.

Male circumcision and the risk of gonorrhoea, syphilis, HIV and human papillomavirus among men in Tanzania.

Olesen TB[1], Munk C[1], Mwaiselage J[2], Kahesa C[2], Rasch V[3], Frederiksen K[4], Iftner T[5], Kjaer SK[1,6].

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Abstract

To examine the association between male circumcision and the risk of gonorrhoea, syphilis, HIV and high-risk (hr) human papillomavirus (HPV). We used data from a cross-sectional study conducted among 1902 men in Tanzania. Circumcision status was assessed at a clinical examination and history of gonorrhoea and syphilis was obtained from questionnaire data. Penile samples were tested for HPV using Hybrid Capture 2 and genotyped by the INNO-LiPA HPV Genotyping Extra test. Blood samples were tested for HIV. Using logistic regression the association between male circumcision and gonorrhoea, syphilis, HIV and hr HPV was assessed estimating odds ratios (ORs) and 95% confidence intervals (CIs). All analyses were adjusted for age and lifetime number of sexual partners. In the multivariable analysis, the odds of gonorrhoea were lower in circumcised men compared with uncircumcised men (OR = 0.52; 95% CI: 0.37–0.74). Likewise, the odds of HIV were considerably lower in circumcised men (OR = 0.42; 95% CI: 0.26–0.67). Furthermore, lower odds of hr HPV were seen in circumcised men compared with uncircumcised men, although not statistically significant (OR = 0.81; 95% CI: 0.56–1.17). Finally, the odds of HPV16 (OR = 0.48; 95% CI: 0.23–0.98) and multiple (≥2) hr HPV types (OR = 0.71; 95% CI: 0.44–1.12) were lower in circumcised men than in uncircumcised men. Circumcised men have a significantly lower risk of gonorrhoea, HIV and HPV16, compared with uncircumcised men.

KEYWORDS:
HIV; Male circumcision; Tanzania; gonorrhoea; human papillomavirus; syphilis
PMID: 31795926
DOI: 10.1177/0956462419874593

https://www.ncbi.nlm.nih.gov/pubmed/31807846
World J Urol. 2019 Dec 5. doi: 10.1007/s00345-019-03030-z. [Epub ahead of print]

Current treatment of lichen sclerosus and stricture.

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Abstract

INTRODUCTION:
Lichen sclerosus (LS) is a common cause of urethral stricture disease. The purpose of this article is to review the literature over the past 5 years, to describe current treatment of lichen sclerosus as it relates to urethral stricture in men.

MATERIALS AND METHODS:
Literature reviews were performed using PUBMED, with search terms "lichen scleros*" and "urethral stenosis", as well as "lichen scleros*" and "urethral stricture". Relevant articles published within the past 5 years were selected for review. A summary of current treatment of lichen sclerosus was prepared and synthesized.

RESULTS:
For LS affecting genital skin, topical steroids are a mainstay of therapy but in advanced cases, surgery may be required such as circumcision. When LS causes urethral stricture, urethral dilatation is unlikely to be successful long term, and surgery is often required, such as meatoplasty, single- or two-stage urethroplasty, or perineal urethrostomy. Oral mucosal grafting is the graft of choice, and usage of genital skin for flaps or grafts is best avoided due to predilection for recurrence. Biopsy and long-term surveillance of LS are recommended, due to its potential association with squamous cell carcinoma development.

CONCLUSION:
Although debate still exists regarding the pathogenesis of LS, it is agreed that LS can pose a treatment challenge to physicians and surgeons. Treatment options for LS range from pharmacological to surgical, depending on severity and location of disease, patient factors, and response of previous treatments.

KEYWORDS:
Dilatation; Lichen sclerosis et atrophicus; Mouth mucosa; Urethra; Urethral cancer; Urethral diseases; Urethral stricture
PMID: 31807846
DOI: 10.1007/s00345-019-03030-z

https://www.ncbi.nlm.nih.gov/pubmed/31804430
Pediatr Emerg Care. 2019 Dec 3. doi: 10.1097/PEC.0000000000001912. [Epub ahead of print]

Assessing the Utility of Urine Testing in Febrile Infants 2 to 12 Months of Age With Bronchiolitis.

Elkhunovich MA[1], Wang VJ[2], Pham P[1], Arpilleda JC[3], Clingenpeel JM[4], Mansour K[5], Riech T[6], Yen K[2], Liu DR[1].

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Abstract

BACKGROUND:
The utility of testing for urinary tract infection (UTI) in febrile infants with bronchiolitis is indeterminate.

OBJECTIVE:
The objective of this study was to investigate if the incidence of UTIs in febrile infants 2 to 12 months of age with bronchiolitis is higher than the presumed incidence of asymptomatic bacteriuria and determine risk factors associated with UTIs in this population.

METHODS:
This prospective multicenter cross-sectional study was conducted in the emergency departments of 6 children's hospitals between November 2011 and June 2015. We obtained a convenience sample of febrile infants with bronchiolitis 2 to 12 months of age who were tested for UTI. Patient characteristics analyzed included age, maximum temperature, duration of fever, ethnicity, sex, and circumcision status.

RESULTS:
A total of 442 patients (including 86 from a previously published pilot study) were enrolled. Mean age was 5.5 months, 65.2% were Latino, 50.9% were male, and 27.6% of male infants were circumcised. Urinary tract infections were found in 33 patients (7.69%, binomial; 95% confidence interval [CI], 5.19%-10.33%). Urinary tract infections were not related to age, height of temperature, duration of fever, or ethnicity. Uncircumcised males were significantly more likely to have UTIs than circumcised males (7.64% vs 0%, P = 0.03). Odds ratios (ORs) were lower for circumcised males but not uncircumcised males when compared with females (OR, 0.12; CI, 0.0-0.71; P = 0.01 vs OR, 0.77; CI, 0.33-1.74; P = 0.64).

CONCLUSIONS:
Febrile infants 2 to 12 months of age with bronchiolitis have a clinically significant incidence of UTI, suggesting that UTI evaluation should be considered in these patients.

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DOI: 10.1097/PEC.0000000000001912

https://www.ncbi.nlm.nih.gov/pubmed/31805578
Aktuelle Urol. 2019 Dec 5. doi: 10.1055/a-1044-5310. [Epub ahead of print]

[Surgical treatment of vesicoureteral reflux in the first year of life?]

[Article in German; Abstract available in German from the publisher]

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Abstract

in English, German

Surgical intervention in children with VUR is rarely indicated in the first year of life. Early surgical intervention is primarily required for male infants with a high-grade reflux, renal impairment due to reflux nephropathy, infravesical obstruction and breakthrough infections like pyelonephritis or urosepsis. Besides the recommended circumcision, this is usually limited to endoscopic infravesical disobstruction of posterior urethral valves, prolapsing ureteroceles or secondary bladder neck obstructions. Concomitant endoscopic reflux therapy with bulking agents such as hyaluronic acid/dextranomer should be regarded as a downstaging of the VUR; the decision should be made on an individual basis. Urinary diversion, e.g. vesicostomy or ureterocutaneostomy, is only required in exceptional cases.

PMID: 31805578

DOI: 10.1055/a-1044-5310

https://www.ncbi.nlm.nih.gov/pubmed/31809358

J Acquir Immune Defic Syndr. 2020 Jan 1;83(1):16-23. doi: 10.1097/QAI.0000000000002198.

Reducing Provider Workload While Preserving Patient Safety: A Randomized Control Trial Using 2-Way Texting for Postoperative Follow-up in Zimbabwe's Voluntary Medical Male Circumcision Program.

Feldacker C[1,2], Murenje V[3], Holeman I[1,4], Xaba S[5], Makunike-Chikwinya B[3], Korir M[4], Gundidza PT[6], Holec M[2], Barnhart S[1,2,7], Tshimanga M[6].

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Abstract

BACKGROUND:

Voluntary medical male circumcisions (MCs) are safe: the majority of men heal without complication. However, guidelines require multiple follow-up visits. In Zimbabwe, where there is high mobile phone ownership, severe health care worker shortages, and rapid MC scale up intersect, we tested a 2-way texting (2wT) intervention to reduce provider workload while safeguarding patient safety.

SETTING:
Two high-volume facilities providing MC near Harare, Zimbabwe.

METHODS:
A prospective, unblinded, noninferiority, randomized control trial of 722 adult MC clients with cell phones randomized 1:1. 2wT clients (n = 362) responded to a daily text with in-person follow-up only if desired or an adverse event (AE) was suspected. The control group (n = 359) received routine in-person visits. All men were asked to return on postoperative day 14 for review. AEs at ≤day 14 visit and the number of in-person visits were compared between the groups.

RESULTS:
Cumulative AEs were identified in 0.84% [95% confidence interval (CI): 0.28 to 2.43] among routine care men as compared with 1.88% (95% CI: 0.86 to 4.03) of 2wT participants. Noninferiority cannot be ruled out (95% CI: -∞ to +2.72); however, AE rates did not differ between the groups (P = 0.32). 2wT men attended an average of 0.30 visits as compared with 1.69 visits among routine care men, a significant reduction (P <0.001).

CONCLUSIONS:
Although noninferiority cannot be demonstrated, increased AEs in the 2wT arm likely reflect improved AE ascertainment. 2wT serves as a proxy for active surveillance, improving the quality of MC patient care. 2wT also reduced provider workload. 2wT provides an option for men to heal safely at home, returning to care when desired or if complications arise. 2wT should be further tested to enable widespread scale-up.

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DOI: 10.1097/QAI.0000000000002198

https://www.ncbi.nlm.nih.gov/pubmed/31799003

BMJ Glob Health. 2019 Nov 5;4(6):e001922. doi: 10.1136/bmjgh-2019-001922. eCollection 2019.

Geospatial assessment of the voluntary medical male circumcision programme in Tanzania, 2011-2016.

Kim H[1], Branscum A[2], Miller FD[3], Cuadros DF[1].

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Abstract

INTRODUCTION:
Tanzania is one of the 14 priority countries in sub-Saharan Africa scaling up voluntary medical male circumcision(VMMC) for HIV prevention. In this study, we assessed the progress of VMMC by evaluating changes in the spatial structure of male circumcision (MC) prevalence and identifying age groups with low MC uptake.

METHODS:
We use data from two waves of the Demographic and Health Survey (DHS) conducted in Tanzania in 2011-2012 and 2015-2016. MC incidence rate was estimated using a method developed to calculate incidence rates from two successive cross-sectional surveys. Continuous surface maps of

MC prevalence were generated for both DHS waves and compared with identified areas with high MC prevalence changes and high density of uncircumcised males.

RESULTS:
National MC prevalence in Tanzania increased from 73.5% in 2011-2012 to 80.0% in 2015-2016. The estimated national MC incidence rate was 4.6 circumcisions per 100 person-years (py). The lowest circumcision rate was observed in males aged 20-24 years, with 0.61 circumcisions per 100 py. An estimated 1 567 253 males aged 15-49 years residing in low-MC prevalence areas were uncircumcised in 2015-2016.

CONCLUSION:
Tanzania has shown substantial progress in the implementation of VMMC. However, extensive spatial variation of MC prevalence still exists in the country, with some areas having an MC prevalence <60%. Here, we identified locations where VMMC needs to be intensified to reach the ~1.5 million uncircumcised males age 15-49 living in these low-MC areas, particularly for men aged 20-34.

KEYWORDS:
HIV; cross-sectional survey; geographic information systems; public health
PMID: 31799003
PMCID: PMC6861090
DOI: 10.1136/bmjgh-2019-001922
Free PMC Article

https://www.ncbi.nlm.nih.gov/pubmed/31808592
Trop Med Int Health. 2019 Dec 6. doi: 10.1111/tmi.13356. [Epub ahead of print]

Spatial Distribution and Characteristics of HIV Clusters in Ethiopia.

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5 Department of Global Health and Population, Harvard T.H. Chan School of Public Health, Boston, USA.

Abstract

OBJECTIVES:
Ethiopia's HIV prevalence has decreased by 75% in the past 20 years with the implementation of antiretroviral therapy, but HIV transmission continues in high-risk clusters. Identifying the spatial and temporal trends, and epidemiologic correlates, of these clusters can lead to targeted interventions.

METHODS:
We used biomarker and survey data from the 2005, 2011, and 2016 Ethiopia Demographic and Health Surveys (DHS). The spatial-temporal distribution of HIV was estimated using the Kulldorff spatial scan statistic, a likelihood-based method for determining clustering. Significant clusters ($p<0.05$) were identified and compared based on HIV risk factors to non-cluster areas.

RESULTS:
In 2005, 2011, and 2016, respectively, 219, 568, and 408 individuals tested positive for HIV. Four HIV clusters were identified, representing 17% of the total population and 43% of all HIV cases. The clusters were centered about Addis Ababa (1), Afar (2), Dire Dawa (3), and Gambella (4). Cluster 1 had higher rates of unsafe injections (4.9% vs. 2.2%, p<0.001) and transactional sex (6.0% vs. 1.6%, p<0.001) than non-cluster regions, but more male circumcision (98.5% vs. 91.3%, p<0.001). Cluster 2 had higher levels of transactional sex (4.9% vs. 1.6%, p<0.01), but lower levels of unsafe injections (0.8% vs. 2.2%, p<0.01). Cluster 3 had fewer individuals with >1 sexual partner (0% vs. 1.7%, p<0.001) and more male circumcision (100% vs. 91.3%, p<0.001). Cluster 4 had less male circumcision (59.1% vs. 91.3%, p<0.01).

CONCLUSIONS:
In Ethiopia, geographic HIV clusters are driven by different risk factors. Decreasing the HIV burden requires targeted interventions.

KEYWORDS:
Ethiopia; HIV; hot spots; risk factors; spatial distribution; sub-Saharan Africa
PMID: 31808592
DOI: 10.1111/tmi.13356

https://www.ncbi.nlm.nih.gov/pubmed/31804321
Medicine (Baltimore). 2019 Dec;98(49):e18106. doi: 10.1097/MD.0000000000018106.

Penile resurfacing using a reverse bilateral anterior scrotal artery flap: A case report of penile skin defects following circumcision.

Gao QG[1], Qu W[2].
Author information
1 Department of Hand surgery, the second Hospital of Jilin University, Changchun.
2 Department of Plastic and Reconstructive Microsurgery, China-Japan Union Hospital of Jilin University, Changchun, Jilin province, China.

Abstract

RATIONALE:
Circumcision is one of the most frequently used surgical procedures worldwide. Extensive penile skin defects, which can occur as a rare but severe complication of circumcision, are serious and frustrating problems for patients who experience them. Procedures for correcting these problems can pose a challenge to plastic surgeons in the clinic.

PATIENT CONCERNS:
A 31-year-old man was admitted to our care with an extensive defect of the penile skin caused by a circumcision performed 20 days previously.

PRIMARY DIAGNOSES:
Infection, necrosis, and defects of the penile skin.

INTERVENTIONS:
A reverse bilateral anterior scrotal flap was used to correct complete penile skin loss following debridement of the infected and necrotic tissue.

OUTCOMES:
The patient experienced no complications during the 10-year follow-up period. The patient reported normal erectile function and the ability to perform intercourse.

LESSONS:
The reverse bilateral anterior scrotal artery flap is suitable for repairing skin defects of the penis and allows for satisfactory cosmetic and functional improvement following defects of the penile skin.
PMID: 31804321
DOI: 10.1097/MD.0000000000018106
Free full text

NOTE: Inadequate time between time of application of EMLA and the circumcision procedure explains why EMLA is ineffective when used by some operators. For more, see the paragraph after this article.

https://www.ncbi.nlm.nih.gov/pubmed/31793482
Niger J Clin Pract. 2019 Dec;22(12):1737-1741. doi: 10.4103/njcp.njcp_266_19.

Comparison of the efficacy of eutectic mixture of local anesthetics (EMLA) and dorsal penile nerve block (DPNB) in neonatal circumcision.

Modekwe VI[1], Ugwu JO[1], Ekwunife OH[1], Osuigwe AN[1], Obiechina SO[1], Okpalike IV[2], Orakwe JC[3].
Author information
1 Paediatric Surgery Unit, Department of Surgery, Nnamdi Azikiwe University Teaching Hospital, Nnewi, Anambra State, Nigeria.
2 Neurosurgery Unit, Department of Surgery, Nnamdi Azikiwe University Teaching Hospital, Nnewi, Anambra State, Nigeria.
3 Urology Unit, Department of Surgery, Nnamdi Azikiwe University Teaching Hospital, Nnewi, Anambra State, Nigeria.

Abstract

BACKGROUND:
Neonates feel pain. There is a concern among practitioners that pain of injecting analgesics to neonates prior to circumcision could as well be the same as the pain of the procedure. This has made many reluctant to offer effective analgesia for circumcision. If eutectic mixture of local anesthetics (EMLA) provides analgesia comparable to dorsal penile nerve block (DPNB), it will obviate needle prick and encourage analgesia use in neonatal circumcision.

AIM:
To determine how the analgesic efficacy of EMLA compares with that of DPNB in neonatal plastibell circumcision.

METHODS:
A prospective study of 110 male neonates for plastibell circumcision randomized into two groups: A and B, of 55 each, received EMLA or DPNB as analgesia prior to circumcision, respectively. The pulse rates and SpO2 were recorded with pulse oximeter pre-procedural and at four stages of the procedure (adhesiolysis, dorsal slit, tying, and excision) for each neonate. Also the modification of neonatal infant pain scale (NIPS) was recorded during the procedure.

RESULTS:

There were differential changes in SpO2 (lower absolute mean values) and pulse rate (higher absolute mean values) for neonates who received EMLA when compared with DPNB before the procedure. These differences were significant with SpO2 at adhesiolysis (91.0% and 95.0%), dorsal slitting (90.9% and 94.7%), and excision stages (93.4% and 95.3), respectively ($P < 0.05$). They were also significant with the pulse rates at adhesiolysis (167.9 and 158.6), dorsal slitting (174.3 and 161.7), and tying stages (182.2 and 169.0), respectively (P values = 0.013, 0.015, and 0.044, respectively). This shows DPNB is better than EMLA. However, the difference was not significant at the tying stage with SpO2 and at excision stage with PR ($P > 0.05$).

CONCLUSION:
EMLA produces analgesic effect. However, it does not provide effective analgesia for plastibell circumcision in neonates. DPNB provides a better analgesia than EMLA for neonatal plastibell circumcision.

KEYWORDS:
Circumcision; DPNB; EMLA; neonate; pain
PMID: 31793482
DOI: 10.4103/njcp.njcp_266_19

NOTE re this article: Many practitioners do not allow sufficient time for EMLA to work. A simple, effective procedure has been described by Dr Terry Russell, Brisbane, Australia [Russell CT, Chaseling J. Topical anaesthesia in neonatal circumcision: a study of 208 consecutive cases. *Aust Fam Physician* 1996; 25 (suppl 1): 30-34]. The technique involves applying EMLA cream thickly to the distal penis 2 hours prior to the procedure. The penis is wrapped in cling-wrap to keep the cream in contact with the penis, but with the end left open to allow for urination. The Plastibell device is then used. The baby does not cry. In those aged less than 7 months, 99% fed immediately afterwards, 96% settled rapidly, 97% had no disturbance of sleep pattern, 93% had little or no apparent pain, and 96% had no pain or difficulty when urinating. None required stronger post-operative analgesia than paracetemol. In fact, Russell claims that virtually no pain is experienced following the surgery, unlike other methods. He attributes this to the 2 hour duration of the EMLA cream prior to surgery, which means 5 hours of analgesia post-operatively, by which time the nerves where the ligature was tied have ceased to function, and says that most doctors do not leave the EMLA cream on long enough before commencing the procedure (Terry Russell, personal communication).
EMLA is an old preparation. In more recent years Russell replaced EMLA with LMX4 lidocaine-based cream. It works faster and more effectively.

https://neweralive.na/posts/usaid-to-fork-out-half-a-billion-on-vmmc
Nov 17, 2019

UUAID to fork out half a billion on VMMC

U.S. Ambassador Lisa Johnson launched the new PEPFAR -funded voluntary medical male circumcision (VMMC) programme "Safe VMMC" in Namibia a programme that will cost the US AID agency a whopping N$497 140 000 over a five-year period.

Circumcision Academy of Australia: https://www.circumcisionaustralia.info

Circumcision Academy of Australia: http://www.circumcisionaustralia.org

Circumcision Academy of America: http://www.circumcisionamerica.org

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Brian J. Morris, AM DSc PhD FAHA
Professor Emeritus
School of Medical Sciences and Bosch Institute
Anderson Stuart Building (F13)
The University of Sydney
Sydney NSW 2006
Australia

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2019/12/11 13:35:54
Delivered Date:	2019/12/11 13:35:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Ellis, Anna (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85a85fdb3ac74715a5387b0f210e0818-ellisap <ellisap@mail.nih.gov>
CC:	Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Subject:	RE: Discussions on Twitter following ACR mtg
Date:	2019/11/13 13:12:00
Priority:	Normal
Type:	Note

Thanks Anna for retweeting.

I am occasionally tagged in anti-circumcision tweets based on my prior work at CDC. I used to ignore them. Inspired by Peter Hotez, I have been responding to some with factual information to correct gross information from anti-circumcision activists. I have not brought FIC into it. It's a strange group that have been tagged. Definitely no need for FIC to respond.

From: Ellis, Anna (NIH/FIC) [E] <ellisap@mail.nih.gov>
Sent: Wednesday, November 13, 2019 1:06 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Cc: Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Subject: FYI: Discussions on Twitter following ACR mtg

Peter,

Ann gave me a heads up about the Nov 12 panel you participated in at ACR. I retweeted the promo from NIAMS the morning of. Laura Lewandowski tweeted photos of you &Dr. Carter speaking.

https://twitter.com/NIH_NIAMS/status/1194242188009443328
https://twitter.com/LauraLewMad11/status/1194251495602085889

Today our official handle - as well as yours and a few others from NIH – was included in a quote of a reply to a thread that disagreed with comments you made on male circumcision:

Quoted tweet: https://twitter.com/peaceniky/status/1194488841618411520
Original thread: https://twitter.com/briandavidearp/status/1194451118769758208

https://twitter.com/briandavidearp
https://clarkrelationshiplab.yale.edu/people/brian-earp
https://www.practicalethics.ox.ac.uk/people/mr-brian-earp
https://www.thehastingscenter.org/who-we-are/service-to-bioethics/collaborations/

Ann and I discussed and we don't plan to respond or engage.

Anna

Anna Pruett Ellis
Web Manager
Fogarty International Center
National Institutes of Health
31 Center Drive, Room B2C/29, MSC 2220
Bethesda MD 20892-2220
301-496-3682
anna.ellis@nih.gov
http://www.fic.nih.gov

Connect with the **Fogarty International Center at NIH**:

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From: Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Sent: Monday, October 21, 2019 10:35 AM
To: Ellis, Anna (NIH/FIC) [E] <ellisap@mail.nih.gov>
Subject: Nov 12: FW: ACR Global Rheum Research Session: Conference Call

Peter is joining these two on a NIAMS panel on Nov 12, in case there's social media going on:

https://www.fic.nih.gov/News/GlobalHealthMatters/november-december-2016/Pages/laura-lewandowski-pediatric-lupus-south-africa.aspx

https://www.fic.nih.gov/News/GlobalHealthMatters/march-april-2013/Pages/osteoporosis-breast-cancer-china-evelyn-hsieh.aspx

---

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Sunday, October 20, 2019 8:33 AM
To: Weymouth, Kristen (NIH/FIC) [E] <weymouthk@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>; Katz, Flora (NIH/FIC) [E] <katzf@mail.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] <glassr@mail.nih.gov>
Subject: FW: ACR Global Rheum Research Session: Conference Call

Hi all,
I'm giving opening remarks (7 minutes) and participating a panel discussion with NIAMS Acting Director Bob Carter at the American College of Rheumatology annual meeting on Nov 12. (Details attached.)

Please help with any relevant info on global rheumatology research, NIH/FIC grantees, etc.
(Note that Evelyn Hsieh and Laura Lewandowski are co-panelists.)

Flora – can Jane provide an analysis of NIAMS-FIC collaboration by November 6? It looks like they are signed on to fellows &scholars and HIV-NCD. Let's please talk about anything I should urge them to join – NCD R21/D43, K43, etc.

Thanks,
PK

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Sunday, October 20, 2019 8:15 AM
To: Hsieh Donroe, Evelyn <evelyn.hsieh@yale.edu>; Carter, Robert (NIH/NIAMS) [E] <carterrob@mail.nih.gov>; Lewandowski, Laura (NIH/NIAMS) [E] <laura.lewandowski@nih.gov>; Bucala, Richard <richard.bucala@yale.edu>; Graciela S Alarcon <galarcon@uab.edu>; chris.scott@uct.ac.za; [redacted] Ngozi Afulezi <nafulezi@rheumatology.org>; [redacted] Bernardo Pons Estel <[redacted]
Subject: RE: ACR Global Rheum Research Session: Conference Call

Hi and thanks Evelyn for the invite and background information. Unfortunately, I'm not available at the time of the call tomorrow, but my task on Nov 12 seems straightforward.

I can speak with or without slides and will aim for about 7 minutes (15/2). Will cover Fogarty perspective on opportunities in global rheumatology research and funding opportunities for research and research training. Suggestions welcome!

I'll be in Atlanta Nov 9-12 and happy to meet, e.g., breakfast, coffee, lunch, etc., individually or as a group with anyone interested in global research. (I'll probably be going to meetings at CDC the afternoon of the 12th.)

Thanks,
PK

Peter H. Kilmarx, MD, FACP, FIDSA
Rear Admiral, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell [redacted] Tel: +1-301-496-1415
Email peter.kilmarx@nih.gov

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-----Original Appointment-----
From: Hsieh Donroe, Evelyn <evelyn.hsieh@yale.edu>

Sent: Saturday, October 19, 2019 3:04 AM
To: Kilmarx, Peter (NIH/FIC) [E]; Carter, Robert (NIH/NIAMS) [E]; Lewandowski, Laura (NIH/NIAMS) [E]; Bucala, Richard; Graciela S Alarcon; chris.scott@uct.ac.za; Redacted by agreement Ngozi Afulezi; Redacted by agreement ; Bernardo Pons Estel
Subject: ACR Global Rheum Research Session: Conference Call
When: Monday, October 21, 2019 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US &Canada).
Where:

Hello Everyone,

Look forward to the call on **Monday Oct 21st, 11am-12noon** (EST). Please find attached the agenda for the call, the final program for the session, and the speaker talking points outline (each item is bookmarked for convenience).

We look forward to everyone's input! I will send out a Zoom link Sunday evening for the call.

Best,
Evelyn

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Ellis, Anna (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85a85fdb3ac74715a5387b0f210e0818-ellisap <ellisap@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Sent Date:	2019/11/13 13:12:14
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To:	Herman-Roloff, Amy (CDC/DDPHSIS/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Smith, Steven (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98d6531f6c8842b2b6061183b1b5f7a2-Steven.Smit <Steven.Smith@hhs.gov>; Redacted by agreement
Subject:	FW: [keypopulations] EpiC South Africa - VMMV - Job Openings (FHI 360)
Date:	2019/09/10 17:48:00
Priority:	Normal
Type:	Note

Hi Amy and Steve,
Some FHI360 positions may be of interest to your networks . . .

Cheers,
PK

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Tuesday, September 10, 2019 5:34 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: [keypopulations] EpiC South Africa - VMMV - Job Openings (FHI 360)

FYI

From: keypopulations@mail-list.com <keypopulations@mail-list.com>
Sent: Tuesday, September 10, 2019 3:53 PM
To: keypopulations-ml@mail-list.com
Subject: [keypopulations] EpiC South Africa - VMMV - Job Openings (FHI 360)

This message was also sent by PSanjana@fhi360.org to: fhi360linkagescountrymanagers@fhi360.org, fhi360linkageshq@fhi360.org

Dear all,

FHI 360 is seeking applications for four key positions for the Meeting Targets and Maintaining Epidemic Control (EpiC) project in South Africa. Meeting Targets and Maintaining Epidemic Control (EpiC) is a five-year global project funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID), is dedicated to achieving and maintaining HIV epidemic control. The project provides strategic technical assistance (TA) and direct service delivery (DSD) to break through barriers to 95-95-95 and promote self-reliant management of national HIV programs by improving HIV case-finding, prevention, and treatment programming. In South Africa, EpiC will be implementing a voluntary medical male circumcision (VMMC) service delivery project which aims to reduce HIV infections through targeted provision of VMMC in pursuit of reaching 95-95-95 goals. To

achieve this goal, the program will increase demand for and provide high quality, high volume cost-efficient VMMC services in South Africa, coordinate with USAID's Global Health Supply Chain implementing partner and support the transition of direct VMMC service delivery to the Government of South Africa.

The following positions are now posted on the FHI 360 website:

- **Project Director**
  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/EpiC-Project-Director--South-Africa-VMMC_Requisition-2019201641
- **Director of Financial Management &Operations**
  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/Director-of-Financial-Management---Operations_Requisition-2019201640
- **Senior Technical Advisor**
  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/Senior-Technical-Advisor_Requisition-2019201639
- **Senior Advisor for Strategic Information**
  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/Senior-Strategic-Information-Advisor_Requisition-2019201638

Please circulate to your networks.

Many thanks,
Parsa

Parsa Sanjana, MPH | Deputy Director, Program Management
Linkages Across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES)
1825 Connecticut Avenue NW, Washington, DC 20009-5721
O: 202.884.8887 | psanjana@fhi360.org | www.fhi360.org
Skype: parsasanjana

Description: Description: Description: Description: Description: fhi 360 email.jpg

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here.
http://cgi.mail-list.com/u?ln=keypopulations&nm=tmastro%40fhi360.org

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Herman-Roloff, Amy (CDC/DDPHSIS/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Smith, Steven (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98d6531f6c8842b2b6061183b1b5f7a2-Steven.Smit <Steven.Smith@hhs.gov>; Redacted by agreement
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Delivered Date:	2019/09/10 17:48:00

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To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	RE: [keypopulations] EpiC South Africa - VMMV - Job Openings (FHI 360)
Date:	2019/09/10 17:47:00
Priority:	Normal
Type:	Note

Hi Tim,
Important positions. If we don't achieve control in RSA, we haven't achieved control. I'll share with folks.

I'm off to U Buffalo tomorrow to talk about global health, sample the wings, and see the falls.

PK

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Tuesday, September 10, 2019 5:34 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: [keypopulations] EpiC South Africa - VMMV - Job Openings (FHI 360)

FYI

From: keypopulations@mail-list.com <keypopulations@mail-list.com>
Sent: Tuesday, September 10, 2019 3:53 PM
To: keypopulations-ml@mail-list.com
Subject: [keypopulations] EpiC South Africa - VMMV - Job Openings (FHI 360)

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implementing partner and support the transition of direct VMMC service delivery to the Government of South Africa.

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  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/EpiC-Project-Director--South-Africa-VMMC_Requisition-2019201641
- **Director of Financial Management &Operations**
  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/Director-of-Financial-Management---Operations_Requisition-2019201640
- **Senior Technical Advisor**
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- **Senior Advisor for Strategic Information**
  https://fhi.wd1.myworkdayjobs.com/en-US/FHI_360_External_Career_Portal/job/Pretoria-South-Africa/Senior-Strategic-Information-Advisor_Requisition-2019201638

Please circulate to your networks.

Many thanks,
Parsa

Parsa Sanjana, MPH | **Deputy Director, Program Management**
Linkages Across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES)
1825 Connecticut Avenue NW, Washington, DC 20009-5721
O: 202.884.8887 | psanjana@fhi360.org | www.fhi360.org
Skype: parsasanjana

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Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2019/09/10 17:47:13
Delivered Date:	2019/09/10 17:47:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Nuriddin, Fajar (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39063267e692432cbd77678653e41d86-nuriddinfb <fajar.nuriddin@nih.gov>
Subject:	RE: PLOS ONE: Agreement to Review PONE-D-19-03571R1 - [EMID:afe681fbb874162b]
Date:	2019/08/19 18:17:00
Priority:	Normal
Type:	Note

Please print attached.

PK

From: em.pone.0.655e28.b48fa1f5@editorialmanager.com <em.pone.0.655e28.b48fa1f5@editorialmanager.com>**On Behalf Of** PLOS ONE
Sent: Monday, August 19, 2019 6:10 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: PLOS ONE: Agreement to Review PONE-D-19-03571R1 - [EMID:afe681fbb874162b]

Manuscript Number: PONE-D-19-03571R1
Manuscript Title: Voluntary Medical Male Circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets

Dear Dr. Kilmarx,

Thank you for agreeing to review manuscript PONE-D-19-03571R1, entitled "Voluntary Medical Male Circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets".

To download the paper now, please click this link: View Submission

Your review due date is Aug 29 2019 11:59PM EST.

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You may submit your comments online at Submit Recommendation. It is very important to submit your review through the electronic system rather than by email. If you do not have your username and password, they can be retrieved by clicking the *Send Username/Password* button in Editorial Manager.

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1. The study presents the results of original research.
2. Results reported have not been published elsewhere.
3. Experiments, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
4. Conclusions are presented in an appropriate fashion and are supported by the data.
5. The article is presented in an intelligible fashion and is written in standard English.
6. The research meets all applicable standards for the ethics of experimentation and research integrity.
7. The article adheres to appropriate reporting guidelines and community standards for data availability.

Therefore, your evaluation of this submission and your recommendation to the Academic Editor should focus on the scientific soundness of the work. Concerns that the work is lacking in novelty, impact, or interest should not be taken into account. Please visit our website for more information about PLOS ONE.

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With kind regards,

PLOS ONE
plosone@plos.org

Note: An iCalendar file is attached to this email which can be used to set a reminder for this review on your default calendar (Outlook, Apple Calendar, Google Calendar, etc.).

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Nuriddin, Fajar (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39063267e692432cbd77678653e41d86-nuriddinfb <fajar.nuriddin@nih.gov>
Sent Date:	2019/08/19 18:18:03
Delivered Date:	2019/08/19 18:17:00

PLOS ONE

Voluntary Medical Male Circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets

--Manuscript Draft--

Manuscript Number:	PONE-D-19-03571R1
Article Type:	Research Article
Full Title:	Voluntary Medical Male Circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets
Short Title:	VMMC and unintended consequences of service-delivery targets in Kenya
Corresponding Author:	Adam Gilbertson Pacific Institute for Research and Evaluation Chapel Hill, North Carolina UNITED STATES
Keywords:	voluntary medical male circumcision; VMMC; targets; public health intervention targets; HIV prevention; VMMC mobilization; VMMC demand creation; VMMC sensitization; public health intervention; service-delivery targets; VMMC recruitment; Ethics; Kenya; western Kenya; qualitative research
Abstract:	Abstract Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female-to-male HIV transmission. Since 2007, VMMC has been a key component of the United States President's Emergency Plan for AIDS Relief's (PEPFAR) strategy to mitigate the HIV epidemic in countries with high HIV prevalence and low circumcision rates. To ensure intended effects, PEPFAR sets ambitious annual circumcision targets and provides funding to implementation partners to deliver local VMMC services. In Kenya to date, 1.9 million males have been circumcised; in 2017, 60% of circumcisions were among 10-14-year-olds. We conducted a qualitative field study to learn more about VMMC program implementation in Kenya. The study setting was a region in Kenya with high HIV prevalence and low male circumcision rates. From March 2017 through April 2018, we carried out in-depth interviews with 29 VMMC stakeholders, including "mobilizers", HIV counselors, clinical providers, schoolteachers, and policy professionals. Additionally, we undertook observation sessions at 14 VMMC clinics while services were provided and observed mobilization activities at 13 community venues including, two schools, four public marketplaces, two fishing villages, and five inland villages. Analysis of interview transcripts and observation field notes revealed multiple unintended consequences linked to the pursuit of targets. Ebbs and flows in the availability of school-age youth together with the drive to meet targets may result in increased burdens on clinics, long waits for care, potentially misleading mobilization practices, and deviations from the standard of care. Our findings indicate shortcomings in the quality of procedures in VMMC programs in a low-resource setting, and more importantly, that the pursuit of ambitious public health targets may lead to compromised service delivery, consent practices, and protocol adherence. There is a need to develop improved or alternative systems to balance the goal of increasing service uptake with the responsible conduct of VMMC.
Order of Authors:	Adam Gilbertson
	Barrack Ongili
	Frederick S. Odongo
	Denise D. Hallfors
	Stuart Rennie
	Daniel Kwaro
	Winnie K. Luseno
Response to Reviewers:	We have revised our manuscript, "Voluntary Medical Male Circumcision for HIV

	prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets" in accordance with our two reviewers' recommendations. These revisions include those aimed to mask the exact location of this study as well as the individuals and organizations involved in it, including removing the "western" from "western Kenya" in the original title. To reduce the risk of deductive disclosure and protect the privacy and confidentiality of our research participants, we have revised our manuscript to be intentionally vague about the location of the study and have made extensive efforts to ensure that our individual participants and their employers (VMMC implementation partners or IPs) cannot be identified.
Additional Information:	
Question	Response
Financial Disclosure Enter a financial disclosure statement that describes the sources of funding for the work included in this submission. Review the submission guidelines for detailed requirements. View published research articles from *PLOS ONE* for specific examples. This statement is required for submission and **will appear in the published article** if the submission is accepted. Please make sure it is accurate. **Unfunded studies** Enter: *The author(s) received no specific funding for this work.* **Funded studies** Enter a statement with the following details: • Initials of the authors who received each award • Grant numbers awarded to each author • The full name of each funder • URL of each funder website • Did the sponsors or funders play any role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript? • **NO** - Include this sentence at the end of your statement: *The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.* • **YES** - Specify the role(s) played. * typeset	This research was funded by the U.S. National Institute of Mental Health grant number 3R01MH102125-03S1 (Luseno, W. K., Principal Investigator) https://www.nimh.nih.gov/index.shtml The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
Competing Interests	The authors have declared that no competing interests exist.

Use the instructions below to enter a competing interest statement for this submission. On behalf of all authors, disclose any competing interests that could be perceived to bias this work—acknowledging all financial support and any other relevant financial or non-financial competing interests. This statement **will appear in the published article** if the submission is accepted. Please make sure it is accurate. View published research articles from *PLOS ONE* for specific examples. **NO authors have competing interests** Enter: *The authors have declared that no competing interests exist.* **Authors with competing interests** Enter competing interest details beginning with this statement: *I have read the journal's policy and the authors of this manuscript have the following competing interests: [insert competing interests here]* * typeset	
Ethics Statement Enter an ethics statement for this submission. This statement is required if the study involved: • Human participants • Human specimens or tissue • Vertebrate animals or cephalopods • Vertebrate embryos or tissues • Field research Write "N/A" if the submission does not require an ethics statement. General guidance is provided below. Consult the submission guidelines for detailed instructions. **Make sure that all**	The institutional review boards of the Pacific Institute for Research and Evaluation (PIRE) and the Kenya Medical Research Institute (KEMRI) approved all study activities, including all the informed consent procedures described above. Locally, the county-level Ministries of Health and Education and the directors of each IP gave us approval to conduct this research. In-depth interview participants were offered the option to provide either written or verbal informed consent to participate. We requested and were granted a waiver of Documentation of Informed Consent for these interviews since the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The type of informed consent (verbal or written) for each participant was recorded in a file by a research staff member. Most interviewees (28 of the 29) chose written consent. Signed consent forms were stored securely at KEMRI. We also conducted observation sessions within VMMC clinics and during mobilization activities in non-clinical settings (e.g., fishing villages, schools, markets). Research staff provided information about the study to those in charge of VMMC facilities. VMMC recruiters known as “mobilizers” provided verbal informed consent to participate, which

information entered here is included in the Methods section of the manuscript. **Format for specific study types** **Human Subject Research (involving human participants and/or tissue)** • Give the name of the institutional review board or ethics committee that approved the study • Include the approval number and/or a statement indicating approval of this research • Indicate the form of consent obtained (written/oral) or the reason that consent was not obtained (e.g. the data were analyzed anonymously) **Animal Research (involving vertebrate animals, embryos or tissues)** • Provide the name of the Institutional Animal Care and Use Committee (IACUC) or other relevant ethics board that reviewed the study protocol, and indicate whether they approved this research or granted a formal waiver of ethical approval • Include an approval number if one was obtained • If the study involved *non-human primates*, add *additional details* about animal welfare and steps taken to ameliorate suffering • If anesthesia, euthanasia, or any kind of animal sacrifice is part of the study, include briefly which substances and/or methods were applied **Field Research** Include the following details if this study involves the collection of plant, animal, or other materials from a natural setting: • Field permit number • Name of the institution or relevant body that granted permission	was noted/confirmed by our research staff who followed a script for administering informed consent procedures). We sought, and were granted, a Waiver of Documentation of Informed Consent for the recruiters and/or mobilizers based on the reason that the research presented no more than minimal risk of harm to subjects and involved no procedures for which written consent is normally required outside of the research context (See International Ethical Guidelines for Health-related Research Involving Humans, CIOMS, 2016, Guideline 9, p. 34-35, https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf). Concerning the observations that took place at VMMC clinics and during mobilization activities in public spaces, neither written nor verbal consent was sought from VMMC clients or their parents since they were observed in the context of a clinic which in this part of Kenya is a de facto public space, and seeking formal consent was not feasible. Study staff approached a clinical officer (or another staff member who could authorize our research activity) at the clinic to explain the research project and the proposed observation. Prior to in-school observation sessions, school authorities and teachers were informed about the research and gave us permission to conduct the research activities. We sought and received a waiver of informed consent for adolescents and their parents (if in attendance) as well as from other individuals in attendance at the clinic (e.g., doctors, nurses, etc.) for the following reasons: the nature of this part of the research was observational and low risk; we were not collecting individual-level data; the waiver would not adversely affect their rights and welfare; the observational data could not be feasibly collected without the waiver; the research had important social value; and the only identifiable record linking the participant and the research would be the consent document, creating a principal risk for potential harm from a breach of confidentiality. This waiver is also consistent with the guidance in the International Ethical Guidelines for Health-Related Research Involving Humans (2016) by the Council for International Organizations of Medical Sciences (CIOMS, Guideline 10, p.37). The ethics committees at the Pacific Institute for Research and Evaluation (PIRE) and the Kenya Medical Research Institute (KEMRI) both approved all our consent procedures.
Data Availability Authors are required to make all data underlying the findings described fully available, without restriction, and from the time of publication. PLOS allows rare exceptions to address legal and ethical	No - some restrictions will apply

concerns. See the PLOS Data Policy and FAQ for detailed information. A Data Availability Statement describing where the data can be found is required at submission. Your answers to this question constitute the Data Availability Statement and **will be published in the article**, if accepted. **Important**: Stating 'data available on request from the author' is not sufficient. If your data are only available upon request, select 'No' for the first question and explain your exceptional situation in the text box. Do the authors confirm that all data underlying the findings described in their manuscript are fully available without restriction?	
Describe where the data may be found in full sentences. If you are copying our sample text, replace any instances of XXX with the appropriate details. • If the data are **held or will be held in a public repository**, include URLs, accession numbers or DOIs. If this information will only be available after acceptance, indicate this by ticking the box below. For example: *All XXX files are available from the XXX database (accession number(s) XXX, XXX.).* • If the data are all contained **within the manuscript and/or Supporting Information files**, enter the following: *All relevant data are within the manuscript and its Supporting Information files.* • If neither of these applies but you are able to provide **details of access elsewhere**, with or without limitations, please do so. For example: *Data cannot be shared publicly because of [XXX]. Data are available from the XXX Institutional Data Access / Ethics Committee (contact via XXX) for researchers who meet the criteria for access to confidential data.*	We conducted a small, qualitative study that gathered sensitive data via in-person, in-depth interviews and field observation sessions. Our participants were VMMC stakeholders including VMMC policy professionals, clinical service providers (e.g., surgeons, nurses, infection prevention officers), VMMC and HIV counsellors, local school teachers, and VMMC client recruiters known as "mobilizers". Identification of participants through deductive disclosure could lead to harm, particularly harm to livelihood and reputation. To reduce the risk of deductive disclosure and protect the privacy and confidentiality of our research participants, we have revised our manuscript to be intentionally vague about the exact location of the study. However, if our data are made publicly available, even in an anonymized form, there remains a risk that the participating stakeholders and/or their employers (local NGOs that receive funding as "Implementation Partners" from PEPFAR, etc. to carry out circumcisions in Kenya) could be identified. This risk of deductive disclosure was our reviewers' top concern. As such, there are strong ethical reasons not to make our data publicly available. Based on advice from our Institutional Review Board (IRB), we have determined that we cannot make the data publicly available because we did not obtain consent from our participants to share their data for other research purposes. Contact information for the PIRE IRB is: Elysia Oudemans-Tilley, Director of Research Integrity and Compliance, PIRE, phone 301-755-2757, oudemans@pire.org.

The data underlying the results presented in the study are available from (include the name of the third party and contact information or URL). • This text is appropriate if the data are owned by a third party and authors do not have permission to share the data. * typeset	
Additional data availability information:	

Title: Voluntary medical male circumcision for HIV prevention among adolescents in Kenya: unintended consequences of pursuing service-delivery targets

Short title: VMMC and unintended consequences of service-delivery targets in Kenya

Authors: Adam Gilbertson,[1,2,3] Barrack Ongili,[4] Frederick S. Odongo,[4] Denise D. Hallfors[1], Stuart Rennie,[2,3] Daniel Kwaro,[4] and Winnie K. Luseno[1]

Affiliations: [1]Pacific Institute for Research and Evaluation (PIRE), Chapel Hill, North Carolina, USA
[2]UNC Center for Bioethics, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA
[3]Department of Social Medicine, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA
[4]Kenya Medical Research Institute (KEMRI), Kenya

Corresponding author:
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Chapel Hill, NC 27514-7038
Telephone: +1 919 265 2623
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Abstract

Voluntary medical male circumcision (VMMC) provides significant reductions in the risk of female-to-male HIV transmission. Since 2007, VMMC has been a key component of the United States President's Emergency Plan for AIDS Relief's (PEPFAR) strategy to mitigate the HIV epidemic in countries with high HIV prevalence and low circumcision rates. To ensure intended effects, PEPFAR sets ambitious annual circumcision targets and provides funding to implementation partners to deliver local VMMC services. In Kenya to date, 1.9 million males have been circumcised; in 2017, 60% of circumcisions were among 10-14-year-olds. We conducted a qualitative field study to learn more about VMMC program implementation in Kenya.

The study setting was a region in Kenya with high HIV prevalence and low male circumcision rates. From March 2017 through April 2018, we carried out in-depth interviews with 29 VMMC stakeholders, including "mobilizers", HIV counselors, clinical providers, schoolteachers, and policy professionals. Additionally, we undertook observation sessions at 14 VMMC clinics while services were provided and observed mobilization activities at 13 community venues including, two schools, four public marketplaces, two fishing villages, and five inland villages. Analysis of interview transcripts and observation field notes revealed multiple unintended consequences linked to the pursuit of targets. Ebbs and flows in the availability of school-age youth together with the drive to meet targets may result in increased burdens on clinics, long waits for care, potentially misleading mobilization practices, and deviations from the standard of care.

Our findings indicate shortcomings in the quality of procedures in VMMC programs in a low-resource setting, and more importantly, that the pursuit of ambitious public health targets may lead to compromised service delivery, consent practices, and protocol adherence. There is a need to develop improved or alternative systems to balance the goal of increasing service uptake with the responsible conduct of VMMC.

From:	<peter.kilmarx@nih.gov>
To:	Nuno Gaspar <ngaspar@usaid.gov>
Subject:	Re: VMMC and HIV prevalence in Tete
Date:	2019/08/09 06:36:54
Priority:	Normal
Type:	Note

Thanks Nuno.

On Aug 9, 2019, at 4:51 AM, Nuno Gaspar <ngaspar@usaid.gov>wrote:

Hi all,

Apologies for not responding sooner but I have been out in the field.
We will revert to you soon on this.

Best,

N

Enviado do meu iPhone

No dia 09/08/2019, às 09:08, Shannon Young <shyoung@usaid.gov>escreveu:

Hi Nuno - just checking in to see if you were able to respond to this request for information.

Best,

Shannon Young
Division Chief - HIV/AIDS &TB
Integrated Health Office
U.S. Agency for International Development - Mozambique

Mobile: Redacted by agreement
Office: +258 2135 2097

---------- Forwarded message ---------
From: **Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT)** <vrm9@cdc.gov>
Date: Mon, Jul 29, 2019 at 11:26 AM
Subject: RE: VMMC and HIV prevalence in Tete
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>, Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) <dps4@cdc.gov>, Greenberg, Seth

<sgreenberg@usaid.gov>, shyoung@usaid.gov <shyoung@usaid.gov>
Cc: Nuno Gaspar <ngaspar@usaid.gov>

Thanks, Dan and Peter.

I have included Nuno Gaspar who is the VMMC POC at USAID and may assist on providing the VMMC data from Tete province.

Best,

Inacio

Inácio D. Malimane, MD
Prevention Deputy Branch Chief
Centers for Disease Control and Prevention
Redacted by agreement cell | IMalimane@cdc.gov
+258 21 31 4747/48 office | +258 21 31 44 60 fax
7th Floor, JAT Complex 4, Av. 267 Zedequias Manganhela
Maputo, Mozambique

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Sunday, July 28, 2019 2:20 PM
To: Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) <dps4@cdc.gov>; Greenberg, Seth <sgreenberg@usaid.gov>; Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>; shyoung@usaid.gov
Subject: RE: VMMC and HIV prevalence in Tete

Hi all and thanks in advance for any information. Dan describes the question well. It would be surprising if the province with the lowest prevalence of MC has the lowest prevalence of HIV. I'm told the MC estimates may be inaccurate and there is actually a lot of traditional MC.

Thanks,
PK

From: Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) <dps4@cdc.gov>
Sent: Saturday, July 27, 2019 10:53 PM
To: Greenberg, Seth <sgreenberg@usaid.gov>; Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>; shyoung@usaid.gov
Cc: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: VMMC and HIV prevalence in Tete

Shannon, Seth, and Inacio,

Peter Kilmarx (cc'd) is the deputy director of the Fogarty International Center at NIH. He wrote to me inquiring on why the HIV prevalence in Tete is so low when the VMMC rate there is also low. As you know, there is a small group of people who think that male circumcision is immoral or abusive, and they are (apparently) making the argument that Tete proves VMMC is not necessary to control HIV.

Peter can clarify/correct the details of the discussion, but he is very interested in understanding what really drives the HIV epidemic in Tete and whether there is any truth to this apparent disparity. Could you provide him updated data and some context to help in a very difficult back-and-forth with some "intactivists"?

Please loop in anyone else appropriate from your teams.

And warm regards from Almaty.

Dan

Daniel A. Singer, MD, MPH, FACP
Regional Director for Central Asia
U.S. Centers for Disease Control and Prevention - Almaty
E-mail: dsinger@cdc.gov

Description: Description: Description: Description: Description: Description: CDC logo for email aw

Enviado do meu iPhone

No dia 29/07/2019, às 11:26, Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>escreveu:

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Best,

Inacio

Inácio D. Malimane, MD
Prevention Deputy Branch Chief
Centers for Disease Control and Prevention
Redacted by agreement cell | IMalimane@cdc.gov

+258 21 31 4747/48 office | +258 21 31 44 60 fax
7th Floor, JAT Complex 4, Av. 267 Zedequias Manganhela
Maputo, Mozambique

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Sent: Sunday, July 28, 2019 2:20 PM
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Sent: Saturday, July 27, 2019 10:53 PM
To: Greenberg, Seth <sgreenberg@usaid.gov>; Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>; shyoung@usaid.gov
Cc: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
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And warm regards from Almaty.

Dan

Daniel A. Singer, MD, MPH, FACP
Regional Director for Central Asia
U.S. Centers for Disease Control and Prevention - Almaty
E-mail: dsinger@cdc.gov

Description: Description:
Description: Description:
Description: Description: CDC
logo for email aw

Sender:	<peter.kilmarx@nih.gov>
Recipient:	Nuno Gaspar <ngaspar@usaid.gov>
Sent Date:	2019/08/09 06:36:53
Delivered Date:	2019/08/09 06:36:54
Message Flags:	Unsent

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	RE: Male circ pubs this week: Psychol distress in uncirc'd; Atopic disease in mental stenosis; Buried penis and penile cancer; Adverse events low in VMMC; Paraphimosis; Zipper
Date:	2019/08/06 16:21:00
Priority:	Normal
Type:	Note

Foreskin-sparing rescue?

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Tuesday, August 6, 2019 4:13 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: Male circ pubs this week: Psychol distress in uncirc'd; Atopic disease in mental stenosis; Buried penis and penile cancer; Adverse events low in VMMC; Paraphimosis; Zipper

Penile foreskin trapped in a zipper: what to do?

I saw the movie.

From: Brian Morris <brian.morris@sydney.edu.au>
Sent: Tuesday, August 06, 2019 4:07 PM
To: sblank@health.nyc.gov; michael.brady@nationwidechildrens.org; diek@u.washington.edu; bioethics@aap.org; Andrew.Freedman@cshs.org; maxwell@email.chop.edu; ealden@aap.net; Timothy Mastro <TMastro@fhi360.org>; Patrick Sullivan <pssulli@emory.edu>; michaek2@chw.edu.au; g.williams@unsw.edu.au; annem3@chw.edu.au; megp@chw.edu.au; davids@chw.edu.au; David Isaacs <david.isaacs@sydney.edu.au>; frank.oberklaid@rch.org.au; spencer.beasley@cdhb.health.nz; msouth@unimelb.edu.au; Shirley Alexander <shirley.alexander@sydney.edu.au>; Patrina Caldwell <patrina.caldwell@sydney.edu.au>; catherine.cole@health.wa.gov.au; paediatrics@markdesouza.net; s.denny@auckland.ac.nz; daryl.efron@rch.org.au; Hasantha Gunasekera <hasantha.gunasekera@sydney.edu.au>; Andrew Holland <andrew.holland@sydney.edu.au>; Joshua.kausman@rch.org.au; cdn@cd.net.au; Craig Mellis <craig.mellis@sydney.edu.au>; david.reith@otago.ac.nz; [Redacted by agreement] admin@wyndhamscc.com.au
Subject: Male circ pubs this week: Psychol distress in uncirc'd; Atopic disease in mental stenosis; Buried penis and penile cancer; Adverse events low in VMMC; Paraphimosis; Zipper

https://www.ncbi.nlm.nih.gov/pubmed/31375957
AIDS Behav. 2019 Aug 2. doi: 10.1007/s10461-019-02620-7. [Epub ahead of print]

Consent Challenges and Psychosocial Distress in the Scale-up of Voluntary Medical Male Circumcision Among Adolescents in Western Kenya.

Luseno WK[1], Field SH[2], Iritani BJ[3], Rennie S[4], Gilbertson A[3], Odongo FS[5], Kwaro D[5], Ongili B[5], Hallfors DD[3].
Author information
1 Pacific Institute for Research and Evaluation (PIRE), 101 Conner Dr., Suite 200, Chapel Hill, NC, USA. wluseno@pire.org.
2 Independent Statistical Consultant, Chapel Hill, NC, USA.
3 Pacific Institute for Research and Evaluation (PIRE), 101 Conner Dr., Suite 200, Chapel Hill, NC, USA.
4 Department of Social Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.
5 Kenya Medical Research Institute (KEMRI), Centre for Global Health Research, Kisumu, Kenya.
Abstract
In priority sub-Saharan African countries, on the ground observations suggest that the success of voluntary medical male circumcision (VMMC) programs should not be based solely on numbers of males circumcised. We identify gaps in the consent process and poor psychosocial outcomes among a key target group: male adolescents. We assessed compliance with consent and assent requirements for VMMC in western Kenya among males aged 15-19 (N = 1939). We also examined differences in quality of life, depression, and anticipated HIV stigma between uncircumcised and circumcised adolescents. A substantial proportion reported receiving VMMC services as minors without parent/guardian consent. In addition, uncircumcised males were significantly more likely than their circumcised peers to have poor quality of life and symptoms of depression. Careful monitoring of male adolescents' well-being is needed in large-scale VMMC programs. There is also urgent need for research to identify effective strategies to address gaps in the delivery of VMMC services.

KEYWORDS:
Adolescent males; Adolescent well-being; Informed consent; Kenya; Voluntary medical male circumcision
PMID: 31375957
DOI: 10.1007/s10461-019-02620-7

Note re the following article: There was no difference in circumcision rate between boys with and those without meatal stenosis.

https://www.ncbi.nlm.nih.gov/pubmed/31375283
J Pediatr Surg. 2019 Jul 22. pii: S0022-3468(19)30466-X. doi: 10.1016/j.jpedsurg.2019.07.011. [Epub ahead of print]

Increased risk of atopic diseases in boys with meatal stenosis: a possible pathophysiological relation.

Nabavizadeh B[1], Akbari P[1], Ladi Seyedian SS[1], Nabavizadeh R[2], Kajbafzadeh AM[3].
Author information
1 Pediatric Urology and Regenerative Medicine Research Center, Children's Medical Center, Tehran University of Medical Sciences, Tehran, Iran.
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3 Pediatric Urology and Regenerative Medicine Research Center, Children's Medical Center, Tehran University of Medical Sciences, Tehran, Iran. Electronic address: kajbafzd@sina.tums.ac.ir.
Abstract

PURPOSE:
To evaluate the role of atopy (i.e. atopic dermatitis, allergic rhinitis, asthma, and food allergies) and its consequences on developing meatal stenosis in boys.

METHODS:
After obtaining ethics approval from institutional review board, a retrospective chart review was conducted to gather records of patients with meatal stenosis (Group A) presented to our pediatric urology center between August 2012 and May 2016. History of any allergic reactions including allergic rhinitis, asthma, skin, food and drug allergies was considered as positive history of atopy. A control group of children referring to our center due to other etiologies were considered as control group (Group B). Data were analyzed using student t-test and Chi-square test.

RESULTS:
During the study period, a total of 206 boys (mean age 41.01 months) were assigned to group A and 221 (mean age 35.56 months) to group B. 126 (61.16%) boys had history of allergic reactions in group A compared to 29 (13.12%) in the control arm (group B). Patients with meatal stenosis have a significantly higher (P-value <0.001) likelihood of suffering from allergic reactions.

CONCLUSIONS:
The pathophysiology of meatal stenosis remains not fully understood yet. This study reveals a significant relation between hypersensitivity reactions and meatal stenosis in boys. Persistent inflammation in meatal area could potentially lead to scarring and stenosis. However, more investigation is required to elucidate this pathophysiology.

TYPE OF STUDY:
Case-control study.

LEVEL OF EVIDENCE:
Level III.

KEYWORDS:
Allergy; Atopy; Circumcision; Meatal stenosis
PMID: 31375283
DOI: 10.1016/j.jpedsurg.2019.07.011

Note re the following article: Penile cancer is most commonly seen in uncircumcised men with phimosis. However, this study finds that circumcised men who suffer from buried penis can also develop penile cancer.

https://www.ncbi.nlm.nih.gov/pubmed/31369750
Urology. 2019 Jul 29. pii: S0090-4295(19)30682-X. doi: 10.1016/j.urology.2019.07.019. [Epub ahead of print]

The Prevalence of Penile Cancer in patients with Adult Acquired Buried Penis.

Pekala KR[1], Pelzman D[2], Theisen KM[2], Rogers D[3], Maganty A[2], Fuller TW[2], Rusilko PJ[2].
Author information

1 Department of Urology. Electronic address: pekalak@upmc.edu.
2 Department of Urology.
3 University of Pittsburgh School of Medicine.

Abstract

OBJECTIVE:
To determine the prevalence of penile cancer in patients with adult acquired buried penis. Penile cancer is a rare but aggressive cancer. Several case reports have recently been published that indicate that adult acquired buried penis (AABP) may increase the risk of penile cancer.

MATERIALS &METHODS:
A retrospective review was conducted of adults diagnosed with AABP and penile cancer between 1/2008 and 12/2018 seen at a tertiary referral center. Demographics including age, BMI, comorbidities, etiology of AABP, smoking history, circumcision status, and premalignant lesions (condyloma, lichen sclerosus (LS) carcinoma in situ (CIS)) were recorded. For patients with penile cancer, AJCC staging, grade, TNM Staging and treatments were recorded. Basic descriptive statistics were performed for the overall cohort. We used Chi-square tests and Fisher exact tests to compare differences between patients with benign pathology and patients with malignant or pre-malignant pathology.

RESULTS:
We identified 150 patients with the diagnosis of adult acquired buried penis. The prevalence of penile squamous cell carcinoma was seven percent. There was a 35% rate of premalignant lesions. This study is limited by its retrospective and single-institution nature.

CONCLUSION:
AABP is a condition that incorporates multiple risk factors for penile cancer. The prevalence of penile cancer appears to be higher in patients with AABP, however more data is needed to confirm these initial findings. Patients with AABP should be counseled on these risks and should be considered for buried penis repair if a physical exam cannot be performed.

KEYWORDS:
Adult acquired buried penis; Hidden penis; Penile cancer; Squamous cell carcinoma
PMID: 31369750
DOI: 10.1016/j.urology.2019.07.019

https://www.ncbi.nlm.nih.gov/pubmed/31368235
J Int AIDS Soc. 2019 Jul;22(7):e25369. doi: 10.1002/jia2.25369.

Adverse events in a large-scale VMMC programme in Tanzania: findings from a case series analysis.

Hellar A[1], Plotkin M[2], Lija G[3], Mwanamsangu A[1], Mkungume S[1], Christensen A[1], Mushi J[3], Machaku M[1], Maokola T[1], Mlanga E[4], Curran K[3,5].

Author information

1 Jhpiego Tanzania, Dar es Salaam, Tanzania.
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3 National AIDS Control Programme, Ministry of Health, Community Development, Gender, the Elderly and Children, Dar es Salaam, Tanzania.
4 United States Agency for International Development Tanzania, Dar es Salaam, Tanzania.
5 Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD, USA.

Abstract

INTRODUCTION:
Adverse events (AEs) rates in voluntary medical male circumcision (VMMC) are critical measures of service quality and safety. While these indicators are key, monitoring AEs in large-scale VMMC programmes is not without challenges. This study presents findings on AEs that occurred in eight years of providing VMMC services in three regions of Tanzania, to provide discussion both on these events and the structural issues around maintaining safety and quality in scaled-up VMMC services.

METHODS:
We look at trends over time, demographic characteristics, model of VMMC and type and timing of AEs for 1307 males who experienced AEs among all males circumcised in Tabora, Njombe and Iringa regions from 2009 to 2017. We analysed deidentified client data from a VMMC programme database and performed multivariable logistic regression with district clustering to determine factors associated with intraoperative and postoperative AEs among VMMC clients.

RESULTS AND DISCUSSION:
Among 741,146 VMMC clients, 0.18% (1307/741,146) experienced a moderate or severe AE. The intraoperative AE rate was 2.02 per 100,000 clients, and postoperative rate was 2.29 per 1000 return clients. Multivariable logistic regression showed that older age (20 to 29 years) was significantly associated with intraoperative AEs (aOR: 3.51, 95% CI: 1.17 to 10.6). There was no statistical significant difference in AE rates by surgical method. Mobile VMMC service delivery was associated with the lowest risk of experiencing postoperative AEs (aOR:0.64, 95% CI: 0.42 to 0.98). AE rates peaked in the first one to three years of the programme and then steadily declined.

CONCLUSIONS:
In a programme with robust AE monitoring methodologies, AE rates reported in these three regions were very low and declined over time. While these findings support the safety of VMMC services, challenges in reporting of AEs in a large-scale VMMC programme are acknowledged. International and national standards of AE reporting in VMMC programmes are clear. As VMMC programmes transition to national ownership, challenges, strengths and learning from AE reporting systems are needed to support safety and quality of services.

KEYWORDS:
HIV prevention; Tanzania; adverse events; intervention; quality; safety; voluntary medical male circumcision
PMID: 31368235
DOI: 10.1002/jia2.25369

https://www.ncbi.nlm.nih.gov/pubmed/31367524
Urol Case Rep. 2019 Jul 16;26:100967. doi: 10.1016/j.eucr.2019.100967. eCollection 2019 Sep.

Double scrotum? A rare ignored paraphimosis - Case report.

Mishra DK[1], Rajenthiran V[2], Vinod Kumar Reddy T[1], Agarwal MS[3].
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1 Global Rainbow Healthcare, Agra, India.
2 Aarupadai Veedu Medical College, Pondicherry, India.
3 Department of Urology, Global Rainbow Healthcare, Agra, India.

Abstract
Paraphimosis is usually acute painful condition. Delay in medical attention might result in dreaded complications like gangrene and auto-amputation. Very rarely patient might present late with large painless paraphimosis as in our case just because it interrupts intromission despite satisfactory painless erection.

KEYWORDS:
Circumcision; Paraphimosis
PMID: 31367524
PMCID: PMC6656690
DOI: 10.1016/j.eucr.2019.100967
Free PMC Article

https://www.ncbi.nlm.nih.gov/pubmed/31364098
Urol J. 2019 Jul 30. doi: 10.22037/uj.v0i0.4973. [Epub ahead of print]

A Comparative Study on the Efficacy of Four Types of Circumcision for Elderly Males with Redundant Prepuce.

Mu J[1], Fan L[2], Liu D[2], Zhu D[3].
Author information
1 Department of Urology, The Second People's Hospital of Lianyungang, No.161, Xingfu Road, Haizhou District, Lianyungang, 222000, P.R.China. mujiagui@sina.com.
2 Department of Urology, The Second People's Hospital of Lianyungang, No.161, Xingfu Road, Haizhou District, Lianyungang, 222000, P.R.China.
3 Tianjin Medical University, No. 22, Qixiangtai Road, Tianjin, 300211, P.R. China.

Abstract

PURPOSE:
Circumcision is a common human urologic surgery performed in males with redundant prepuce to prevent the transmission and reduce the risk of urologic diseases. However, the optimal circumcision method for elderly men remains to be determined. Herein, the current study was conducted to characterize the efficacy of four different kinds of circumcision for elderly males with redundant prepuce.

METHODS:
This retrospective study included 132 elderly males diagnosed with redundant prepuce who underwent circumcision at the outpatient department. Among them, 38 cases were subjected to traditional surgery (Group A), 23 cases to sleeve circumcision (Group B), and 42 cases to Shang Ring circumcision (Group C) and 29 cases to suturing device circumcision (Group D). Subsequently,

the operation time, loss of blood, postoperative pain, complications, wound healing, and the satisfaction were respectively compared and analyzed.

RESULTS:
The operation time of these 4 groups was calculated to be 27.3 ± 2.39 min, 30.4 ± 2.23 min, 6.3 ± 1.33 min, 7.6 ± 1.29 min, in Group A, Group B, Group C, Group D, respectively (P <0.05). Besides, the loss of blood was 15.6 ± 2.84 mL, 11.8 ± 1.73 mL, 1.3 ± 0.44 mL, 3.7 ± 1.41 mL, respectively (P <0.05). The elderly males who underwent Shang Ring circumcision exhibited the highest postoperative pain score, the longest pain duration, the longest healing time, the lowest recovery satisfaction rate and the highest operation experience satisfaction rate (P <0.05).

CONCLUSION:
Taken together, all four types of male circumcision present with advantages and drawbacks. The traditional male circumcision and sleeve circumcision led to longer operation time and more bleeding, but no additional medical equipment was needed. Meanwhile, the Shang Ring circumcision caused the shortest operation time and the least bleeding, accompanied by the longest pain duration and recovery time. Therefore, the application of sleeve circumcision or a suturing device was recommended for elderly males suffering from redundant prepuce.
PMID: 31364098
DOI: 10.22037/uj.v0i0.4973
Free full text

https://www.ncbi.nlm.nih.gov/pubmed/29877561
unis Med. 2017 Novembre;95(11):998-999.

Penile foreskin trapped in a zipper: what to do?

Sallami S, Zribi S, Abou El Makarim S, Touinsi H.
PMID: 29877561
[Indexed for MEDLINE]
Free full text

Comment re the article below: The BMA 'NTMC' guidance is a case in point. Astonishingly, despite being a medical body, it claimed to be incapable of performing a review of the medical evidence in developing its 'guidance' in infant male circumcision. As a result, it relied instead on opinion. The consequences for public health and individual well-being were thereby disregarded.
https://www.bmj.com/content/366/bmj.l4606?utm_source=etoc&utm_medium=email&utm_campaign=tbmj&utm_content=weekly&utm_term=20190802

Distinguishing opinion from evidence in guidelines

BMJ 2019; 366 doi: https://doi.org/10.1136/bmj.l4606

The experience of experts can be useful when developing guidelines, but structures need to be in place to avoid opinion being confused with evidence

Key messages

- The role of experts in a guideline panel is to make judgments informed by the best available evidence
- When research evidence is not available, they can also provide expert evidence

- Expert evidence is different from expert opinion, which includes a judgment on the evidence
- Expert evidence should be collected systematically and available to panel members before meetings

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Circumcision Academy of Australia: https://www.circumcisionaustralia.info

Circumcision Academy of Australia: http://www.circumcisionaustralia.org

Circumcision Academy of America: http://www.circumcisionamerica.org

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Brian J. Morris, AM DSc PhD FAHA
Professor Emeritus
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Australia

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2019/08/06 16:21:33
Delivered Date:	2019/08/06 16:21:00

From:	<peter.kilmarx@nih.gov>
To:	Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10f89e41b6144db3b6463bf9a5b0499e-vrm9 <vrm9@cdc.gov>
CC:	Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d03e39b81a14c80b2627f4101514fb2-dps4 <dps4@cdc.gov>; Greenberg, Seth <sgreenberg@usaid.gov>; <shyoung@usaid.gov>; Nuno Gaspar <ngaspar@usaid.gov>
Subject:	Re: VMMC and HIV prevalence in Tete
Date:	2019/07/29 06:23:38
Priority:	Normal
Type:	Note

Hi and thanks Inacio and Nuno.

Peter Kilmarx
Fogarty International Center, NIH

On Jul 29, 2019, at 5:26 AM, Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>wrote:

Thanks, Dan and Peter.

I have included Nuno Gaspar who is the VMMC POC at USAID and may assist on providing the VMMC data from Tete province.

Best,

Inacio

Inácio D. Malimane, MD
Prevention Deputy Branch Chief
Centers for Disease Control and Prevention
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+258 21 31 4747/48 office | +258 21 31 44 60 fax
7th Floor, JAT Complex 4, Av. 267 Zedequias Manganhela
Maputo, Mozambique

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Sunday, July 28, 2019 2:20 PM
To: Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) <dps4@cdc.gov>; Greenberg, Seth <sgreenberg@usaid.gov>; Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>; shyoung@usaid.gov
Subject: RE: VMMC and HIV prevalence in Tete

Hi all and thanks in advance for any information. Dan describes the question well. It would be surprising if the province with the lowest prevalence of MC has the lowest prevalence of HIV. I'm told the MC estimates may be inaccurate and there is actually a lot of traditional MC.

Thanks,
PK

From: Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) <dps4@cdc.gov>
Sent: Saturday, July 27, 2019 10:53 PM
To: Greenberg, Seth <sgreenberg@usaid.gov>; Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) <vrm9@cdc.gov>; shyoung@usaid.gov
Cc: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: VMMC and HIV prevalence in Tete

Shannon, Seth, and Inacio,

Peter Kilmarx (cc'd) is the deputy director of the Fogarty International Center at NIH. He wrote to me inquiring on why the HIV prevalence in Tete is so low when the VMMC rate there is also low. As you know, there is a small group of people who think that male circumcision is immoral or abusive, and they are (apparently) making the argument that Tete proves VMMC is not necessary to control HIV.

Peter can clarify/correct the details of the discussion, but he is very interested in understanding what really drives the HIV epidemic in Tete and whether there is any truth to this apparent disparity. Could you provide him updated data and some context to help in a very difficult back-and-forth with some "intactivists"?

Please loop in anyone else appropriate from your teams.

And warm regards from Almaty.

Dan

Daniel A. Singer, MD, MPH, FACP
Regional Director for Central Asia
U.S. Centers for Disease Control and Prevention - Almaty
E-mail: dsinger@cdc.gov

Description: Description:
Description: Description:
Description: Description: CDC
logo for email aw

Sender:	<peter.kilmarx@nih.gov>
Recipient:	Malimane, Inacio (CDC/DDPHSIS/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10f89e41b6144db3b6463bf9a5b0499e-vrm9

	<vrm9@cdc.gov>; Singer, Daniel (Dan) (CDC/DDPHSIS/CGH/DGHP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d03e39b81a14c80b2627f4101514fb2-dps4 <dps4@cdc.gov>; Greenberg, Seth <sgreenberg@usaid.gov>; <shyoung@usaid.gov>; Nuno Gaspar <ngaspar@usaid.gov>
Sent Date:	2019/07/29 06:23:36
Delivered Date:	2019/07/29 06:23:38
Message Flags:	Unsent

Nomination of Dr. Owen Mugurungi for the Roux Prize

Final – January 30, 2019

Name: Dr. Owen Mugurungi

Title: Director HIV and TB Department

Organization: Ministry of Health and Child Care

Country: Zimbabwe

Email: Redacted by agreement

Phone:

Describe the nominee's accomplishments and use of health evidence. (496 words, limit 500):

As Director of Zimbabwe's HIV and TB Department since 2000, Dr. Mugurungi is widely recognized as the national leader of the HIV/AIDS response. The national program results are his results. According to the *Global Burden of Disease* database, HIV/AIDS was the number one cause of death in Zimbabwe in 2000 at 833 deaths per 100,000 population. By 2017, it had fallen to number three at 111/100,000, an 87% decline. From UNAIDS data, in 2000 there were an estimated 1.7 million people living with HIV infection (PLHIV), an adult prevalence of 25.1%; 110,000 new HIV infections per year; and 120,000 AIDS-related deaths. By 2017, the annual number of new HIV infections had declined to 41,000, a 63% decrease, and AIDS-related deaths declined to 22,000, an 82% decrease. During that time, the incidence-prevalence ratio declined from 0.07 to 0.03, which is the UNAIDS-defined threshold for "epidemic control."

In 2000, programs for HIV testing and treatment were in their infancy. Under Dr. Mugurungi's leadership, by 2017, 85% of PLHIV (1.1 million) had been diagnosed, >95% of them were on antiretroviral treatment (ART), and 81% of those on ART had an undetectable (suppressed) viral load (2016 estimate). This represents outstanding progress towards the UNAIDS "90-90-90" goals for achieving 90% in each of these measurements by the year 2020. In 2017 alone, 160,000 PLHIV initiated HIV treatment and an estimated 56,000 AIDS-related deaths were averted by the national program.

Early in the 2000s, before HIV treatment and biomedical prevention interventions were widely available, Dr. Mugurungi led a one of the few successful national programs for behavioral HIV prevention. Longitudinal studies showed an annual HIV incidence decline from 2.1% in 2000 to 0.63% in 2010, largely due to reduced sexual risk behavior – lower numbers of casual partners and high condom use in non-regular partnerships. Educational messaging continues and condom use, both male and female, remains high in Zimbabwe.

With Dr. Mugurungi's hands-on direction, by 2017 the national program for prevention of mother-to-child transmission of NIH (PMTCT) reached >95% coverage of HIV testing of pregnant women and 90% of HIV-infected women received antiretroviral drugs. The MTCT transmission rate at 18 months was 7.0%;

without intervention it would be 40%. The annual number of infant infections through MTCT fell from an estimated 26,000 in 2000 to 4,300 in 2017, an 84% decline. Dr. Mugurungi was at the forefront of implementing evidence-based policies, for example, "Option-B+" to provide ART to all HIV-infected pregnant women regardless of CD4 count to benefit the woman's health as well as preventing infant infection.

Dr. Mugurungi has also led an evidence-based, data-driven national program of voluntary medical male circumcision (VMMC), which is 60-70% effective in reducing female-to-male HIV transmission. Under his leadership, by 2017, 1.2 million circumcisions had been carried out nationally, with more than 220,000 procedures in 2017.

In summary, Dr. Mugurungi exemplifies the ideal of using health evidence in innovative ways to improve population health. For these accomplishments and impacts, he is truly deserving of the Roux Prize.

How has the nominee used evidence to impact health? (492 words, limit 500):

As Director of the HIV and TB Department in Zimbabwe since 2000, Dr. Mugurungi has led the HIV response in Zimbabwe, which has been very strongly grounded in epidemiologic and programmatic data, and, despite limited resources and occasional national emergencies, very successful. Dr. Mugurungi has been a principal investigator or senior scientist in research, program implementation, and evaluations including HIV surveillance; HIV prevention, including voluntary medical male circumcision (VMMC) and prevention of mother-to-child transmission (PMTCT); and HIV care and treatment. He has taken a population-wide, public health approach, always with evidence and data at the forefront.

His department is responsible for HIV surveillance activities and for producing national and regional HIV estimates. He has led the design and implemention of routine HIV surveillance systems and surveys and in interpreting and disseminating the results. As one example, he led studies to transition from use of special periodic antenatal surveys to use of routine PMTCT program records.

Dr. Mugurungi is a global leader in conducting research to develop methods for VMMC that are less dependent on clinicians and are more acceptable to men. This research has ranged from studies to identify barriers to uptake of VMMC to development of biomedical tools and procedures for male circumcision. With his direct involvement, the national VMMC program uses a specialized program planning tool. VMMC data were harmonized with nationally representative household-level data and are monitored with weekly data from Ministry dashboards and the national District Health Information System (DHIS2). Quality of program implementation is assessed through biannual national quality reports.

He has led the national PMTCT program with extensive use of data and evaluation, including development and implementation of a cell-phone based system to track infant HIV test specimens to centralized laboratories with test results transmitted by SMS back to the clinic and with an SMS notification to the mother.

Dr. Mugurungi was a co-principal investigator on the pioneering DART trial ("Development of AntiRetroviral Therapy") and co-led research on more feasible approaches to HIV testing, point-of-care

equipment for CD4 measurement, and accelerated ART initiation. National surveillance and data systems track HIV testing, test results, initiation and retention in HIV treatment, viral load, and HIV drug resistance at national and provincial and, for some elements, district and clinic level by sex and age group.

Dr. Mugurungi has evaluated the population-level impact of national HIV control programs with studies have included in-depth, mixed-method investigations and mathematical models to interpret trends in the HIV epidemic and to evaluate the potential impact of alternative implementation strategies.

Ongoing innovations in data use led by Dr. Mugurungi include 1) expanding the national DHIS2 system, which captures all HIV program data, to support scale-up of an electronic health record and include data from other disease programs and 2) implementation of case-based surveillance of new HIV infections with behavioral risk factors as well as bio-markers to design and implement innovative and efficient differentiated models of care, which will be crucial to access increasingly hard-to-reach populations.

Attachments (limit of five):

1. Dr. Mugurungi's CV.
2. EXTENDED ZIMBABWE NATIONAL HIV AND AIDS STRATEGIC PLAN (ZNASP) 2015 – 2020 http://procurement-notices.undp.org/view_file.cfm?doc_id=114051 [Note – no mention of Owen]
3. Mugurungi O. Country Progress towards 90-90-90 targets: Innovative approaches to close the gaps across the continuum of care. 90-90-90 Targets Workshop; July 22-23, 2017, Paris. http://www.iapac.org/909090-workshop/presentations/909090tw17-Sa1530-Mugurungi.pdf
4. Publication: Gregson S, Gonese E, Hallett TB, Taruberekera N, Hargrove JW, Lopman B, Corbett EL, Dorrington R, Dube S, Dehne K, Mugurungi O. HIV decline in Zimbabwe due to reductions in risky sex? Evidence from a comprehensive epidemiological review. Int J Epidemiol. 2010 Oct;39(5):1311-23.
5. Publication: Mutasa-Apollo T, Shiraishi RW, Takarinda KC, Dzangare J, Mugurungi O, Murungu J, Abdul-Quader A, Woodfill CJ. Patient retention, clinical outcomes and attrition-associated factors of HIV-infected patients enrolled in Zimbabwe's National Antiretroviral Therapy Programme, 2007-2010. PLoS One. 2014 Jan 29;9(1):e86305.

Nomination of Dr. Owen Mugurungi for the Roux Prize

DRAFT – January 24, 2019

Name: Dr. Owen Mugurungi

Title: Director HIV and TB Department

Organization: Ministry of Health and Child Care

Country: Zimbabwe

Email: Redacted by agreement

Phone: _____

Describe the nominee's accomplishments and use of health evidence. (limit 500 words, currently 499):

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As Director of the HIV and TB Department in Zimbabwe since 2000, Dr. Mugurungi has led the HIV response in Zimbabwe, which has been very strongly grounded in epidemiologic and programmatic data, and, despite limited resources and occasional national emergencies, very successful. Dr. Mugurungi has been a principal investigator or senior scientist in research, program implementation, and evaluations including HIV surveillance; HIV prevention, including voluntary medical male circumcision (VMMC) and prevention of mother-to-child transmission (PMTCT); and HIV care and treatment. He has taken a population-wide, public health approach, always with evidence and data at the forefront.

His department is responsible for HIV surveillance activities and for producing national and regional HIV estimates. He has led the design and implemention of routine HIV surveillance systems and surveys and in interpreting and disseminating the results. As one example, he led studies to transition from use of special periodic antenatal surveys to use of routine PMTCT program records.

Dr. Mugurungi is a global leader in conducting research to develop methods for VMMC that are less dependent on clinicians and are more acceptable to men. This research has ranged from studies to identify barriers to uptake of VMMC to development of biomedical tools and procedures for male circumcision. With his direct involvement, the national VMMC program uses a specialized program planning pool. VMMC data were harmonized with nationally representative household-level data and are monitored with weekly data from Ministry dashboards and the national District Health Information System (DHIS2). Quality of program implementation is assessed through biannual national quality reports.

He has led the national PMTCT program with extensive use of data and evaluation, including development and implementation of a cell-phone based system to track infant HIV test specimens to centralized laboratories with test results transmitted by SMS back to the clinic and with an SMS notification to the mother.

Dr. Mugurungi was a co-principal investigator on the pioneering DART trial ("Development of AntiRetroviral Therapy") and co-led research on more feasible approaches to HIV testing, point-of-care

equipment for CD4 measurement, and accelerated ART initiation. National surveillance and data systems track HIV testing, test results, initiation and retention in HIV treatment, viral load, and HIV drug resistance at national and provincial and in some cases district and clinic level by sex and age group.

Dr. Mugurungi has evaluated the population-level impact of national HIV control programs with studies have included in-depth, mixed-method investigations of trends in the HIV epidemic, progress in implementing national programs, and mathematical models to interpret trends in the HIV epidemic and to evaluate the potential impact of alternative implementation strategies.

Ongoing innovations in data use led by Dr. Mugurungi include expanding the national DHIS2 system, which captures all HIV program data, to support scale-up of an electronic health record and include data from other disease programs and implementation of case-based surveillance of new HIV infections with behavioral risk factors as well as bio-markers to design and implement innovative and efficient differentiated models of care and be crucial to reach increasingly hard-to-reach populations.

Potential Attachments (limit of five, need to delete two):

1. Dr. Mugurungi's CV.
2. EXTENDED ZIMBABWE NATIONAL HIV AND AIDS STRATEGIC PLAN (ZNASP) 2015 – 2020 http://procurement-notices.undp.org/view_file.cfm?doc_id=114051 [Note – no mention of Owen]
3. Mugurungi O. Country Progress towards 90-90-90 targets: Innovative approaches to close the gaps across the continuum of care. 90-90-90 Targets Workshop; July 22-23, 2017, Paris. http://www.iapac.org/909090-workshop/presentations/909090tw17-Sa1530-Mugurungi.pdf
4. Publication: Gregson S, Gonese E, Hallett TB, Taruberekera N, Hargrove JW, Lopman B, Corbett EL, Dorrington R, Dube S, Dehne K, Mugurungi O. HIV decline in Zimbabwe due to reductions in risky sex? Evidence from a comprehensive epidemiological review. Int J Epidemiol. 2010 Oct;39(5):1311-23.
5. Publication: Hatzold K, Mavhu W, Jasi P, Chatora K, Cowan FM, Taruberekera N, Mugurungi O, Ahanda K, Njeuhmeli E. Barriers and motivators to voluntary medical male circumcision uptake among different age groups of men in Zimbabwe: results from a mixed methods study. PLoS One. 2014 May 6;9(5):e85051.
6. Publication: Mutasa-Apollo T, Shiraishi RW, Takarinda KC, Dzangare J, Mugurungi O, Murungu J, Abdul-Quader A, Woodfill CJ. Patient retention, clinical outcomes and attrition-associated factors of HIV-infected patients enrolled in Zimbabwe's National Antiretroviral Therapy Programme, 2007-2010. PLoS One. 2014 Jan 29;9(1):e86305.
7. Publication: Dinh TH, Mushavi A, Shiraishi RW, Tippett Barr B, Balachandra S, Shambira G, Nyakura J, Zinyowera S, Tshimanga M, Mugurungi O, Kilmarx PH. Impact of Timing of Antiretroviral Treatment and Birth Weight on Mother-to-Child Human Immunodeficiency Virus Transmission: Findings From an 18-Month Prospective Cohort of a Nationally Representative Sample of Mother-Infant Pairs During the Transition from Option A to Option B+ in Zimbabwe. Clin Infect Dis. 2018 Feb 1;66(4):576-585

From:	<peter.kilmarx@nih.gov>
To:	KRETSINGER, Katrina <kretsingerk@who.int>
Subject:	Re: Items on Male Circumcision, 2018 to Date
Date:	2018/12/11 07:28:21
Priority:	Normal
Type:	Note

Thanks Katrina. I am pretty happy with the progress being made with VMMC for HIV prevention in Africa, although it seems underemphasized relative to other prevention modalities. I still occasionally get tweeted at by intactivists. A luta continua!

I'll be in Geneva in March and will get in touch.

Stay well,
PK

On Dec 10, 2018, at 11:50 PM, KRETSINGER, Katrina <kretsingerk@who.int>wrote:

Not sure who might be the best audience for this anymore, but thought you might! Cheers, Katrina

Sent from my iPhone

Peter Kilmarx
Fogarty International Center, NIH

Begin forwarded message:

Resent-From: <kok4@cdc.gov>
From: Kaguimah Anthony <info@childmortality-prevention.org>
Date: 11 December 2018 at 00:56:19 CET
To: kok4@cdc.gov
Subject: Items on Male Circumcision, 2018 to Date

Items on Male Circumcision, 2018 to Date

Please see below, ranked by viewership, items on male circumcision to appear on www.childsurvival.net in 2018. While most items are from Africa, there are also items from Indonesia (item 1), Papua New Guinea (10), Texas (12), Thailand (13), Poland (16), and China (17).

Good reading.

Article Title	No of Hits
1. • Voluntary Medical Male Circumcision to Prevent HIV in Tanah Papua, Indonesia: Field Trial to Assess Acceptability and Feasibility. http://www.childsurvival.net/?content=com_articles&artid=7400	41
2. • What device would be best for early infant male circumcision in east and southern Africa? Provider experiences and opinions with three different devices in Kenya. http://www.childsurvival.net/?content=com_articles&artid=7007	38
3. • Acceptability and feasibility of early infant male circumcision for HIV prevention in Malawi http://www.childsurvival.net/?content=com_articles&artid=7005	36
4. • Scale-Up of Voluntary Medical Male Circumcision Services for HIV Prevention - 12 Countries in Southern and Eastern Africa, 2013-2016. http://www.childsurvival.net/?content=com_articles&artid=6998	34
5. • Effect of male circumcision on risk of sexually transmitted infections and cervical cancer in women http://www.childsurvival.net/?content=com_articles&artid=7001	33
6. • Obtaining a male circumcision prevalence rate of 80% among adults in a short time: An observational prospective intervention study in the Orange Farm township of South Africa	32

http://www.childsurvival.net/?content=com_articles&artid=7008

7. • Use of the ShangRing circumcision device in boys below 18 years old in Kenya: results from a pilot study. 30

http://www.childsurvival.net/?content=com_articles&artid=7003

8. • Evidence that promotion of male circumcision did not lead to sexual risk compensation in prioritized Sub-Saharan countries 30

http://www.childsurvival.net/?content=com_articles&artid=7004

9. • Geographic Coverage of Male Circumcision in Western Kenya 30

http://www.childsurvival.net/?content=com_articles&artid=7009

10. • Re-establishing safer medical-circumcision-integrated initiation ceremonies for HIV prevention in a rural setting in Papua New Guinea. A multi-method acceptability study. 30

http://www.childsurvival.net/?content=com_articles&artid=7401

11. • CDC Male Circumcision Recommendations Represent a Key Public Health Measure 29

http://www.childsurvival.net/?content=com_articles&artid=7006

12. • Why are we cutting? A Survey of Cultural Views on Circumcision in the Texas Panhandle 29

http://www.childsurvival.net/?content=com_articles&artid=7397

13. • Physicians´ and nurses´ thoughts and concerns about introducing neonatal male circumcision in Thailand: a qualitative study. 29

http://www.childsurvival.net/?content=com_articles&artid=7398

14. • Modifying the health system to maximize voluntary medical male circumcision uptake: a qualitative study in Botswana 28

http://www.childsurvival.net/?content=com_articles&artid=6997

15. • [Post-circumcision] Tetanus in adult males, Bugando Medical Centre, United Republic of Tanzania 27

http://www.childsurvival.net/?content=com_articles&artid=7000

16. • Attitudes, Beliefs and Predictors of Male Circumcision Promotion among Medical University Students in a Traditionally Non-Circumcising Region. [Poland] 27

http://www.childsurvival.net/?content=com_articles&artid=7399

17. • Impact of Educational Interventions on Acceptance and Uptake of Male Circumcision in the General Population of Western China: A Multicenter Cohort Study. 27

http://www.childsurvival.net/?content=com_articles&artid=7402

18. • Predictors of voluntary medical male circumcision prevalence among men aged 25-39 years in Nyanza region, Kenya: Results from the baseline survey of the TASCO study. 26

http://www.childsurvival.net/?content=com_articles&artid=7002

<powerphplist.png>

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Sender:	<peter.kilmarx@nih.gov>
Recipient:	KRETSINGER, Katrina <kretsingerk@who.int>
Sent Date:	2018/12/11 07:28:20
Delivered Date:	2018/12/11 07:28:21
Message Flags:	Unsent

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Catherine Hankins [Redacted by agreement]
Subject:	RE: Marking World AIDS Day 2018 and thanking you
Date:	2018/12/02 17:14:00
Priority:	Normal
Type:	Note

Thanks Cate for your note. Our time and work together in recent years has been a joy. I'm thankful for all that you do and the opportunity to sometimes get to do it with you.

[Redacted by agreement]

Warm holiday wishes,
PK

From: Catherine Hankins [Redacted by agreement]
Sent: Sunday, December 2, 2018 4:57 PM
Subject: Marking World AIDS Day 2018 and thanking you

Dear family and friends,
Yesterday marked the 30th anniversary of World AIDS Day – the first one was inaugurated by Jonathan Mann, head of the World AIDS programme, in 1988. As you may recall, he was killed 10 years later in the Swissair New York-to-Geneva flight that came down near Peggy's Cove, Nova Scotia.

Jonathan would be astounded at how big the HIV epidemic became and how many people have died – 35 million. I remember the day in June 1981 when the CDC report arrived on my desk describing the first cases of what we now know was AIDS. We still don't have either a vaccine or a cure but a lot of progress has been made in rolling out effective antiretroviral treatment and HIV prevention tools (male and female condoms, medical male circumcision, and oral pre-exposure prophylaxis). An estimated 75% of all people living with HIV worldwide know their HIV-positive status (the goal for 2020 is 90%) and 59% of all people living with HIV are on treatment (the goal for 2020 is 81%). People on treatment who achieve suppression of the virus do not transmit HIV to other people (U=U: undetectable=untransmittable) and benefit clinically themselves and can live long and healthy lives.

I am writing to you because I want to thank you for your support over the years to me and others fighting the HIV pandemic. It has been such a long haul so far – and despite all of the successes to date, the road ahead will be long. Your interest and encouragement in all kinds of ways have been so helpful to me personally over the years.

Two quick local achievements to report:

> The Mayor of Montreal Valerie Laplante launched *Montreal sans sida* on Friday, making Montreal the first Canadian city to aim to eliminate AIDS by 2020 (photo at City Hall attached). I

have had the honour of being a member of the Coordinating Committee overseeing this initiative.

Yesterday, following a letter that five of us who are scientists and clinicians wrote to the Attorney-General of Canada Jody Wilson-Raybould -- it was accompanied by statements from the Canadian Legal HIV/AIDS Network and the Canadian Coalition to Reform HIV Criminalisation -- the Attorney-General announced a new directive on HIV criminalization to federal prosecutors that will finally bring Canadian jurisprudence regarding HIV non-disclosure in line with the scientific evidence. https://www.newswire.ca/news-releases/attorney-general-of-canada-to-issue-directive-regarding-prosecutions-of-hiv-non-disclosure-cases-701701791.html

Both of these are both positive moves in the right direction!
Thanking you and hoping this finds you enjoying a fine December wherever you are.
Cathy/Cate

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Catherine Hankins [Redacted by agreement]
Sent Date:	2018/12/02 17:14:14
Delivered Date:	2018/12/02 17:14:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Gordon, Latoya (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43d702b63f14d0fad8e8eb2c32777ce-gordonlr <latoya.gordon@nih.gov>
Subject:	RE: 6284539: Manuscript Review
Date:	2018/10/21 05:26:00
Priority:	Normal
Type:	Note

Hi Latoya,
Please print attached for me.

Thanks,
PK

-----Original Message-----
From: Advances in Urology <heba.abdelsabour@hindawi.com>
Sent: Sunday, October 21, 2018 5:24 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: 6284539: Manuscript Review

Dear Dr. Kilmarx,

Thank you for agreeing to review the Review Article titled "Arguments Opposing Male Circumcision Are Undermined by Strong Scientific Evidence From a Systematic Review" by Brian Morris, Stephen Moreton and John N. Krieger.

You can view the full PDF file of the manuscript and post your review report using the following URL:

http://mts.hindawi.com/reviewer/8924231586213940/

Best regards,

--
****
Heba Abdelsabour
Editorial Office
Hindawi
http://www.hindawi.com
****

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Gordon, Latoya (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43d702b63f14d0fad8e8eb2c32777ce-gordonlr <latoya.gordon@nih.gov>
Sent Date:	2018/10/21 05:26:25
Delivered Date:	2018/10/21 05:26:00

Aug 9, 2018

Advances in Urology
Word count:
Abstract: 299
Main text: 11,558
References: 396

Arguments Opposing Male Circumcision Are Undermined by Strong Scientific Evidence From a Systematic Review

Brian J. Morris,[1] Stephen Moreton,[2] John N. Krieger[3]

[1]School of Medical Sciences and Bosch Institute, University of Sydney, Sydney, New South Wales, 2006, Australia

[2]33 Marina Avenue, Warrington, England, WA5 1HY, UK

[3]Department of Urology, University of Washington School of Medicine, Seattle, Washington, 98195, USA

Correspondence should be addressed to Brian J. Morris; brian.morris@sydney.edu.au

Email addresses of all authors: brian.morris@sydney.edu.au; stephenmoreton@totalise.co.uk; jkrieger@uw.edu

Abstract

Multiple claims are used by opponents in arguing against male circumcision (MC), especially in minors. We evaluated such claims by a PRISMA-compliant systematic review of the scientific evidence from searches of PubMed, Google Scholar, EMBASE and Cochrane databases. Database searches retrieved 283 publications for inclusion. Examination of bibliographies of these yielded 69 further publications. Evaluation of arguments and evidence claiming that MC is either unnecessary or harmful, when compared with scientific data rated by quality found: (1) frequency of adverse events from early infant MC by medical providers using local anesthesia is low (approximately 0.5%). (2) Virtually all adverse events are minor and easily treated with complete resolution. (3) The evidence shows no long-term psychological harm. (4) There are no adverse effects on sexual function or pleasure. (5) MC provides a lifetime of protection against urinary tract infections, oncogenic types of human papillomavirus, genital herpes, human immunodeficiency virus, various other sexually transmitted infections (STIs), candidiasis, inferior hygiene, penile inflammatory conditions, very strong protection against penile cancer and modest protection against prostate cancer. (6) In female sexual partners, MC reduces the risk of cervical cancer and various STIs. To maximize benefits and minimize risks, the evidence supported early infant MC rather than delay of the procedure until males are old enough to decide for themselves. Risk-benefit analyses have reported that benefits exceed risks by 100–200 to 1. A balanced evaluation of ethical issues supported the rights of children to be provided with low-risk, high-benefit interventions such MC in order to protect their health. Expert evaluations of case-law have supported the legality of MC of minors. Other data have demonstrated that early infant MC is cost-saving to health systems. In conclusion, arguments opposing MC are supported mostly by low quality evidence and opinion and are contradicted by strong scientific evidence.

Key words: Male circumcision; infancy; adulthood; evidence, arguments; public health; urinary tract infection; sexually transmitted infection; complications; sexual function; sexual pleasure; ethics; policy

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>
Subject:	RE: Release of CDC Male Circumcision Recommendations - PLEASE READ
Date:	2018/08/31 11:36:00
Priority:	Normal
Type:	Note

Thanks Bob. If I were in a less prominent USG job, I'd probably be more vocal about the issue. Peter Hotez is a role model.

Best,
PK

From: Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>
Sent: Friday, August 31, 2018 11:29 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Release of CDC Male Circumcision Recommendations - PLEASE READ

Hi Peter, sorry you were a pioneer in being abused by social media on controversial issues, hope this better prepared you for your current job.... Bob

---

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Friday, August 31, 2018 11:08 AM
To: Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>
Subject: RE: Release of CDC Male Circumcision Recommendations - PLEASE READ

Thanks Bob. I heard from Ken and suggested be also share with you and the list below. Went into clearance in 2010!

I'm still getting stuff like: https://twitter.com/Intaction1/status/1022963512329596928

All the best,
PK

From: Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>
Sent: Friday, August 31, 2018 11:04 AM
To: Charles Lebaron [Redacted by agreement]; Charbel El Bcheraoui <charbel@uw.edu>; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: Release of CDC Male Circumcision Recommendations - PLEASE READ

FYI, after very long gestation ☺

From: Circumcision (CDC)
Sent: Thursday, August 30, 2018 5:36 PM
To: Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>; 'Greg.Millett@amfar.org' <Greg.Millett@amfar.org>; 'tmastro@fhi360.org' <tmastro@fhi360.org>; Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>; 'pssulli@emory.edu' <pssulli@emory.edu>; Warner, Lee (CDC/ONDIEH/NCCDPHP) <dlw7@cdc.gov>; Redacted by agreement
Subject: Release of CDC Male Circumcision Recommendations - PLEASE READ

Dear Colleague:

The Division of HIV/AIDS Prevention (DHAP) at the Centers for Disease Control and Prevention (CDC) wishes to inform you that CDC has developed *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes*. In addition, CDC developed documents to describe the evidence that serves as the basis for this information, and to provide CDC responses to peer and public review.

Today, the following documents were posted to the CDC website at https://www.cdc.gov/hiv/risk/male-circumcision.html:

1) ***Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes****
This document is intended to assist health care providers in the United States who share information with men and parents of male infants during decision making about male circumcision conducted by health care providers (i.e., medically performed) as it relates to the prevention of human immunodeficiency virus (HIV) infection, sexually transmitted infections, and other health outcomes. A brief bulleted summary of the health benefits and risks of elective medically performed male circumcision is provided at the end of the document.
Appendices I and II provide a grading scheme and grading of the evidence for key statements made in the document.

a) **Appendix I. Grading Scheme and Criteria for Inclusion of Citations, for *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes***
Appendix 1 includes the grading scheme and criteria for inclusion of citations and specific considerations for use of the scheme for Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes

b) **Appendix II. Grading of Citations, for *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcome***
Appendix 2 includes a list of key statements in *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes* and the consensus grade applied to the citation supporting that statement. Descriptive information for each citation is also provided including methodology (randomized clinical trial, observational study, case control, expert opinion, etc.), outcome of interest

(HIV/ sexually transmitted infection, penile cancer, urinary tract infection, etc.), effect of circumcision on outcome of interest (increase, decrease, no change, not applicable), study population (location, risk behavior, gender, race/ethnicity, age group, and any additional comments).

2) **Background, Methods, and Synthesis of Scientific Information Used to Inform *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes*****
This is a companion document *to Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes* that describes the methods for evidence review and provides a description of the evidence about the preventive health benefits, safety, and risks of medical male circumcision; the acceptability of, provider attitudes towards, access to, and cost-effectiveness of male circumcision; and related ethical considerations. The data examined are mainly in the context of the United States, but data from other countries are included to inform the U.S. experience.

3) **Peer Review Comments and CDC Responses for *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes*** and *Background, Methods, and Synthesis of Scientific Information Used to Inform "Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes"*****
This document presents a compilation of all the comments received and the corresponding CDC responses during the first peer review comment period for a) *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes** and b) *Background, Methods, and Synthesis of Scientific Information Used to Inform "Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes"****

4) **Summary of Public Comments and CDC Responses to Public Comments for *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes*****
This document presents a compilation of all the comments received and the corresponding CDC responses during the public comment period for the document *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes**

5) **Summary of Peer Review Comments and CDC Responses to Second Round of Peer Review Comments for *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes*****
This document presents a compilation of all the comments received and the corresponding CDC responses during the second peer review comment period for the document: *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes.**

CDC's Division of HIV/AIDS Prevention encourages you to share information about these documents with fellow colleagues. We thank you for joining CDC in our commitment to HIV/AIDS prevention in the United States.

Cordially yours,

Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

*Formerly titled *Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes*
**Formerly titled *Background, Methods, and Synthesis of Scientific Information Used to Inform the "Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes*.

PLEASE NOTE THAT THIS EMAIL BOX IS NOT MONITORED.
PLEASE DO NOT REPLY TO THIS EMAIL.

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>
Sent Date:	2018/08/31 11:36:46
Delivered Date:	2018/08/31 11:36:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>
Subject:	RE: Good News!
Date:	2018/08/31 10:14:00
Priority:	Normal
Type:	Note

Still getting this: https://twitter.com/Intaction1/status/1022963512329596928

It would have made sense to talk about the recommendations at the ASTDA meeting, but nothing.

From: Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>
Sent: Friday, August 31, 2018 10:13 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Good News!

Very. And, you will still be getting some hate mail.

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Friday, August 31, 2018 10:08 AM
To: Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>
Subject: RE: Good News!

Kind of sad how the intactivists have been able to shut this down.

From: Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>
Sent: Friday, August 31, 2018 10:00 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Good News!

Peter, 20 million cases later, but I guess there are still some folks getting HIV. Tom

---

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Thursday, August 30, 2018 3:45 PM
To: Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>
Subject: FW: Good News!

Hi Tom,
Recommendations are finally out, 11 years after our Atlanta consultation -
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2788411/

CDC male circumcision recommendations and background documents as well as the public and peer review comments and CDC responses were posted on the CDC DHAP website today and can be accessed via the following link: https://www.cdc.gov/hiv/risk/male-circumcision.html.

Not a lot of public communication planned.

Best,
PK

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>
Sent Date:	2018/08/31 10:15:00
Delivered Date:	2018/08/31 10:14:00

From:	<peter.kilmarx@nih.gov>
To:	KRETSINGER, Katrina <kretsingerk@who.int>
Subject:	Re: Good News!
Date:	2018/08/31 06:41:29
Priority:	Normal
Type:	Note

Longest. Clearance. Ever.

Best,
PK

On Aug 31, 2018, at 2:10 AM, KRETSINGER, Katrina <kretsingerk@who.int>wrote:

Whoa!!!! A ghost from the past!

Sent from my iPhone

Peter Kilmarx
Deputy Director, Fogarty International Center, NIH
Rear Admiral, USPHS

On 31 Aug 2018, at 00:28, Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>wrote:

Thanks Ken. Great to see this.

The WHO consultation in Montreaux was in March 2007. We had our consultation in Atlanta in April 2007, the first country to do so. The recommendations went into clearance in December 2010, as I recall.

Others you could include:

- • Tom Peterman
- • Chris Cagle
- • Tim Mastro
- • Bob Chen
- • Greg Millett
- • Patrick Sullivan
- • Lee Warner
- • Others from 2007 consultation – see : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2788411/

Best to all,
PK

Peter H. Kilmarx, MD, FACP, FIDSA
Rear Admiral, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell [Redacted by agreement] Tel: +1-301-496-1415
Email peter.kilmarx@nih.gov
<image001.jpg><image002.png><image003.png>
Impact · Integrity · Innovation

From: Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>
Sent: Thursday, August 30, 2018 3:01 PM
To: Smith, Dawn (CDC/OID/NCHHSTP) <dks0@CDC.GOV>; Taylor, Allan W. (CDC/CGH/OD) <avt0@CDC.GOV>; Kretsinger, Katrina (CDC/CGH/GID) <kok4@CDC.GOV>; Kretsinger, Katrina (CDC who.int) <kretsingerk@who.int>; [Redacted by agreement]; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Gust, Deborah (CDC/OID/NCHHSTP) <dgg6@CDC.GOV>; Porter, Sarah E. (CDC/CGH/DGHT) <icj9@cdc.gov>; Gant, Zanetta (CDC/OID/NCHHSTP) <uwf5@cdc.gov>; Patel, Unnati (FDA/CBER) (CTR) <Unnati.Patel@fda.hhs.gov>
Cc: Hoover, Karen W. (CDC/OID/NCHHSTP) <ffw6@CDC.GOV>; Samandari, Taraz (CDC/OID/NCHHSTP) <tts0@CDC.GOV>; Alan Greenberg <aeg1@gwu.edu>
Subject: Good News!

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Am happy to announce that the CDC male circumcision recommendations and background documents as well as the public and peer review comments and CDC responses were posted on the CDC DHAP website today and can be accessed via the following link: https://www.cdc.gov/hiv/risk/male-circumcision.html.

Due to security reasons, please do not forward this email.

Best wishes for a great holiday weekend!

Thanks!

Ken Dominguez

Sender:	<peter.kilmarx@nih.gov>
Recipient:	KRETSINGER, Katrina <kretsingerk@who.int>
Sent Date:	2018/08/31 06:41:29
Message Flags:	Unsent

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	RE: Release of CDC Male Circumcision Recommendations - PLEASE READ
Date:	2018/08/30 17:48:00
Priority:	Normal
Type:	Note

Shouldn't be. They should have sent by BCC: even to this group.

I still get stuff like: https://twitter.com/Intaction1/status/1022963512329596928

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Thursday, August 30, 2018 5:45 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Release of CDC Male Circumcision Recommendations - PLEASE READ

Just as long as my e-mail and cell number aren't linked to it

---

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Thursday, August 30, 2018 5:43 PM
To: Timothy Mastro <TMastro@fhi360.org>
Subject: RE: Release of CDC Male Circumcision Recommendations - PLEASE READ

Nice of them to send to you and other stalwarts.

PK

From: Timothy Mastro <TMastro@fhi360.org>
Sent: Thursday, August 30, 2018 5:41 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: Release of CDC Male Circumcision Recommendations - PLEASE READ

Thank you!

From: Circumcision (CDC) <circumcision@cdc.gov>
Sent: Thursday, August 30, 2018 5:36 PM
To: Peterman, Thomas (CDC/OID/NCHHSTP) <tap1@cdc.gov>; 'Greg.Millett@amfar.org' <Greg.Millett@amfar.org>; Timothy Mastro <TMastro@fhi360.org>; Chen, Robert (Bob) (CDC/OID/NCHHSTP) <rtc1@cdc.gov>; Patrick Sullivan <pssulli@emory.edu>; Warner, Lee (CDC/ONDIEH/NCCDPHP) <dlw7@cdc.gov>; Redacted by agreement
Subject: Release of CDC Male Circumcision Recommendations - PLEASE READ

Dear Colleague:

The Division of HIV/AIDS Prevention (DHAP) at the Centers for Disease Control and Prevention (CDC) wishes to inform you that CDC has developed *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes*. In addition, CDC developed documents to describe the evidence that serves as the basis for this information, and to provide CDC responses to peer and public review.

Today, the following documents were posted to the CDC website at https://www.cdc.gov/hiv/risk/male-circumcision.html:

1) ***Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes****
This document is intended to assist health care providers in the United States who share information with men and parents of male infants during decision making about male circumcision conducted by health care providers (i.e., medically performed) as it relates to the prevention of human immunodeficiency virus (HIV) infection, sexually transmitted infections, and other health outcomes. A brief bulleted summary of the health benefits and risks of elective medically performed male circumcision is provided at the end of the document.
Appendices I and II provide a grading scheme and grading of the evidence for key statements made in the document.

a) **Appendix I. Grading Scheme and Criteria for Inclusion of Citations, for *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes***
Appendix 1 includes the grading scheme and criteria for inclusion of citations and specific considerations for use of the scheme for Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes

b) **Appendix II. Grading of Citations, for *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcome***
Appendix 2 includes a list of key statements in *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes* and the consensus grade applied to the citation supporting that statement. Descriptive information for each citation is also provided including methodology (randomized clinical trial, observational study, case control, expert opinion, etc.), outcome of interest (HIV/ sexually transmitted infection, penile cancer, urinary tract infection, etc.), effect of circumcision on outcome of interest (increase, decrease, no change, not applicable), study population (location, risk behavior, gender, race/ethnicity, age group, and any additional comments).

2) **Background, Methods, and Synthesis of Scientific Information Used to Inform *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes*****
This is a companion document *to Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and*

other Health Outcomes that describes the methods for evidence review and provides a description of the evidence about the preventive health benefits, safety, and risks of medical male circumcision; the acceptability of, provider attitudes towards, access to, and cost-effectiveness of male circumcision; and related ethical considerations. The data examined are mainly in the context of the United States, but data from other countries are included to inform the U.S. experience.

3) **Peer Review Comments and CDC Responses for *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes**** and ***Background, Methods, and Synthesis of Scientific Information Used to Inform "Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes"*****
This document presents a compilation of all the comments received and the corresponding CDC responses during the first peer review comment period for a) *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes** and b) *Background, Methods, and Synthesis of Scientific Information Used to Inform "Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes"***

4) **Summary of Public Comments and CDC Responses to Public Comments for *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes****
This document presents a compilation of all the comments received and the corresponding CDC responses during the public comment period for the document *Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes**

5) **Summary of Peer Review Comments and CDC Responses to Second Round of Peer Review Comments for *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes****
This document presents a compilation of all the comments received and the corresponding CDC responses during the second peer review comment period for the document: *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes.**

CDC's Division of HIV/AIDS Prevention encourages you to share information about these documents with fellow colleagues. We thank you for joining CDC in our commitment to HIV/AIDS prevention in the United States.

Cordially yours,

Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

*Formerly titled *Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes*

**Formerly titled *Background, Methods, and Synthesis of Scientific Information Used to Inform the "Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes.*

PLEASE NOTE THAT THIS EMAIL BOX IS NOT MONITORED.
PLEASE DO NOT REPLY TO THIS EMAIL.

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2018/08/30 17:48:06
Delivered Date:	2018/08/30 17:48:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>
Subject:	RE: Good News!
Date:	2018/08/30 17:40:00
Priority:	Normal
Type:	Note

Thanks Ken. I don't think you need to send to everyone, but would aim for the lead folks from other OPDIVS – Laura Cheever, Carl Dieffenbach, etc.

Best,
PK

From: Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>
Sent: Thursday, August 30, 2018 5:35 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Good News!

Was able to get the message out to the individuals on your list. Will work on obtaining emails for the other folks from the consultation!

Thanks Peter!

Kenneth L. Dominguez, MD, MPH
CAPT, U.S. Public Health Service
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention
Epidemiology Branch, Prevention for Negatives Team

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Thursday, August 30, 2018 3:29 PM
To: Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>; Smith, Dawn (CDC/OID/NCHHSTP) <dks0@cdc.gov>; Taylor, Allan W. (CDC/CGH/OD) <avt0@cdc.gov>; Kretsinger, Katrina (CDC/CGH/GID) <kok4@cdc.gov>; Kretsinger, Katrina (CDC who.int) <kretsingerk@who.int>; Redacted by agreement Gust, Deborah (CDC/OID/NCHHSTP) <dgg6@cdc.gov>; Porter, Sarah E. (CDC/CGH/DGHT) <icj9@cdc.gov>; Gant, Zanetta (CDC/OID/NCHHSTP) <uwf5@cdc.gov>; Patel, Unnati (FDA/CBER) (CTR) <Unnati.Patel@fda.hhs.gov>
Cc: Hoover, Karen W. (CDC/OID/NCHHSTP) <ffw6@cdc.gov>; Samandari, Taraz (CDC/OID/NCHHSTP) <tts0@cdc.gov>; Greenberg, Alan (CDC gwu.edu) <aeg1@gwu.edu>
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- • Greg Millett
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- • Lee Warner
- • Others from 2007 consultation – see : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2788411/

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Peter H. Kilmarx, MD, FACP, FIDSA
Rear Admiral, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell [Redacted by] Tel: +1-301-496-1415
Email peter.kilmarx@nih.gov

FIC  FB icon  Twitter icon

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From: Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>
Sent: Thursday, August 30, 2018 3:01 PM
To: Smith, Dawn (CDC/OID/NCHHSTP) <dks0@CDC.GOV>; Taylor, Allan W. (CDC/CGH/OD) <avt0@CDC.GOV>; Kretsinger, Katrina (CDC/CGH/GID) <kok4@CDC.GOV>; Kretsinger, Katrina (CDC who.int) <kretsingerk@who.int>; [Redacted by agreement] Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Gust, Deborah (CDC/OID/NCHHSTP) <dgg6@CDC.GOV>; Porter, Sarah E. (CDC/CGH/DGHT) <icj9@cdc.gov>; Gant, Zanetta (CDC/OID/NCHHSTP) <uwf5@cdc.gov>; Patel, Unnati (FDA/CBER) (CTR) <Unnati.Patel@fda.hhs.gov>
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Thanks!

Ken Dominguez

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>
Sent Date:	2018/08/30 17:40:21
Delivered Date:	2018/08/30 17:40:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	FW: Good News! (VMMC)
Date:	2018/08/30 15:33:00
Priority:	Normal
Type:	Note

Tim,
Amazing gestation period for this. Names redacted to protect the innocent.

PK

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To:
Cc:
Subject: RE: Good News!

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Peter H. Kilmarx, MD, FACP, FIDSA
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Cell Redacted by agreement Tel: +1-301-496-1415
Email peter.kilmarx@nih.gov

FIC FB icon Twitter icon
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Cc:
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Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2018/08/30 15:33:40
Delivered Date:	2018/08/30 15:33:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	St. Louis, Mike (CDC/CGH/DGHT) <mes2@cdc.gov>; Habel, Melissa (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86e8a460da5441f1a8925736ffd402d8-evh6 <evh6@CDC.GOV>; Toledo, Carlos (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32aa94f055d748d0804e00958e423598-COT8 <cot8@CDC.GOV>; Benech, Irene (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d41d7713b44cfd956d2e834e5a3aef-hvm6 <hvm6@cdc.gov>; Oluoch, Tom O. (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95760e5ce7d946a38b18c6f0fede946b-HOF0 <hof0@cdc.gov>; Warner, Alicia Hunter (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d62d9a85e5440c882fa345e36c9d6c6-APH6 <aph6@CDC.GOV>
CC:	Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Balachandra, Shirish (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c68f8ebc627b444f977085c662e9b75e-ymx1 <ymx1@cdc.gov>; Tan, Sze-Yee A <stan45@gatech.edu>; Belinda GT Zhang (belinda.zhang@gatech.edu) <belinda.zhang@gatech.edu>; Kelsie GaTech Thomas [Redacted by agreement]
Subject:	RE: FETP program in Zim is STILL the gift that keeps on giving to fight global HIV ! (including demand creation for VMMC)
Date:	2018/06/05 11:22:00
Priority:	Normal
Type:	Note

Hi and thanks Mike. Great to see this!

The PEPFAR funding was cut in COP '15, but, as I recall, Shannon Hader found some funds to continue. I don't know the current status.

Best,
PK

From: St. Louis, Mike (CDC/CGH/DGHT) <mes2@cdc.gov>
Sent: Tuesday, June 5, 2018 10:32 AM
To: Habel, Melissa (CDC/CGH/DGHT) <evh6@CDC.GOV>; Toledo, Carlos (CDC/CGH/DGHT) <cot8@CDC.GOV>; Benech, Irene (CDC/CGH/DGHT) <hvm6@cdc.gov>; Oluoch, Tom O. (CDC/CGH/DGHT) <hof0@cdc.gov>; Warner, Alicia Hunter (CDC/CGH/DGHT) <aph6@CDC.GOV>
Cc: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Balachandra, Shirish (CDC/CGH/DGHT) <ymx1@cdc.gov>; Tan, Sze-Yee A <stan45@gatech.edu>; Belinda GT Zhang (belinda.zhang@gatech.edu) <belinda.zhang@gatech.edu>; Kelsie GaTech Thomas [Redacted by agreement]
Subject: FETP program in Zim is STILL the gift that keeps on giving to fight global HIV ! (including demand creation for VMMC)

CDC-Zim got forced to cut out its support to the FETP about 5 years ago, I think?

But Mufuta, Tsitsi, and the FETP team just keep cranking out publications on important HIV implementation issues.

https://www.researchgate.net/publication/325372882_Effectiveness_of_Demand_creation_promotions_and_demand_creation_personnel_in_creating_demand_for_Voluntary_Medical_Male_Circumcision_Chitungwiza_District_Zimbabwe_in_2016

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
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Sent Date:	2018/06/05 11:22:39
Delivered Date:	2018/06/05 11:22:00

From:	<peter.kilmarx@nih.gov>
To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	Re: Novel Male Circumcision
Date:	2018/06/04 15:53:37
Priority:	Normal
Type:	Note

Sounds good to me!

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On Jun 4, 2018, at 3:49 PM, Timothy Mastro <TMastro@fhi360.org> wrote:

Another breakgthrough!

From: Boris Wang [Redacted by agreement]
Sent: Monday, June 04, 2018 4:54 AM
To: Timothy Mastro <TMastro@fhi360.org>
Subject: Novel Male Circumcision

Dear Dr. T.Mastro.

How are you today? This is Boris Wang from China. I'm also a member of IAS (International Aids Society), and reading through your paper on the IAS. Hope everything is going well in your side! I'm working in Jinagxi Langhe Medical Instrument Co., Ltd that manufactures novel disposable circumcision suture device.

As we known, there is substantial evidence that male circumcision protects against several diseases, like: urinary tract infections, syphilis, chancroid and invasive penile cancer, as well as HIV.

Disposable Circumcision Suture Device is our patented product, we invented in 2009 with our own patent for inventions, since then we are working with urologist and now have already widely promoted and spread in Chinese public hospitals, meanwhile, we have exported to Malaysia, Indonesia, India, Italy, Botswana and South Africa. We are the original inventor and standard setter of this circumcision suture device, also the leader in this technology, till now our device have verified by more than TWO MILLION cases, averaged 1,500 patients circumcised by our device per day.

Disposable Circumcision Suture Device is a novel circumcision device, and It designed based on bowel anastomotic stapler principles. It is operated by simply squeezing its handles to trigger the circular scalpel blade and stapler, thereby removing the foreskin and creating the anastomosis at the same time. The cicatrices created smooth appearance as compared to the more nodular appearance found in the suturing method. An average of 7.7 minutes was achieved in a study conducted on 62 patients as opposed to far greater times for traditional methods.

Post-operative edema is also greatly reduced. It completes hemostasis and severance in one easy step by a simple firing mechanism of the device. A great reduction in pain renders not only the overall patient experience but allows easier change of dressings greatly reducing any risk of post-operative infections. When new tissue grows will push staple out and staple will drop automatically after one week, 30-45 days drop completed.

Disposable Circumcision Suture Device is easy to operate and free surgeons hand at utmost, it's also provided a new circumcision concept and new treatment option to both doctors and patients. More information please download operation video and academic paper from below our company website, or search "LANGHE MEDICAL" in YouTube.

https://www.youtube.com/channel/UCDCJC7vFPaZGD4Z-apTuW4g

I'm looking forward your reply!

Best Wishes,

Boris Wang

Mobile/WhatsApp: Redacted by agreement

Jinagxi Langhe Medical Instrument Co., Ltd

Office: 4F, Tower D, Wanli Trade Center,
No. 346 Panyu Ave. North, Guangzhou, Guangdong, 511400, P.R.China

Tel: +86 20-31046082
Web: http://www.langhemedical.com/en/index.php

Boris Wang
Mobile/WhatsApp: Redacted by agreement
Jinagxi Langhe Medical Instrument Co., Ltd
Office: 4F, Tower D, Wanli Trade Center,
No. 346 Panyu Ave. North, Guangzhou, Guangdong, 511400, P.R.China
Web: http://www.langhemedical.com/en/index.php
<CIRCCURER™ Introduction.pdf>

Sender:	<peter.kilmarx@nih.gov>
Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2018/06/04 15:53:37
Message Flags:	Unsent

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Vuyelwa T S Chitimbire <chitimbire@zach.org.zw>
Subject:	Re: Now available: your article is in an issue of Global Health Action
Date:	2018/01/14 12:58:45
Priority:	Normal
Type:	Note

Hi Vee,
Great to hear from you. I'm very proud of you guys and out PBF model. I'll let Ambassador Wharton know when I see him :)

Best wishes for new year!

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On Jan 14, 2018, at 6:59 PM, Vuyelwa T S Chitimbire <chitimbire@zach.org.zw>wrote:

Dear Peter,
Could not resist to say hello- long time and compliments of the New Year. Hoping that you are all good. The VMMC program has done well under CDC – I am reminded of the days we started, when a lot of people did not have much confidence in our performance. Now we have a good model and PBF is working well.
All the best and greetings to your better half.
Vee Chitimbire

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Friday, January 12, 2018 10:32 PM
To: Scott Barnhart <sbht@uw.edu>; Caryl Feldacker <cfeld@uw.edu>; Redacted by agreement chitimbire@zach.org.zw; Marrianne M. Holec <mmholec@uw.edu>; Abby R Stepaniak <arstep@uw.edu>; Aaron Bochner <bochner@uw.edu>; bmakunike@itech-zimbabwe.org; vmurenje@itech-zimbabwe.org; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Subject: RE: Now available: your article is in an issue of Global Health Action

Adding my thanks and congratulations to all for a very successful program.

Caryl – great to see this finally published. Thanks for your perseverance.

PK

From: Scott Barnhart [mailto:sbht@uw.edu]
Sent: Thursday, January 11, 2018 11:42 AM
To: Caryl Feldacker <cfeld@uw.edu>; Redacted by agreement chitimbire@zach.org.zw; Marrianne M. Holec <mmholec@uw.edu>; Abby R Stepaniak <arstep@uw.edu>; Aaron Bochner

<bochner@uw.edu>; bmakunike@itech-zimbabwe.org; vmurenje@itech-zimbabwe.org; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Subject: Re: Now available: your article is in an issue of Global Health Action

And a very big thank you to you Caryl. That was a long and heavy lift. Really glad to see this published but more importantly it a privilege to work with this entire group that made this integrated approach successful. Compliments of the new season to all, Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

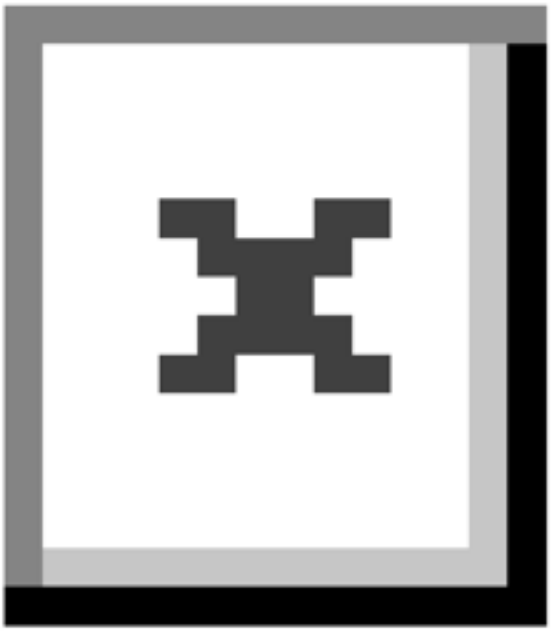
"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Caryl Feldacker <cfeld@uw.edu>
Sent: Thursday, January 11, 2018 8:26 AM
To: Scott Barnhart; Redacted by agreement chitimbire@zach.org.zw; Marrianne M. Holec; Abby R Stepaniak; Aaron Bochner; bmakunike@itech-zimbabwe.org; vmurenje@itech-zimbabwe.org; peter.kilmarx@nih.gov; bjy2@cdc.gov
Subject: Now available: your article is in an issue of Global Health Action

Congrats to us all on the final publication of this manuscript!
Best,
Caryl

Begin forwarded message:

From: "info@tandfonline.com" <info@tandfonline.com>
Date: January 11, 2018 at 3:53:50 AM PST
To: cfeld@uw.edu
Subject: Taylor &Francis author update: congratulations, your article is in an issue of Global Health Action
Reply-To: noreply@tandfonline.com



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Dear Caryl Feldacker,

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Recipient:	Vuyelwa T S Chitimbire <chitimbire@zach.org.zw>
Sent Date:	2018/01/14 12:58:44
Delivered Date:	2018/01/14 12:58:45

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Glass, Roger (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03506bbbb1a2472790395288d4970bc0-glassr <glassr@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Subject:	FW: Taylor & Francis author update: congratulations, your article is in an issue of Global Health Action
Date:	2018/01/12 15:22:00
Priority:	Normal
Type:	Note

A new article from CDC days.

I initiated a cost-reimbursement incentive for public clinics to conduct male circumcision in Zimbabwe. It worked.

PK

From: info@tandfonline.com [mailto:info@tandfonline.com]
Sent: Thursday, January 11, 2018 7:23 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: Taylor &Francis author update: congratulations, your article is in an issue of Global Health Action

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Dear author,

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	Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Sent Date:	2018/01/12 15:22:03
Delivered Date:	2018/01/12 15:22:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>
Subject:	Fwd: Male cir pubs this week: Lichen sclerosus (BXO) in boys; PrePex device; Long foreskin
Date:	2017/12/26 19:11:04
Priority:	Normal
Type:	Note

Hi Amy,
Congratulations on this publication! I remember talking to the Hubert fellow about this a few years ago.

Happy holidays,
PK

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

Begin forwarded message:

From: Brian Morris <brian.morris@sydney.edu.au>
Date: December 26, 2017 at 6:10:26 PM EST
To: Brian Morris <brian.morris@sydney.edu.au>
Subject: Male cir pubs this week: Lichen sclerosus (BXO) in boys; PrePex device; Long foreskin

https://www.ncbi.nlm.nih.gov/pubmed/29266891
Cir Pediatr. 2017 Oct 25;30(4):211-215.
[Clinical and immunohistochemical correlation of balanitis xerotica obliterans].
[Article in Spanish; Abstract available in Spanish from the publisher]
Betancourth-Alvarenga JE[1], Vázquez Rueda F[2], Siu Uribe A[1], Escassi Gil A[1], Vargas Cruz V[1], Sánchez Sánchez R[3], Ortega Salas R[3], Paredes Esteban RM[1].
Author information
1 Cirugía Pediátrica. Hospital Universitario Reina Sofía. Córdoba.
2 Cirugía Pediátrica. Hospital Universitario Reina Sofía. Córdoba. Profesor Asociado de la Facultad de Medicina de la Universidad de Córdoba e Investigador del Instituto Maimónides de Investigación Biomédica de Córdoba.
3 Patología. Hospital Universitario Reina Sofía. Córdoba.
Abstract
in English, Spanish
AIM:
Balanitis xerotica obliterans (BXO) [lichen sclerosis] is a disease of the skin and mucosa of male genitals of unknown etiology that may affect children of any age. It has a low incidence (9-19%) and in adults is considered a potential premalignant lesion. The aim of our study is to establish the incidence of BXO in our center and to determine its correlation between the clinical and immunohistochemical (IHC) findings.
METHODS:

Prospective cohort including all children < 14 years with foreskin pathology that required a circumcision between 2014-2016. Statistical analysis of the clinical characteristics, histological and IHC findings searching for inflammatory response, premalignant lesions and microbiological findings.

RESULTS:

A total of 176 boys with phimosis had circumcision with a mean age of 7 ± 3 years (Range 2-14). Presurgical diagnosis of BXO was suspected in 28.4% (n= 50) whereas the AP confirmed a total of 29.5% (n= 53) with a very good interobserver concordance (kappa= 0.81: p< 0.01). Previous treatment with corticoids in BXO was found in 63.5% (n= 33/52). Meatal stenosis was found in 7.69% (n= 4/52) requiring meatal/urethral dilations. Patients with BXO had a T-Lymphocytes CD3+ mediated inflammatory response with a positive correlation between tumor suppressing protein (p53) expression and chronic inflammation.

CONCLUSIONS:

BXO is a chronic inflammatory disease mediated by T-lymphocytes with an incidence greater than previously reported. Surgeons' criterion has a very good concordance with the AP findings. The elevation of p53 in children with BXO may indicate a plausible malignant potential that may require a surgical treatment (circumcision) and an adequate follow-up.

KEYWORDS:

Balanitis xerotica obliterans; Children; Circumcision; T-Lymphocytes; Tumor suppressing protein p53

PMID: 29266891

https://www.ncbi.nlm.nih.gov/pubmed/29272320

PLoS One. 2017 Dec 22;12(12):e0190055. doi: 10.1371/journal.pone.0190055. eCollection 2017.

A systems-based assessment of the PrePex device adverse events active surveillance system in Zimbabwe.

Adamson PC[1,2], Tafuma TA[3], Davis SM[4], Xaba S[5], Herman-Roloff A[3].

Author information

1 School of Medicine, University of California San Francisco, San Francisco, California, United States of America.

2 CDC-Hubert Global Health Fellowship, Division of Scientific Education and Professional Development, Centers for Disease Control and Prevention, Atlanta, Georgia, United States of America.

3 U.S. Centers for Disease Control and Prevention, Harare, Zimbabwe.

4 U.S. Centers for Disease Control and Prevention, Atlanta, Georgia, United States of America.

5 AIDS and TB Programme, Ministry of Health and Child Care, Harare, Zimbabwe.

Abstract

BACKGROUND:

Voluntary Medical Male Circumcision (VMMC) is an effective method for HIV prevention and the World Health Organization (WHO) has recommended its expansion in 14 African countries with a high prevalence of HIV and low prevalence of male circumcision. The WHO has recently pre-qualified the PrePex device, a non-surgical male circumcision device, which reduces procedure time, can increase acceptability of VMMC, and can expand the set of potential provider cadres. The PrePex device was introduced in Zimbabwe as a way to scale-up VMMC services in the country. With the rapid scale-up of the PrePex device, as well as other similar devices, a strong surveillance system to detect adverse events (AE) is needed to monitor the safety profile of these devices. We performed a systems-based evaluation of the PrePex device AE active surveillance system in Zimbabwe.

METHODS:

The evaluation was based on the Centers for Disease Control and Prevention's Updated Guidelines for Evaluating Public Health Surveillance Systems. We adapted these guidelines to fit our local context. The evaluation incorporated the review of the standard operating procedures and surveillance system documents. Additionally, structured, in-person interviews were performed with

key stakeholders who were users of the surveillance system at various levels. These key stakeholders were from the Ministry of Health, implementing partners, and health facilities in Harare.

RESULTS:

Clients were requested to return to the facility for follow-up on days 7, 14 and 49 after placement of the device. In the event of a severe AE, a standard report was generated by the health facility and relayed to the Ministry of Health Child and Care and donor agencies through predefined channels within 24 hours of diagnosis. Clinic staff reported difficulties with the amount of documentation required to follow up with clients and to report AEs. The surveillance system's acceptability among users interviewed was high, and users were motivated to identify all possible AEs related to this device. The surveillance system was purely paper-based and both duplicate and discrepant reporting forms between sites were identified.

CONCLUSION:

The PrePex AE active surveillance system was well accepted among participants in the health system. However, the amount of documentation which was required to follow-up with patients was a major barrier within the system, and might lead to decreased timeliness and quality of reporting. A passive surveillance system supported by electronic reporting would improve acceptance of the program.

PMID: 29272320
DOI: 10.1371/journal.pone.0190055

http://www.infosurhoy.com/cocoon/saii/xhtml/en_GB/topstories/the-worlds-largest-penis-is-not-what-it-seems/

The World's Largest Penis Is Not What It Seems

BY DENIS BEDOYA ON DECEMBER 23, 2017

.... Roberto Esquivel Cabrera, the man with possibly the world's biggest penis. The 54-year-old from Saltillo in Mexico rose to fame in 2015 after a video of his 48-centimeter (18.9-inch) penis went viral. [But] his [Cabrera's] penis isn't 19 inches.

Doctors have acknowledged this and said he could have a normal sex life if he is essentially circumcised. The man stretched his foreskin constantly, from what I understand, but it's normal underneath. The penis itself is just about 16 to 18 centimeters [6.2 to 7 inches] from the pubis. The rest of the tissue ... is just foreskin, blood vessels, and some inflammation of the skin. So, effectively, the majority of the length comes from his foreskin. It also appears that Cabrera's penis isn't naturally in this state. Although he strongly denies this, Cabrera told a psychiatrist that he had put bands with weights on his penis [foreskin] when he was younger in order to make it longer.

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AND
http://www.circumcisionaustralia.info
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Bondi Junction, NSW 2022
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Brian J. Morris, DSc PhD FAHA
Professor Emeritus
School of Medical Sciences and Bosch Institute
Anderson Stuart Building (F13)
Sydney Medical School
The University of Sydney
Sydney, NSW 2006, Australia

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>
Sent Date:	2017/12/26 19:11:04

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Glass, Roger (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03506bbbb1a2472790395288d4970bc0-glassr <glassr@mail.nih.gov>
Subject:	RE: Male circ pubs this week: PrePex device; Lichen sclerosis (BXO) is much higher in obese boys
Date:	2017/12/13 17:02:00
Priority:	Normal
Type:	Note

Thanks Roger. Trying to. A half dozen more coming from CDC.

Since Monday, I'm taking the lead on writing up a short commentary from our Grand Challenges track.

I've also discussed with Nicki and Adrienne writing up our background quantitative work on research metrics.

PK

From: Glass, Roger (NIH/FIC) [E]
Sent: Wednesday, December 13, 2017 4:56 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Male circ pubs this week: PrePex device; Lichen sclerosis (BXO) is much higher in obese boys

Peter,

Very nice! You have a great track record of publications. Keep it up!

Roger

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Wednesday, December 13, 2017 12:42 PM
To: Glass, Roger (NIH/FIC) [E] <glassr@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Subject: FW: Male circ pubs this week: PrePex device; Lichen sclerosis (BXO) is much higher in obese boys

FYI – a new publication from CDC days. We found that use of the PrePex device for male circumcision was safe and effective for HIV positive men. This obviates the need for HIV testing prior to male circumcision, which is the leading barrier to the procedure. Nice to be the lead article in this weekly digest!

PK

From: Brian Morris [mailto:brian.morris@sydney.edu.au]
Sent: Tuesday, December 12, 2017 6:30 PM
To: Brian Morris <brian.morris@sydney.edu.au>
Subject: Male circ pubs this week: PrePex device; Lichen sclerosis (BXO) is much higher in obese boys

https://www.ncbi.nlm.nih.gov/pubmed/29220392

PLoS One. 2017 Dec 8;12(12):e0189146. doi: 10.1371/journal.pone.0189146. eCollection 2017.
Safety and efficacy of the PrePex device in HIV-positive men: A single-arm study in Zimbabwe.
Tshimanga M[1], Makunike-Chikwinya B[2], Mangwiro T[3], Tapiwa Gundidza P[1], Chatikobo P[1], Murenje V[2], Herman-Roloff A[4], Kilmarx PH[4], Holec M[5], Gwinji G[6], Mugurungi O[6], Murwira M[7], Xaba S[6], Barnhart S[5,8,9], Feldacker C[5,9].
Author information
1 Zimbabwe Community Health Intervention Project (ZiCHIRe), Harare, Zimbabwe.
2 International Training and Education Center for Health (I-TECH), Harare, Zimbabwe.
3 Department of Health Sciences, University of Zimbabwe, Harare, Zimbabwe.
4 U.S. Centers for Disease Control and Prevention, Harare, Zimbabwe.
5 International Training and Education Center for Health (I-TECH), Seattle, Washington, United States of America.
6 Ministry of Health and Child Care, Harare, Zimbabwe.
7 Zimbabwe National Family Planning Council (ZNFPC), Harare, Zimbabwe.
8 Department of Medicine, University of Washington, Seattle, Washington, United States of America.
9 Department of Global Health, University of Washington, Seattle, Washington, United States of America.
Abstract
METHODS:
We aimed to determine if the adverse event (AE) rate was non-inferior to an AE rate of 2%, a rate considered the global standard of MC safety. Study procedures, AE definitions, and study staff were unchanged from previous PrePex Zimbabwe trials. After PrePex placement and removal, weekly visits assessed wound healing. Men returned on Day 90. Safety was defined as occurrence of moderate and serious clinical AEs. Efficacy was defined as ability to reach the endpoint of complete circumcision.
RESULTS:
Among 400 healthy, HIV-positive, consenting adults, median age was 40 years (IQR: 34, 46); 79.5% in WHO stage 2; median CD4 was 336.5c/μl (IQR: 232, 459); 337 (85%) on anti-retroviral therapy. Among 385 (96%) observed completely healed, median days to complete healing was 42 (IQR: 35-49). There was no association between time to healing and CD4 (p = 0.66). Four study-related severe AEs and no moderate AEs were reported: severe/moderate AE rate of 1.0% (95% CI: 0.27% to 2.5). This was non-inferior to 2% AEs (p = 0.0003). All AEs were device displacements resulting in surgical MC and, subsequently, complete healing.
CONCLUSION:
Male circumcision among healthy, HIV-positive men using PrePex is safe and effective. Reducing the barrier of HIV testing while improving counseling for safer sex practices among all MC clients could increase MC uptake and avert more HIV infections.
PMID: 29220392
DOI: 10.1371/journal.pone.0189146
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https://www.ncbi.nlm.nih.gov/pubmed/29204461
Glob Pediatr Health. 2017 Nov 24;4:2333794X17742749. doi: 10.1177/2333794X17742749. eCollection 2017.

The Association Between BXO and Obesity in Boys Undergoing Circumcision.

Fuchs ME[1], Beecroft N[2], Dajusta DG[1], McLeod DJ[1,3].
Author information

Abstract
This study investigated whether boys with balanitis xerotica obliterans (BXO) have increased rates of obesity compared with boys with no concern for BXO (NCB). Boys ≤18 years old with circumcision pathology-confirmed BXO were compared with an age-matched group who had NCB during circumcision. Boys with BXO were found to have a mean body mass index of 70.64 percentile for age compared with 52.43 percentile in age-matched controls (P = .0005). The rate of obesity was significantly higher in boys with BXO (42%) compared with 12.4% in boys with NCB (odds ratio = 5.12; 95% CI = 2.6 to 10.06). Given the increasing rates of childhood obesity and the long-term health consequences of both BXO and obesity, special attention should be paid to this population. Further research is needed to determine if BXO in obese children may represent an early indicator of a systemic disease process where intervention may be warranted.

KEYWORDS:
BXO; balanitis xerotica obliterans; circumcision; lichen sclerosus; obesity
PMID: 29204461
PMCID: PMC5703089
DOI: 10.1177/2333794X17742749
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To:	Caryl Feldacker <cfeld@uw.edu>; Mufuta Tshimanga [redacted]; [redacted]; Scott Barnhart <sbht@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Vernon Murenje <vmurenje@itech-zimbabwe.org>; Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Marrianne M. Holec <mmholec@uw.edu>; Owen Mugurungi [redacted]
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Date:	2017/12/13 12:49:00
Priority:	Normal
Type:	Note

Hi and congratulations to all on our publication! Nice to see that it is the lead abstract in this weekly digest. I've attached the .pdf.

Please share with your network, communications staff, Twitter, etc. This is an important advance in VMMC. Getting the word out will make a difference in implementation as well as the rate of article citation.

Best wishes to all,
PK

Peter H. Kilmarx, MD, FACP, FIDSA
Rear Admiral, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell [redacted] Tel: +1-301-496-1415
Email peter.kilmarx@nih.gov

FIC FB icon Twitter icon

From: Brian Morris [mailto:brian.morris@sydney.edu.au]
Sent: Tuesday, December 12, 2017 6:30 PM
To: Brian Morris <brian.morris@sydney.edu.au>
Subject: Male circ pubs this week: PrePex device; Lichen sclerosis (BXO) is much higher in obese boys

https://www.ncbi.nlm.nih.gov/pubmed/29220392

PLoS One. 2017 Dec 8;12(12):e0189146. doi: 10.1371/journal.pone.0189146. eCollection 2017.
Safety and efficacy of the PrePex device in HIV-positive men: A single-arm study in Zimbabwe.

Tshimanga M[1], Makunike-Chikwinya B[2], Mangwiro T[3], Tapiwa Gundidza P[1], Chatikobo P[1], Murenje V[2], Herman-Roloff A[4], Kilmarx PH[4], Holec M[5], Gwinji G[6], Mugurungi O[6], Murwira M[7], Xaba S[6], Barnhart S[5,8,9], Feldacker C[5,9].

Author information

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3 Department of Health Sciences, University of Zimbabwe, Harare, Zimbabwe.
4 U.S. Centers for Disease Control and Prevention, Harare, Zimbabwe.
5 International Training and Education Center for Health (I-TECH), Seattle, Washington, United States of America.
6 Ministry of Health and Child Care, Harare, Zimbabwe.
7 Zimbabwe National Family Planning Council (ZNFPC), Harare, Zimbabwe.
8 Department of Medicine, University of Washington, Seattle, Washington, United States of America.
9 Department of Global Health, University of Washington, Seattle, Washington, United States of America.

Abstract

METHODS:

We aimed to determine if the adverse event (AE) rate was non-inferior to an AE rate of 2%, a rate considered the global standard of MC safety. Study procedures, AE definitions, and study staff were unchanged from previous PrePex Zimbabwe trials. After PrePex placement and removal, weekly visits assessed wound healing. Men returned on Day 90. Safety was defined as occurrence of moderate and serious clinical AEs. Efficacy was defined as ability to reach the endpoint of complete circumcision.

RESULTS:

Among 400 healthy, HIV-positive, consenting adults, median age was 40 years (IQR: 34, 46); 79.5% in WHO stage 2; median CD4 was 336.5c/μl (IQR: 232, 459); 337 (85%) on anti-retroviral therapy. Among 385 (96%) observed completely healed, median days to complete healing was 42 (IQR: 35-49). There was no association between time to healing and CD4 (p = 0.66). Four study-related severe AEs and no moderate AEs were reported: severe/moderate AE rate of 1.0% (95% CI: 0.27% to 2.5). This was non-inferior to 2% AEs (p = 0.0003). All AEs were device displacements resulting in surgical MC and, subsequently, complete healing.

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Fuchs ME[1], Beecroft N[2], Dajusta DG[1], McLeod DJ[1,3].

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pathology-confirmed BXO were compared with an age-matched group who had NCB during circumcision. Boys with BXO were found to have a mean body mass index of 70.64 percentile for age compared with 52.43 percentile in age-matched controls (P = .0005). The rate of obesity was significantly higher in boys with BXO (42%) compared with 12.4% in boys with NCB (odds ratio = 5.12; 95% CI = 2.6 to 10.06). Given the increasing rates of childhood obesity and the long-term health consequences of both BXO and obesity, special attention should be paid to this population. Further research is needed to determine if BXO in obese children may represent an early indicator of a systemic disease process where intervention may be warranted.
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PMID: 29204461
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DOI: 10.1177/2333794X17742749
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PLOS ONE

RESEARCH ARTICLE

Safety and efficacy of the PrePex device in HIV-positive men: A single-arm study in Zimbabwe

Mufuta Tshimanga[1], Batsirai Makunike-Chikwinya[2], Tonderayi Mangwiro[3], Patricia Tapiwa Gundidza[1], Pesanai Chatikobo[1], Vernon Murenje[2], Amy Herman-Roloff[4], Peter H. Kilmarx[4], Marrianne Holec[5], Gerald Gwinji[6], Owen Mugurungi[6], Munyaradzi Murwira[7], Sinokuthemba Xaba[6], Scott Barnhart[5,8,9], Caryl Feldacker[5,9]*

1 Zimbabwe Community Health Intervention Project (ZiCHIRe), Harare, Zimbabwe, **2** International Training and Education Center for Health (I-TECH), Harare, Zimbabwe, **3** Department of Health Sciences, University of Zimbabwe, Harare, Zimbabwe, **4** U.S. Centers for Disease Control and Prevention, Harare, Zimbabwe, **5** International Training and Education Center for Health (I-TECH), Seattle, Washington, United States of America, **6** Ministry of Health and Child Care, Harare, Zimbabwe, **7** Zimbabwe National Family Planning Council (ZNFPC), Harare, Zimbabwe, **8** Department of Medicine, University of Washington, Seattle, Washington, United States of America, **9** Department of Global Health, University of Washington, Seattle, Washington, United States of America

* cfeld@uw.edu

Citation: Tshimanga M, Makunike-Chikwinya B, Mangwiro T, Tapiwa Gundidza P, Chatikobo P, Murenje V, et al. (2017) Safety and efficacy of the PrePex device in HIV-positive men: A single-arm study in Zimbabwe. PLoS ONE 12(12): e0189146. https://doi.org/10.1371/journal.pone.0189146

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Data Availability Statement: Due to ethical restrictions imposed by the University of Washington (UW), the data underlying this study are available to qualified researchers upon request. Queries related to data access may be submitted to the corresponding author or to Jane Edelson jedelson@uw.edu, Regulatory Specialist at the UW.

Funding: This work has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of

Abstract

Male circumcision (MC) for sexually active, HIV-negative men reduces HIV transmission and averts HIV infections. Excluding HIV-positive men from MC decreases access to additional health and hygiene benefits. In settings where HIV-testing is, or is perceived to be, required for MC, testing may reduce MC uptake. Reducing promotion of HIV testing within MC settings and promoting device-based MC may speed MC scale-up. To assess safety and efficacy of PrePex MC device among HIV-positive men, we conducted a one-arm, open-label, prospective study in otherwise healthy HIV-positive men in Zimbabwe.

Methods

We aimed to determine if the adverse event (AE) rate was non-inferior to an AE rate of 2%, a rate considered the global standard of MC safety. Study procedures, AE definitions, and study staff were unchanged from previous PrePex Zimbabwe trials. After PrePex placement and removal, weekly visits assessed wound healing. Men returned on Day 90. Safety was defined as occurrence of moderate and serious clinical AEs. Efficacy was defined as ability to reach the endpoint of complete circumcision.

Results

Among 400 healthy, HIV-positive, consenting adults, median age was 40 years (IQR: 34, 46); 79.5% in WHO stage 2; median CD4 was 336.5c/μl (IQR: 232, 459); 337 (85%) on anti-retroviral therapy. Among 385 (96%) observed completely healed, median days to complete healing was 42 (IQR: 35–49). There was no association between time to healing and CD4 (p = 0.66). Four study-related severe AEs and no moderate AEs were reported: severe/moderate AE rate of 1.0% (95% CI: 0.27% to 2.5). This was non-inferior to 2% AEs

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Subject:	Re: Male circ pubs this week: Benefits to women; Treatment of penile cancer; VMMC; MSM
Date:	2017/10/14 01:13:56
Priority:	Normal
Type:	Note

See you soon, inshallah.

On Oct 13, 2017, at 11:40 PM, Cate Hankins <c.hankins@aighd.org>wrote:

Thanks! See you tomorrow if all works well. iMessage is fine to use and email at Schipol.

C Hankins MD PhD FRCPC CM
+1 450 775 0032; +31 20 566 1233; +44 745 204 3167

On Oct 11, 2017, at 01:30, Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>wrote:

Hi Cate,
Great article! Hope to see you in a few days.

PK

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

Begin forwarded message:

From: Brian Morris <brian.morris@sydney.edu.au>
Date: October 11, 2017 at 1:41:29 AM GMT+2
To: <brian.morris@sydney.edu.au>
Subject: Male circ pubs this week: Benefits to women; Treatment of penile cancer; VMMC; MSM

http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(17)30386-8/fulltext
THE LANCET Global Health Volume 5, No. 11, e1054–e1055, November 2017
Effect of male circumcision on risk of sexually transmitted infections and cervical cancer in women
Brian J Morris<image001.png>, Catherine A Hankins

- • School of Medical Sciences and Bosch Institute, University of Sydney, Sydney, NSW 2006, Australia; Amsterdam Institute for Global Health and Development, Amsterdam, Netherlands; Faculty of Medicine, McGill University, Montreal, Canada;

- • London School of Hygiene and Tropical Medicine, London, UK
- • Email the author Brian J Morris

https://www.ncbi.nlm.nih.gov/pubmed/28972681
BJU Int. 2017 Oct 3. doi: 10.1111/bju.14037. [Epub ahead of print]

Surgical Management of Penile Carcinoma in Situ: Results from an International Collaborative Study and Review of the Literature.

Chipollini J[1], Yan S[2], Ottenhof SR[3], Zhu Y[4], Draeger D[5], Baumgarten AS[6], Tang DH[1], Protzel C[5], Ye DW[4], Hakenberg OW[5], Horenblas S[3], Watkin NA[2], Spiess PE[1].

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4 Department of Urology, Fudan University Shanghai Cancer Center, Shanghai, 200032, P.R. China.
5 Department of Urology, University Hospital Rostock, Rostock, Germany.
6 Department of Urology, University of South Florida Morsani College of Medicine, Tampa, FL, USA.

Abstract

OBJECTIVES:

To evaluate recurrence after penile sparing surgery (PSS) in the management of carcinoma-in-situ (CIS) of the penis in a large multicenter cohort of patients.

PATIENTS AND METHODS:

We identified consecutive patients from 5 major, academic centers treated from June 1986 to November 2014 who underwent PSS for pathologically proven penile CIS. Primary outcome was local recurrence free survival (RFS) and estimated using the Kaplan-Meier method.

RESULTS:

A total of 205 patients were identified. Treatment modalities included circumcision, glansectomy, wide local excision, laser therapy and total glans resurfacing. Over a median follow-up of 40 months (interquartile range [IQR]: 26-65.6), there were 48 local recurrences with 45.8% occurring in the first year and 81.3% occurring by year 5. Majority of recurrences were observed in the laser group (58.3%). Median time to local recurrence was 15.9 months (5.66-26.14). The 1, 2, and 5-yr RFS were 88.4, 85.6, and 75%, respectively; and the median RFS was 106.5 months (80.2-132.2).

CONCLUSIONS:

Among patients with penile CIS selected for surgical management, durable responses at intermediate to long-term follow-up were noted. For those with glandular CIS, glans resurfacing offered the best outcomes. This article is protected by copyright. All rights reserved.

KEYWORDS:

Penile cancer; carcinoma-in-situ; recurrences

PMID: 28972681
DOI: 10.1111/bju.14037

https://www.ncbi.nlm.nih.gov/pubmed/28982175
PLoS One. 2017 Oct 5;12(10):e0185872. doi: 10.1371/journal.pone.0185872. eCollection 2017.

Predictors of voluntary medical male circumcision prevalence among men aged 25-39 years in Nyanza region, Kenya: Results from the baseline survey of the TASCO study.

Odoyo-June E[1], Agot K[2], Grund JM[3], Onchiri F[1], Musingila P[1], Mboya E[2], Emusu D[1], Onyango J[2], Ohaga S[2], Soo L[1], Otieno-Nyunya B[1].
Author information
1 Division of Global HIV &TB (DGHT), U.S. Centers for Disease Control and Prevention (CDC), Nairobi, Kenya.
2 Impact Research and Development Organization, Kisumu, Kenya.
3 Division of Global HIV &TB (DGHT), U.S. Centers for Disease Control and Prevention (CDC), Atlanta, GA, United States of America.
Abstract
INTRODUCTION:
Uptake of voluntary medical male circumcision (VMMC) as an intervention for prevention of HIV acquisition has been low among men aged ≥25 years in Nyanza region, western Kenya. We conducted a baseline survey of the prevalence and predictors of VMMC among men ages 25-39 years as part of the preparations for a cluster randomized controlled trial (cRCT) called the Target, Speed and Coverage (TASCO) Study. The TASCO Study aimed to assess the impact of two demand creation interventions-interpersonal communication (IPC) and dedicated service outlets (DSO), delivered separately and together (IPC + DSO)-on VMMC uptake.
METHODS:
As part of the preparatory work for implementation of the cRCT to evaluate tailored interventions to improve uptake of VMMC, we conducted a survey of men aged 25-39 years from a traditionally non-circumcising Kenyan ethnic community within non-contiguous locations selected as study sites. We determined their circumcision status, estimated the baseline circumcision prevalence and assessed predictors of being circumcised using univariate and multivariate logistic regression.
RESULTS:
A total of 5,639 men were enrolled of which 2,851 (50.6%) reported being circumcised. The odds of being circumcised were greater for men with secondary education (adjusted Odds Ratio (aOR) = 1.65; 95% CI: 1.45-1.86, p<0.001), post-secondary education (aOR = 1.72; 95% CI: 1.44-2.06, p <0.001), and those employed (aOR = 1.32; 95% CI: 1.18-1.47, p <0.001). However, the odds were lower for men with a history of being married (currently married, divorced, separated, or widowed).
CONCLUSION:
Among adult men in the rural Nyanza region of Kenya, men with post-primary education and employed were more likely to be circumcised. VMMC programs should focus on specific sub-groups of men, including those aged 25-39 years who are married, divorced/separated/ widowed, and of low socio-economic status (low education and unemployed).
PMID: 28982175
DOI: 10.1371/journal.pone.0185872
Free full text

https://www.ncbi.nlm.nih.gov/pubmed/28978292
Afr J AIDS Res. 2017 Sep;16(3):251-256. doi: 10.2989/16085906.2017.1369441.
Factors associated with the take-up of voluntary medical male circumcision amongst learners in rural KwaZulu-Natal.
George G[1], Govender K[1,2], Beckett S[1], Montague C[3], Frohlich J[3].
Author information
1 Health Economics and HIV/AIDS Research Division (HEARD), University of KwaZulu-Natal, Durban, South Africa.

2 School of Psychology, University of KwaZulu-Natal, Durban, South Africa.
3Centre for the AIDS Programme of Research in South Africa (CAPRISA), KwaZulu-Natal, Durban, South Africa.

Abstract

Voluntary medical male circumcision (VMMC) is an integral part of South Africa's HIV prevention programme. School-going males, in particular, are considered a cost-effective target population. However, ambitious policy targets have not been achieved due to the plateau in demand for VMMC. This study documents the factors influencing demand for VMMC amongst school-going males. Data were collected from 750 learners (251 circumcised and 499 uncircumcised) from 42 secondary schools in KwaZulu-Natal, South Africa. There was a positive association between the perceived benefit of VMMC and the likelihood of undergoing circumcision (AOR: 1.41, p = 0.01). There was a negative association between self-efficacy to use condoms and likelihood of undergoing VMMC (AOR: 0.75, p <0.01). Learners who perceived VMMC as having a number of health benefits, including reducting of the chances of contracting HIV and sexually transmitted infections (STIs), increasing penile hygiene and the belief that VMMC allows them to use condoms less frequently, were more likely to undergo VMMC. Of concern, learners who were confident in their ability to access condoms and t use a condom with their partner were less likely to undergo VMMC.

KEYWORDS:

HIV prevention; HIV/AIDS; South Africa; adolescent friendly health services; circumcision for HIV prevention; demand for circumcision

PMID: 28978292

DOI: 10.2989/16085906.2017.1369441

https://www.ncbi.nlm.nih.gov/pubmed/26607929

AIDS Behav. 2016 Nov;20(11):2543-2544.

Higher Frequency of Unprotected Insertive Anal Sex Among Young Black MSM Who are Circumcised.

Frisch M[1,2].

Author information

1 Department of Epidemiology Research, Statens Serum Institut, 5 Artillerivej, 2300, Copenhagen S, Denmark. mfr@ssi.dk.

2 Center for Sexology Research, Aalborg University, Aalborg, Denmark. mfr@ssi.dk.

Comment on

- Circumcision Status is Not Associated with Condom Use and Prevalence of Sexually Transmitted Infections Among Young Black MSM. [AIDS Behav. 2016]

PMID: 26607929

DOI: 10.1007/s10461-015-1251-3

[Indexed for MEDLINE]

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Sydney, NSW 2006, Australia

<image001.png>

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Sent Date:	2017/10/14 01:13:55
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To:	Caryl Feldacker <cfeld@uw.edu>; Scott Barnhart <sbht@uw.edu>; [redacted by agreement] Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>
Subject:	RE: REVISION ATTACHED: Fwd: PLOS ONE Decision: Revision required [PONE-D-17-23346] - [EMID:041d2173f70a5e85]
Date:	2017/10/09 13:48:00
Priority:	Normal
Type:	Note

Hi Caryl,
Thanks for your continued work on this. Your responses look good. I added some suggestions to the attached.

One point to response: I would pull out the numbers from references 42-44 on HIV testing as a barrier to VMMC and add them to the text of the paper. As I recall, HIV testing is the greatest or one of the greatest barriers to VMMC. It is worth spelling out explicitly that HIV testing is a major barrier to VMMC, but it is needed for use PrePex unless such use is proven to be safe for HIV+ men, which we have just done. This is not some nuance of counselling messages; this study addresses a major barrier to VMMC.

Good luck with resubmission!

PK

From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Friday, October 06, 2017 1:05 PM
To: Scott Barnhart <sbht@uw.edu>[redacted by agreement] Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Subject: REVISION ATTACHED: Fwd: PLOS ONE Decision: Revision required [PONE-D-17-23346] - [EMID:041d2173f70a5e85]
Importance: High

Dear Prof, Scott, Peter and Amy,

Attached please find my revised HIV+ paper and my response to reviewers. I did significantly revise the conclusions and made meaningful changes throughout. This version is tracked, and we must submit a tracked version with the final clean copy. Please review my response letter and my revisions, paying special attention to the highlights and to the conclusion. I was responding to the reviewer who did not buy our argument against mandatory testing, so I hope that is a stronger conclusion. Use track changes if you edit, please.

Please try to have your comments back to me within 2 weeks. Otherwise, I will assume you are find with my changes and resubmit.

Thank you for your help in getting this published!
Best,
Caryl

From: Scott Barnhart [mailto:sbht@uw.edu]
Sent: Wednesday, September 27, 2017 5:11 AM
To: Caryl Feldacker <cfeld@uw.edu>
Cc: Dr. Batsi Makunike-Chikwinya <bmakunike@itech-zimbabwe.org>; Marrianne M. Holec <mmholec@uw.edu>; [Redacted by agreement] pessy@zichire.org
Subject: Re: Fwd: PLOS ONE Decision: Revision required [PONE-D-17-23346] - [EMID:041d2173f70a5e85]

Great!

Scott Barnhart, MD, MPH
Professor of Medicine and Global Health
University of Washington

On Sep 27, 2017 2:05 PM, Caryl Feldacker <cfeld@uw.edu>wrote:
Good news! I'll start working on the revision as soon as the RFA is finished.

Best,
Caryl

Begin forwarded message:

From: "PLOS ONE" <em@editorialmanager.com>
Date: September 27, 2017 at 2:29:26 AM PDT
To: "Caryl Feldacker" <cfeld@uw.edu>
Subject: PLOS ONE Decision: Revision required [PONE-D-17-23346] - [EMID:041d2173f70a5e85]
Reply-To: PLOS ONE <plosone@plos.org>

PONE-D-17-23346
Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe
PLOS ONE

Dear Dr. Feldacker,

Thank you for submitting your manuscript to PLOS ONE. After careful consideration, we feel that it has merit but does not fully meet PLOS ONE's publication criteria as it currently stands. Therefore, we invite you to submit a revised version of the manuscript that addresses the points raised during the review process.

We would appreciate receiving your revised manuscript by Nov 11 2017 11:59PM. When you

are ready to submit your revision, log on to http://pone.edmgr.com/ and select the 'Submissions Needing Revision' folder to locate your manuscript file.

If you would like to make changes to your financial disclosure, please include your updated statement in your cover letter.

To enhance the reproducibility of your results, we recommend that if applicable you deposit your laboratory protocols in protocols.io, where a protocol can be assigned its own identifier (DOI) such that it can be cited independently in the future. For instructions see: http://journals.plos.org/plosone/s/submission-guidelines#loc-laboratory-protocols

Please include the following items when submitting your revised manuscript:

- • A rebuttal letter that responds to each point raised by the academic editor and reviewer(s). This letter should be uploaded as separate file and labeled 'Response to Reviewers'.
- • A marked-up copy of your manuscript that highlights changes made to the original version. This file should be uploaded as separate file and labeled 'Revised Manuscript with Track Changes'.
- • An unmarked version of your revised paper without tracked changes. This file should be uploaded as separate file and labeled 'Manuscript'.

We look forward to receiving your revised manuscript.

Kind regards,

D William Cameron, MD
Academic Editor
PLOS ONE

Journal Requirements:

When submitting your revision, we need you to address these additional requirements.

1. Please ensure that your manuscript meets PLOS ONE's style requirements, including those for file naming. The PLOS ONE style templates can be found at http://www.journals.plos.org/plosone/s/file?id=wjVg/PLOSOne_formatting_sample_main_body.pdf and http://www.journals.plos.org/plosone/s/file?id=ba62/PLOSOne_formatting_sample_title_authors_affiliations.pdf

2. Please amend your current ethics statement to address the following concerns:
a) Did participants provide their written or verbal informed consent to participate in this study?
b) If consent was verbal, please explain i) why written consent was not obtained, ii) how you documented participant consent, and iii) whether the ethics committees/IRB approved this consent procedure.

3. We note that you have indicated that data from this study are available upon request. PLOS only allows data to be available upon request if there are legal or ethical restrictions on sharing data publicly. For information on unacceptable data access restrictions, please see http://journals.plos.org/plosone/s/data-availability#loc-unacceptable-data-access-restrictions.

In your revised cover letter, please address the following prompts:

a) If there are ethical or legal restrictions on sharing a de-identified data set, please explain them in detail (e.g., data contain potentially identifying or sensitive patient information) and who has imposed them (e.g., an ethics committee). Please also provide contact information for a data access committee, ethics committee, or other institutional body to which data requests may be sent.

b) If there are no restrictions, please upload the minimal anonymized data set necessary to replicate your study findings as either Supporting Information files or to a stable, public repository and provide us with the relevant URLs, DOIs, or accession numbers. Please see http://www.bmj.com/content/340/bmj.c181.long for guidelines on how to de-identify and prepare clinical data for publication. For a list of acceptable repositories, please see http://journals.plos.org/plosone/s/data-availability#loc-recommended-repositories.

We will update your Data Availability statement on your behalf to reflect the information you provide.

4. Please include a separate caption for each figure in your manuscript.

5. We note you have included a table to which you do not refer in the text of your manuscript. Please ensure that you refer to Table 4 in your text; if accepted, production will need this reference to link the reader to the Table.

6. Please include captions for your Supporting Information files at the end of your manuscript, and update any in-text citations to match accordingly. Please see our Supporting Information guidelines for more information: http://journals.plos.org/plosone/s/supporting-information.

Page 281 of 561 to Page 285 of 561

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

Comments from PK
October 9, 2017

PONE-D-17-23346
Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe
PLOS ONE

Dear Dr. Feldacker,

Thank you for submitting your manuscript to PLOS ONE. After careful consideration, we feel that it has merit but does not fully meet PLOS ONE's publication criteria as it currently stands. Therefore, we invite you to submit a revised version of the manuscript that addresses the points raised during the review process.

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If you would like to make changes to your financial disclosure, please include your updated statement in your cover letter.

To enhance the reproducibility of your results, we recommend that if applicable you deposit your laboratory protocols in protocols.io, where a protocol can be assigned its own identifier (DOI) such that it can be cited independently in the future. For instructions see: http://journals.plos.org/plosone/s/submission-guidelines#loc-laboratory-protocols

Please include the following items when submitting your revised manuscript:

- A rebuttal letter that responds to each point raised by the academic editor and reviewer(s). This letter should be uploaded as separate file and labeled 'Response to Reviewers'.
- A marked-up copy of your manuscript that highlights changes made to the original version. This file should be uploaded as separate file and labeled 'Revised Manuscript with Track Changes'.
- An unmarked version of your revised paper without tracked changes. This file should be uploaded as separate file and labeled 'Manuscript'.

We look forward to receiving your revised manuscript.

Kind regards,

D William Cameron, MD
Academic Editor
PLOS ONE

Journal Requirements:

Page 287 of 561 to Page 295 of 561

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Officer, Jackie (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f79d039e79844c0932985349a2921d6-officerjm <jackie.officer@nih.gov>; Collins, Dexter (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466875329d1644fbbc76c0fd04363f6d-collinsd <collinsd@mail.nih.gov>; Bridbord, Ken (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=faa0977cecee4195a15bc1527b51a472-bridbork <bridbork@ficod.fic.nih.gov>; Katz, Flora (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b14300668a5843ca91afa75e1d2368e8-katzf <katzf@mail.nih.gov>; Anand, Nalini (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccacfb05a5d44358a0f9022b7553f072-anandn <anandn@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>; Spiro, David (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfe0d2b827c94f73ad0df4d1ca369322-spirodj <david.spiro@nih.gov>; Eiss, Robert (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=707887ee7ba548e1a0ae55f683ce2017-eissr <eissr@mail.nih.gov>
Subject:	RE: WF 367515 - FYI ONLY - George Denniston writes to Dr. Collins about a project, funded by the Gates Foundation, which operates on men in Africa (circumcision) to prevent the spread of AIDS
Date:	2017/09/12 15:29:00
Priority:	Normal
Type:	Note

Dr. Collins could proudly affirm:

1. • It was large part NIH research that proved medical male circumcision (MMC) substantially reduces the risk of female-to-male HIV transmission.
2. • The U.S. government is the largest funder of MMC (not the Gates Foundation).
3. • The numbers of men accessing MMC in Africa are in the millions (not hundreds of thousands).
4. • (And, incidentally, unsafe injection accounts for a few percent of HIV transmission in Africa, not 30%).

PK

From: Officer, Jackie (NIH/FIC) [E]
Sent: Tuesday, September 12, 2017 2:59 PM
To: Collins, Dexter (NIH/FIC) [E] <collinsd@mail.nih.gov>; Bridbord, Ken (NIH/FIC) [E] <bridbork@ficod.fic.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Katz, Flora (NIH/FIC) [E] <katzf@mail.nih.gov>; Anand, Nalini (NIH/FIC) [E] <anandn@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>; Spiro, David (NIH/FIC) [E] <david.spiro@nih.gov>; Eiss, Robert (NIH/FIC) [E] <eissr@mail.nih.gov>
Subject: WF 367515 - FYI ONLY - George Denniston writes to Dr. Collins about a project, funded by the Gates Foundation, which operates on men in Africa (circumcision) to prevent the spread of AIDS

FYI's to FIC and OAR. Assigned to NIAID for Direct Reply. Thanks

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Officer, Jackie (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f79d039e79844c0932985349a2921d6-officerjm <jackie.officer@nih.gov>; Collins, Dexter (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466875329d1644fbbc76c0fd04363f6d-collinsd <collinsd@mail.nih.gov>; Bridbord, Ken (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=faa0977cecee4195a15bc1527b51a472-bridbork <bridbork@ficod.fic.nih.gov>; Katz, Flora (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b14300668a5843ca91afa75e1d2368e8-katzf <katzf@mail.nih.gov>; Anand, Nalini (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccacfb05a5d44358a0f9022b7553f072-anandn <anandn@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>; Spiro, David (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfe0d2b827c94f73ad0df4d1ca369322-spirodj <david.spiro@nih.gov>; Eiss, Robert (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=707887ee7ba548e1a0ae55f683ce2017-eissr <eissr@mail.nih.gov>
Sent Date:	2017/09/12 15:29:40
Delivered Date:	2017/09/12 15:29:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Zeitvogel, Karin (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88c10b27b17344b8a564d9a5fd55db6e-zeitvogelkd <karin.zeitvogel@nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Subject:	FW: IAS 2017: A week in review
Date:	2017/07/28 15:57:00
Priority:	Normal
Type:	Note

More - was in my junk email folder.

PK

-----Original Message-----
From: IAS 2017 [mailto:conference.news@ias2017.org]
Sent: Thursday, July 27, 2017 6:18 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: IAS 2017: A week in review

It's been an extraordinary week for HIV science. An extraordinary week for the HIV response.
9th IAS Conference on HIV Science
View this email in your browser <http://mailchi.mp/iasociety/ias-2017-daily-digest-monday-24-july-975433?e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=6b12837572&e=bdf6fe42bc>
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/3a141f18-fd4e-477e-922a-8164aa12401d.jpg>
<http://iasociety.us6.list-manage2.com/track/click?u=3746d12bbc6932846a58d505c&id=4925ff27b2&e=bdf6fe42bc>
<http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=1b905cbcba&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=a8b5df6f5c&e=bdf6fe42bc>
<http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=42f48b2a4b&e=bdf6fe42bc>
THANK YOU FOR BEING A PART OF IAS 2017
It's been an extraordinary week for HIV science. An extraordinary week for the HIV response. The 9th International AIDS Society Conference on HIV Science <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=14eac3726f&e=bdf6fe42bc> (IAS 2017) in Paris has come to an end, with nearly 8,000 researchers, advocates, policy makers, funders and community leaders from more than 140 countries.

Thank you to everyone who participated in moving HIV science into policy and practice. To end the week, here's a quick summary of some of what made news inside the Palais des Congrès, and our recap of the top five stories generating global attention from IAS 2017.

1. The future is injectable, as treatment for HIV and its co-infections continues to improve The quest for better, easier-to-take treatments for HIV and related diseases continued its advance this week at IAS 2017. Results from the 96-week LATTE-2 study <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=3296b50816&e=bdf6fe42bc> on a long-acting, injectable HIV treatment regimen raised the prospect that monthly or bimonthly injections of antiretroviral therapy (ART) could soon replace daily pills for people living with HIV, while a report from HPTN 077 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=5acd9014ad&e=bdf6fe42bc> supports the prospect of long-acting injectable pre-exposure prophylaxis (PrEP) as well. A faster and less expensive treatment for HIV-associated cryptococcol meningitis <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=412b8446648&e=bdf6fe42bc> could revolutionize treatment for the infection, which kills more than 100,000 people living with HIV each year. And the TAC ANRS 12311 study <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=3beef066e0&e=bdf6fe42bc> showed that direct-acting antiviral therapies are safe and effective for treating hepatitis C in sub-Saharan Africa, including for people co-infected with HIV.

2. The prevention toolbox goes bigger and broader, too A Phase 1/2a vaccine study called APPROACH <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=8d68c2894a&e=bdf6fe42bc> evaluated seven different "prime boost" HIV vaccine regimens and identified the most promising candidate for an upcoming proof-of-concept efficacy study. A new subgroup analysis of the IPERGAY study <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=380cd58620&e=bdf6fe42bc> supports the on-demand use of PrEP for men who have sex with men (MSM), even if they have sex less frequently. Evidence builds that HIV self-testing can play a vital role in supporting rapid linkage to care for key populations, including female sex workers <http://iasociety.us6.list-

manage.com/track/click?u=3746d12bbc6932846a58d505c&id=961917efe3&e=bdf6fe42bc> . And a large study in serodiscordant MSM couples <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=8906c13388&e=bdf6fe42bc> supports the growing body of evidence that "Undetectable = Untransmittable" (U=U).

3. Meeting targets saves lives
On the eve of IAS 2017, UNAIDS announced <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=cf93469cbb&e=bdf6fe42bc> that a record-setting 53% of adults living with HIV worldwide were accessing therapy in 2016, and AIDS-related deaths have dropped by nearly 50% since 2005. As a growing number of countries reach or approach the 90-90-90 targets, however, numerous studies here highlighted regions, countries and populations that are not receiving the benefits of advances in HIV prevention and treatment. A breakthrough study featured new data from Swaziland <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=8dbba0ffa2&e=bdf6fe42bc> demonstrating the remarkable nationwide impact of expanded HIV prevention and treatment in the nation with the highest HIV incidence in the world. The incidence of HIV in that country has almost halved in the past five years.

4. Exploring the links between HIV cure and cancer Identifying new strategies to achieve the long-term remission or cure of HIV infection, courtesy of collaborations between HIV and cancer research, was the focus of a standing-room-only pre-conference meeting, the IAS HIV Cure & Cancer Forum <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=b1b4de8a9f&e=bdf6fe42bc> . Sponsored by the IAS Towards an HIV Cure initiative <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=652436e99e&e=bdf6fe42bc> , the Forum was the first major scientific gathering to address the links between, and potential synergies in the treatment of HIV and cancer.

5. Science matters… and so does money.
IAS set the tone for the week with the launch of the Paris Statement <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=03e653963b&e=bdf6fe42bc> , which reiterated that "scientific knowledge is the backbone of the HIV response" and called for "an unfaltering commitment to research." "A golden age in HIV science" was the catchphrase heard repeatedly throughout the week. But IAS President Linda-Gail Bekker warned in her speech <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=46599d218d&e=bdf6fe42bc> at the opening ceremony that if the proposed funding cuts by the US administration to HIV programmes and research become a reality, the impact on current and future scientific advances would be "devastating" for the global response to the epidemic. A new Kaiser Family Foundation/UNAIDS report <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=84a67f9ece&e=bdf6fe42bc> showed that donor government funding for HIV fell 7% last year to the lowest level since 2010, while the Resource Tracking Working Group <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=d72dce4880&e=bdf6fe42bc> found the lowest annual investment in HIV prevention R&D in more than a decade. Advocates and policy makers meeting here called for concerted efforts to reverse the cuts and promote the tremendous impact, seen in hundreds of presentations at IAS 2017, of investing in HIV R&D, treatment and prevention.

See below for more resources and materials that came out of IAS 2017. We look forward to seeing you at the 22nd International AIDS Conference <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=e492638536&e=bdf6fe42bc> (AIDS 2018) in Amsterdam, Netherlands.

<http://iasociety.us6.list-manage2.com/track/click?u=3746d12bbc6932846a58d505c&id=f7bf96fdb1&e=bdf6fe42bc>
<http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=33c92bce07&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=3d8fab6a65&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=f20c60e76a&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=c8d40672fa&e=bdf6fe42bc>
IAS 2017 FOLLOW-UP WEBINARS
Clinical Care Options and the IAS present live CME/CE-certified webinars IAS President-Elect Anton Pozniak will explore how data presented at IAS 2017 may affect patient care strategies and will answer your questions today (27 July 2017) at 9:00 PDT/12:00 EDT/18:00 CEST. Click here <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=178f461be0&e=bdf6fe42bc> to register (it's free!) and submit questions, or visit CCO's coverage of IAS 2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=8603135d44&e=bdf6fe42bc> at next week to download the slides and an audio recording.

IAS 2017 IN THE HEADLINES

> What can science learn from a child who has controlled HIV without drugs for more than 8 years?
> — Science <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=ff7ea644e3&e=bdf6fe42bc>

> Monthly shot could be the 'next revolution' in HIV therapy, replacing daily pills

— The Washington Post <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=5faeef145f&e=bdf6fe42bc>

Undetectable viral load "completely effective" at stopping HIV transmission, study finds
— BuzzFeed News <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=74d95c2b5a&e=bdf6fe42bc>

Sida: le Swaziland, pays le plus touché au monde, a divisé par deux les contaminations
— Agence France Presse <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=3f8c71365d&e=bdf6fe42bc>

YESTERDAY AT IAS 2017: WHAT YOU MISSED
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/9bb4131e-8791-4c64-9b09-5104c6932cc4.jpg>
Real-world solutions for fighting HIV among young people IAS President Linda-Gail Bekker began the final official IAS 2017 press conference with a round of applause for the more than 400 journalists who attended and reported on the conference, and the countless additional reporters who followed the news on the IAS 2017 Live Feed. <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=9ce5af1158&e=bdf6fe42bc> That global media attention keeps the world focused on HIV, and the science-driven strategies that can defeat it.

Focusing the final briefing on HIV among young people was appropriate, Bekker noted, because it means we leave Paris with their needs fresh on our minds. Citing the disproportionate global impact of HIV on young people, and especially young women, South African HIV director Yogan Pillay reminded the audience that HIV is "a social disease as much as a biomedical disease," and that keeping young girls in school, reducing unwanted pregnancies, addressing sexual and gender violence and creating economic opportunities for young people are all key to halting the epidemic. Kate Thomson discussed a new Global Fund strategy to scale up gender responsive HIV and sexual and reproductive health programmes for young people, and support young people to engage in decision-making on programmes that will affect their lives. Speaking of how her personal experience informs her work as a peer counsellor, IAS Youth Ambassador Shanine Mushonga of Zimbabwe said, "What rings true is the passion of my peers when I was lost, and didn't know what was happening to my body." And Anna Grimsrud of the IAS spoke on the need to make HIV treatment and other services more accessible for young people and their families through innovative differentiated care strategies tailored to their lives and needs.

<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/c771638b-023f-44fd-aa46-8a1b0065e078.jpg>
Women, girls and HIV
New research on HIV and STI prevention presented at IAS 2017 could impact the lives of women at risk worldwide. Among the presentations creating buzz on Wednesday were:

* A cross-sectional analysis of more than 4,700 women in South Africa evaluating differences in HIV and STI rates between women whose partners were circumcised or uncircumcised. The report provides critical evidence that male circumcision presents health benefits for women as well as men. (TUAC0404 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=478bb7f5aa&e=bdf6fe42bc>)
* An analysis from the MTN-020/ASPIRE study of the dapivirine vaginal ring. This large study, one of the few to evaluate STI risk among users of hormonal implants and intrauterine devices (IUDs), which are commonly used in many African settings, analysed STI acquisition risk among women using different popular contraceptive methods. (WEPDC0102 <http://iasociety.us6.list-manage2.com/track/click?u=3746d12bbc6932846a58d505c&id=d992298513&e=bdf6fe42bc>)
* New data from South Africa supporting community-based counselling and testing for adolescent girls and young women (AGYW). AGYW in South Africa have an HIV incidence rate four times higher than their male counterparts, but also had the highest testing uptake of any age groups of either gender in this study involving more than 660,000 people. (TUAC0201 <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=f5b4eeebaf8&e=bdf6fe42bc>)

Turning to the prevention of HIV transmission in childbirth, attendees heard about:

* A Thai study offering encouraging data about the ability of the integrase inhibitor raltegravir to block HIV perinatal transmission among late-presenting HIV-positive pregnant women (WEAC0202 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=14da66bb5d&e=bdf6fe42bc>); a Brazilian study of late-presenting pregnant women that found that that raltegravir was associated with significantly higher rate of undetectable viral load at delivery and lower incidence of adverse events, as compared with lopinavir/ritonavir (WEAC0201 <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=e5a1257751&e=bdf6fe42bc>); and a large French cohort study that found no significant association between 1st trimester exposure to raltegravir and birth defects. (MOAB0204 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=1f07dab7e5&e=bdf6fe42bc>)

COMMUNITY CORNER
<http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=6127eeadba&e=bdf6fe42bc>
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/32cc6644-1e28-469a-9fe3-16c62244eede.jpg>

<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/879f7f07-67df-4c3d-82fc-5cb6c82fd90e.jpg>

The global HIV/AIDS epidemic: progress and challenges – editorial and this week's cover #IAS2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=8dd09a7543&e=bdf6fe42bc> #UNAIDS <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=20738ca8a5&e=bdf6fe42bc> https://t.co/auYd1dOtdm <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=fcf6e0e95f&e=bdf6fe42bc> pic.twitter.com/MErBFjtT47 <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=d5a4c0d822&e=bdf6fe42bc>

— The Lancet (@TheLancet) July 21, 2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=d0425f05a7&e=bdf6fe42bc>

Study tested 3 placebo #MPTs <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=7e9a9dedd4&e=bdf6fe42bc> in women in SA & Kenya, injectables rated most highly, then rings, then pills. #IAS2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=916a73e29e&e=bdf6fe42bc> https://t.co/zp0JFHPs2A <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=7f50a56b01&e=bdf6fe42bc>

— Chelsea Polis, PhD (@cbpolis) July 26, 2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=0dbdd5cd4c&e=bdf6fe42bc>

MSF launches new algorithms for decision making to treat #AIDS <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=e0639abe22&e=bdf6fe42bc> patients in low resource settings; complement to new @WHO <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=1907f7676e&e=bdf6fe42bc> guidelines #IAS2017 <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=869bff3662&e=bdf6fe42bc> pic.twitter.com/nbHD7k69nS <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=a48d4105d2&e=bdf6fe42bc>

— MSF HIV (@MSF_HIV) July 23, 2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=88a3bb119d&e=bdf6fe42bc>

It's been a momentous week for the #UequalsU <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=35a09add5e&e=bdf6fe42bc> message with so much support coming out at #IAS2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=69e4e10f4a&e=bdf6fe42bc> . Onwards and upwards #HIVTIP <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=d296f1b940&e=bdf6fe42bc> pic.twitter.com/upSIDKoZmA <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=3b88000d56&e=bdf6fe42bc>

— Andrew Kev Goyvaerts (@PMovingOnCICCEO) July 26, 2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=95b3dd0056&e=bdf6fe42bc>

"It's now or never... We have a window of opportunity to end #AIDS <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=088ee7f2a8&e=bdf6fe42bc> ," says @MichelSidibe <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=2f07046dde&e=bdf6fe42bc> at #IAS2017 <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=ce53742f62&e=bdf6fe42bc> . Watch live: https://t.co/xQE88TorYx <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=98b8ce8e7f&e=bdf6fe42bc> pic.twitter.com/GUOXEQnRPS <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=7eb9d1aeeb&e=bdf6fe42bc>

— UNAIDS (@UNAIDS) July 23, 2017 <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=fbc7afac36&e=bdf6fe42bc>

Dr. Jeffrey Joy from the @bccfe <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=bf482baf94&e=bdf6fe42bc> explains phylogenetic clustering of HIV

in Canada at #IAS2017 <http://iasociety.us6.list-manage2.com/track/click?u=3746d12bbc6932846a58d505c&id=75157c1c1d&e=bdf6fe42bc> . @IAS_conference <http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=6a32f670da&e=bdf6fe42bc> pic.twitter.com/DEhdORqgqE <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=31256db20e&e=bdf6fe42bc>

— Ana Cecilia Ulloa (@ACUlloa) July 26, 2017 <http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=92a5c9646e&e=bdf6fe42bc>

<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/542fe78a-b800-467e-86f6-115c2e35750b.jpg>
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/da9e2567-2435-4615-b4c9-dfb24a4cc804.jpg>
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/2a20603f-c0e7-40c8-a42f-6cbfb432468a.jpg>

<http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=16a07e2b68&e=bdf6fe42bc>
For more highlights from the web and social media check out the Crowd360 Digital Hub.

<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=38902a2643&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=cf700a6f5b&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=3e8d82c59d&e=bdf6fe42bc>
<http://iasociety.us6.list-manage1.com/track/click?u=3746d12bbc6932846a58d505c&id=2468392b3d&e=bdf6fe42bc>
<http://iasociety.us6.list-manage.com/track/click?u=3746d12bbc6932846a58d505c&id=6545d10fbb&e=bdf6fe42bc>
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/8c2770a2-bd38-4056-9d97-9cadee258ce4.png>
<https://gallery.mailchimp.com/3746d12bbc6932846a58d505c/images/4f1c7799-8623-4fec-823e-7e0ac2b63adf.png>

Our mailing address is:

International AIDS Society
23 Avenue de France
Geneva 1202
Switzerland

Add us to your address book <http://iasociety.us6.list-manage1.com/vcard?u=3746d12bbc6932846a58d505c&id=58c4aa5b50>

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<http://iasociety.us6.list-manage.com/track/open.php?u=3746d12bbc6932846a58d505c&id=0bafb3a45a&e=bdf6fe42bc>

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Zeitvogel, Karin (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88c10b27b17344b8a564d9a5fd55db6e-zeitvogelkd <karin.zeitvogel@nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Sent Date:	2017/07/28 15:57:07
Delivered Date:	2017/07/28 15:57:00

From:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
To:	Caryl Feldacker <cfeld@uw.edu>
Subject:	Re: Decision on your submission to [redacted]
Date:	2017/05/23 23:07:56
Priority:	Normal
Type:	Note

Hope so!

On May 23, 2017, at 10:31 PM, Caryl Feldacker <cfeld@uw.edu>wrote:

I did send BMC a quick note. I am hoping [redacted] may be positive. Holding out hope!

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Tuesday, May 23, 2017 1:20 PM
To: Caryl Feldacker <cfeld@uw.edu>
Subject: Re: Decision on your submission to [redacted]

Up to you of course. [redacted] can be slow - FYI.

On May 23, 2017, at 10:12 PM, Caryl Feldacker <cfeld@uw.edu>wrote:

I do not know. I feel like they have been less than reasonable with the initial submission and revision process. I am happy to try, however. I am currently revising the paper, yet again, with this latest 6 months of data.

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Tuesday, May 23, 2017 1:06 PM
To: Caryl Feldacker <cfeld@uw.edu>
Cc: Scott Barnhart <sbht@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Marrianne M. Holec <mmholec@uw.edu>
Subject: Re: Decision on your submission to [redacted]

Is it worth reminding them of this? That it is not a simple resubmission?

PK

On May 23, 2017, at 5:58 PM, Caryl Feldacker <cfeld@uw.edu>wrote:

It was submitted as research and now, decreased by 3000 words, as a debate to another [redacted]

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Tuesday, May 23, 2017 8:36 AM
To: Caryl Feldacker <cfeld@uw.edu>
Cc: Scott Barnhart <sbht@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Marrianne M. Holec <mmholec@uw.edu>
Subject: Re: Decision on your submission to [redacted]

Hi Caryl and sorry this is so challenging. I'm confused. Are they incorrect when they said it is a resubmission of the same paper?

Thanks,
PK

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On May 23, 2017, at 5:17 PM, Caryl Feldacker <cfeld@uw.edu>wrote:

Just ridiculous. It was rejected as research by [redacted] so we tried as a debate. Different papers. This is infuriating.

-----Original Message-----
[redacted]
[redacted]
Sent: Tuesday, May 23, 2017 7:24 AM
To: Caryl Feldacker <cfeld@uw.edu>
Subject: Decision on your submission to [redacted]
[redacted]

(b)(4); (b)(6)

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
Recipient:	Caryl Feldacker <cfeld@uw.edu>
Sent Date:	2017/05/23 23:07:55
Delivered Date:	2017/05/23 23:07:56

From:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
To:	Caryl Feldacker <cfeld@uw.edu>
CC:	Scott Barnhart <sbht@uw.edu>; Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Mufuta Tshimanga [redacted] [redacted] [redacted]
Subject:	Re: Prepex among HIV+ men for CDC review
Date:	2017/05/03 20:43:06
Priority:	Normal
Type:	Note

Thanks Caryl and good luck with revision.

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On May 3, 2017, at 5:06 PM, Caryl Feldacker <cfeld@uw.edu>wrote:

Hi All,

I will take a first stab at the comments and send around a revised paper in the coming week or two. Nothing too major, but still time consuming.

Best,
Caryl

From: Masawi, Muchada (CDC/CGH/DGHT) [mailto:hok2@cdc.gov] On Behalf Of ZIM-ADS (CDC)
Sent: Tuesday, May 2, 2017 11:18 PM
To: Caryl Feldacker <cfeld@uw.edu>; ZIM-ADS (CDC) <zimads@cdc.gov>
Cc: Mandisarisa, John (CDC/CGH/DGHT) <HOK3@cdc.gov>; Balachandra, Shirish (CDC/CGH/DGHT) <ymx1@cdc.gov>; Rogers, John H. (CDC/CGH/DGHT) <yet6@cdc.gov>
Subject: RE: Prepex among HIV+ men for CDC review

Hi Caryl,

Please find attached comments on the above. As usual, please revise and resubmit to us a clean and a tracked version of the manuscript.

Thank you.

Best regards,
Muchada

[Description: Description: Description: CDC logo for email aw]<http://www.cdc.gov/globalhealth/countries/zimbabwe/>Muchada Masawi
ADS/COAG Analyst, Zimbabwe
U.S. Centers for Disease Control and Prevention (CDC)
+263 (0) 772-129-118 mmasawi@cdc.gov<mailto:mmasawi@cdc.gov>
www.cdc.gov/globalhealth/countries/zimbabwe<http://www.cdc.gov/globalhealth/countries/zimbabwe>

From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Wednesday, April 26, 2017 6:27 AM
To: ZIM-ADS (CDC) <zimads@cdc.gov<mailto:zimads@cdc.gov>>
Cc: Mandisarisa, John (CDC/CGH/DGHT) <HOK3@cdc.gov<mailto:HOK3@cdc.gov>>; Balachandra, Shirish (CDC/CGH/DGHT) <ymx1@cdc.gov<mailto:ymx1@cdc.gov>>; Rogers, John H. (CDC/CGH/DGHT) <yet6@cdc.gov<mailto:yet6@cdc.gov>>
Subject: RE: Prepex among HIV+ men for CDC review

Thank you, Muchada!

Sorry for the omission of the affiliations. I added in the remaining missing information, and I placed the disclaimer and acknowledgement before the references as journal submission requires. Thank you for added in those pieces.

I think this should be ready for submission!
Best,
Caryl

From: Masawi, Muchada (CDC/CGH/DGHT) [mailto:hok2@cdc.gov] On Behalf Of ZIM-ADS (CDC)
Sent: Tuesday, April 25, 2017 7:18 AM
To: Caryl Feldacker <cfeld@uw.edu<mailto:cfeld@uw.edu>>; ZIM-ADS (CDC) <zimads@cdc.gov<mailto:zimads@cdc.gov>>
Cc: Mandisarisa, John (CDC/CGH/DGHT) <HOK3@cdc.gov<mailto:HOK3@cdc.gov>>; Balachandra, Shirish (CDC/CGH/DGHT) <ymx1@cdc.gov<mailto:ymx1@cdc.gov>>; Rogers, John H. (CDC/CGH/DGHT) <yet6@cdc.gov<mailto:yet6@cdc.gov>>
Subject: RE: Prepex among HIV+ men for CDC review

Hi Caryl,

We have received comments regarding the above paper. Feedback requested that author affiliations, PEPFAR acknowledgements and the CDC disclaimer be included on the paper which I have gone ahead and done but I would like for you to finalize the information and ensure that it is correct. Please also include information on who the corresponding author is. As soon as this is done, we can have the paper re-submitted in eClearance.

Thanks!

Muchada

[Description: Description: Description: CDC logo for email aw]<http://www.cdc.gov/globalhealth/countries/zimbabwe/>Muchada Masawi
ADS/COAG Analyst, Zimbabwe
U.S. Centers for Disease Control and Prevention (CDC)
+263 (0) 772-129-118 mmasawi@cdc.gov<mailto:mmasawi@cdc.gov>
www.cdc.gov/globalhealth/countries/zimbabwe<http://www.cdc.gov/globalhealth/countries/zimbabwe>

From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Tuesday, March 28, 2017 5:32 PM
To: Masawi, Muchada (CDC/CGH/DGHT) <hok2@cdc.gov<mailto:hok2@cdc.gov>>; ZIM-ADS (CDC) <zimads@cdc.gov<mailto:zimads@cdc.gov>>
Cc: Mandisarisa, John (CDC/CGH/DGHT) <HOK3@cdc.gov<mailto:HOK3@cdc.gov>>; Balachandra, Shirish (CDC/CGH/DGHT) <ymx1@cdc.gov<mailto:ymx1@cdc.gov>>
Subject: RE: Prepex among HIV+ men for CDC review

Dear Muchada,

I accidentally omitted Sino's concurrence, now included below. Of course, I, too, concur:
I, Caryl Feldacker, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Please pass on our paper on Prepex among HIV+ men paper. We hope this will quickly pass through CDC review so that it may be published in a timely manner. Thank you very much!
Best,
Caryl Feldacker

From: Caryl Feldacker
Sent: Monday, March 27, 2017 9:03 AM
To: Masawi, Muchada (CDC/CGH/DGHA) (hok2@cdc.gov<mailto:hok2@cdc.gov>) <hok2@cdc.gov<mailto:hok2@cdc.gov>>
Cc: John Mandisarisa <HOK3@cdc.gov<mailto:HOK3@cdc.gov>>; Balachandra, Shirish (CDC/CGH/DGHA) (ymx1@cdc.gov<mailto:ymx1@cdc.gov>) <ymx1@cdc.gov<mailto:ymx1@cdc.gov>>
Subject: Prepex among HIV+ men for CDC review
Importance: High

Dear Muchada,

Please receive our paper on Prepex among HIV+ men paper. We hope this will quickly pass

through CDC review so that it may be published in a timely manner. Thank you very much!
Best,
Caryl Feldacker

Hi Caryl,
This is in great shape. Congratulations.

I, Peter Kilmarx, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On Mar 24, 2017, at 5:36 PM, Caryl Feldacker <cfeld@uw.edu<mailto:cfeld@uw.edu>>

I, Gerald Gwinji, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

On Fri, Mar 24, 2017 at 11:32 PM, Caryl Feldacker
<cfeld@uw.edu<mailto:cfeld@uw.edu>>wrote:

--
Thank you, Sino! I will submit this statement with the paper.

Best,
Caryl

From: Sinokuthemba Xaba [Redacted by agreement]
Sent: Tuesday, March 28, 2017 6:11 AM
To: Caryl Feldacker <cfeld@uw.edu<mailto:cfeld@uw.edu>>
Cc: Vernon Murenje <vmurenje@itech-zimbabwe.org<mailto:vmurenje@itech-zimbabwe.org>>
Subject: Re: Reminder: Concurrence needed for HIV+ study paper 1 for CDC submission

Dear Caryl

Thank you for the email, I concur to be a co-author of this study paper:
I, Sinokuthemba Xaba, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Kind regards

Sinokuthemba Xaba
National Male Circumcision Co-ordinator
Ministry of Health and Child Care (MoHCC)
HARARE
Cell No.: Redacted by agreement
e-mail: Redacted by agreement

Brigadier General (Dr) G Gwinji
(MB ChB, MSc, MPH, MCPCPZ)

"Whatever work you do, do your best"
Ecclesiastes 9:10

I, Owen Mugurungi agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

On Fri, 24 Mar, 2017 at 11:33 PM Caryl Feldacker <cfeld@uw.edu<mailto:cfeld@uw.edu>>wrote:

Dear Caryl

I, Mufuta Tshimannga, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Thanks you

Mufuta

Prof. Mufuta Tshimanga, MD

Director/Coordinator, ZimFETP

Department of Community Medicine

University of Zimbabwe
Cell: Redacted by agreement
Office: 002634733675

Hi Caryl -

Thanks for all of your work!

I, Amy Herman-Roloff, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Thanks!
Amy

From: Dr Batsirai Makunike-Chikwinya [mailto:bmakunike@itech-zimbabwe.org]
Sent: Tuesday, March 21, 2017 12:06 AM
To: Caryl Feldacker <cfeld@uw.edu<mailto:cfeld@uw.edu>>
Subject: RE: Concurrence language needed for HIV+ study paper 1 for CDC submission

I, Batsirai Makunike-Chikwinya, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Regards
Batsi

Dear Caryl

I, Munyaradzi Murwira, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Regards
Dr. M. Murwira (MBChB, MPH, MBA)
Executive Director
Zimbabwe National Family Planning Council (ZNFPC)
Box ST 220 Southerton
Harare - Zimbabwe
Tel :- +263-4-621909
Cell:- [Redacted by agreement]
e-mail:- ed@znfpc.org.zw<mailto:ed@znfpc.org.zw>
Website:- www.znfpc.org.zw<http://www.znfpc.org.zw/>
Family Planning: Its Your Choice

Hi Caryl,

I, Pesanai Chatikobo agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Thank you!

Pesanai Chatikobo

From: Patricia Tapiwa Gundidza
Redacted by agreement
Sent: Monday, March 20, 2017 12:03 PM
To: Caryl Feldacker <cfeld@uw.edu<mailto:cfeld@uw.edu>>
Subject: Re: Concurrence language needed for HIV+ study paper 1 for CDC submission

Caryl
As requested

I, Patricia T. Gundidza, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Kind regards
Patricia

I , Tonderayi I Mangwiro, agree to be co author on the paper titled " Safety and Efficacy of the Prepex Device in HIV infected men: a single - arm study in Zimbabwe", for CDC review in anticipation of submission to PLOS ONE for publication.
Sent from Yahoo Mail on Android<https://overview.mail.yahoo.com/mobile/?.src=Android>

On Mon, 20 Mar 2017 at 20:34, Caryl Feldacker

Hi

I, Vernon Murenje, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Best regards,

Vernon Murenje | VMMC Program Manager

International Training &Education Centre for Health (I-TECH)

4 Bath Road | Belgravia | Harare | Zimbabwe

Work: +263-4-700585/15<tel:%2B263-4-704890>| Cell: Redacted by agreement

429<tel:%2B263%2071%202%20632%20923>

Email: vmurenje@itech-zimbabwe.org<mailto:smabaya@itech-zimbabwe.org> | Skype: murenje.vernon<http://www.go2itech.org/>

I, Marrianne Holec, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Thank you,
Marrianne

I, Scott Barnhart, agree to be a co-author on the paper titled "Safety and Efficacy of the PrePex Device in HIV-infected men: a single-arm study in Zimbabwe ", for CDC review in anticipation of submission to PLOS ONE.

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: +[(b)(6), Redacted by agreement]
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

Caryl Feldacker, PhD, MPH
Clinical Assistant Professor
Research &Evaluation Advisor/Zimbabwe

International Training &Education Center for Health (I-TECH)
Department of Global Health, University of Washington
HMC #359932, 325 9th Avenue, Seattle, WA. 98104-2499
Phone: +1 (206) 543-3456 Fax: +1 (206) 221-4945
Skype: caryl.feldacker
Website: http://www.go2itech.org<http://www.go2itech.org/>

<image001.png>
<Comments-%20Safety%20and%20Efficacy%20of%20the%20PrePex%20Device%20in%20....pdf>

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
Recipient:	Scott Barnhart <sbht@uw.edu>; Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Mufuta Tshimanga (b)(6); Redacted by agreement Redacted by agreement ; Caryl Feldacker <cfeld@uw.edu>
Sent Date:	2017/05/03 20:43:05
Delivered Date:	2017/05/03 20:43:06


CDC

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Caryl Feldacker <cfeld@uw.edu>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>
CC:	Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>
Subject:	RE: next steps with integration paper
Date:	2017/04/14 14:43:00
Priority:	Normal
Type:	Note

Let's hope the 7th time is the charm!

From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Friday, April 14, 2017 1:18 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>
Subject: RE: next steps with integration paper

HI Peter,

We will try to [b)(4); (b)(6)] as a debate article. No need for your review. If we get a revise and resubmit, that timing might be better for your input.

Thank you very much!
Best,
Caryl

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Friday, April 14, 2017 10:05 AM
To: Scott Barnhart <sbht@uw.edu>; Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>
Subject: RE: next steps with integration paper

Hi,
I agree we don't need to go for review if we are just shortening or changing authors.

I would go with [b)(4); (b)(6)] There have published several papers on implementation of VMMC in Africa.

Things are pretty crazy here with our elimination in the President's Budget. I'm going on leave for the next week and already have a briefcase full. I'd suggest not waiting for me to review. Otherwise it would be at least a couple weeks.

PK

From: Scott Barnhart [mailto:sbht@uw.edu]
Sent: Friday, April 14, 2017 12:58 PM
To: Caryl Feldacker <cfeld@uw.edu>; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>
Subject: Re: next steps with integration paper

Hi Caryl: We do not need to go back to CDC for re-review. Thanks for persisting. Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Caryl Feldacker <cfeld@uw.edu>
Sent: Friday, April 14, 2017 9:27 AM
To: Kilmarx, Peter (NIH/FIC) [E]; Herman-Roloff, Amy (CDC/CGH/DGHT); Scott Barnhart
Cc: Marrianne M. Holec; Batsi Makunike
Subject: next steps with integration paper

Hi Peter and team,

(b)(4); (b)(6)

(b)(4); (b)(6)

Which do you think we would have a better chance with? We have a version with 3500 words, attached, if you all would like to see the greatly pared down version. It could benefit from some comments at this point as I significantly condensed it and updated the information including adding in the pivot as otherwise the data was too old and outdated.

Also, is it time to change the authors on this? Add Vernon? Add Shirish from CDC? Do we need to go back through CDC review?

Thoughts?
Best,
Caryl

-----Original Message-----
From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Thursday, April 13, 2017 2:10 PM
To: Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Caryl Feldacker <cfeld@uw.edu>; Scott Barnhart <sbht@uw.edu>
Cc: Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: Your submission to (b)(4); (b)(6)

(b)(4); (b)(6)

PK

-----Original Message-----
From: Herman-Roloff, Amy (CDC/CGH/DGHT) [mailto:bjy2@cdc.gov]
Sent: Thursday, April 13, 2017 12:10 PM
To: Caryl Feldacker <cfeld@uw.edu>; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Scott Barnhart <sbht@uw.edu>
Cc: Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: Your submission to (b)(4); (b)(6)

Hi Peter -

Would greatly appreciate your insight on this. Caryl and I have brainstormed the journals to submit to to-date....do you have any other ideas?

Thanks -
Amy

-----Original Message-----
From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Thursday, April 13, 2017 6:04 PM

To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: Your submission to [redacted]

Hi Peter,

We submitted to [redacted]

It is now 2500 down from its original 6000.

Best,
Caryl

-----Original Message-----
From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Wednesday, April 5, 2017 2:24 PM
To: Caryl Feldacker <cfeld@uw.edu>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: Your submission to [redacted]

Hi - if you can share the list of where you have sent already, we can think of other possibilities.

PK

-----Original Message-----
From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Tuesday, April 04, 2017 10:56 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: Your submission to [redacted]

This is about the 6th rejection. I think my plan now is to update with 2016 information, include the pivot, and reduce to 2000 words as a commentary.

Other ideas?

Caryl

-----Original Message-----
From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Tuesday, April 4, 2017 3:22 PM
To: Caryl Feldacker <cfeld@uw.edu>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Subject: RE: Your submission to [redacted]

Sorry and a bit surprised to see this. Next step?

Best,
PK

-----Original Message-----

(b)(4); (b)(6)

Sent: Tuesday, April 04, 2017 1:05 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: Your submission to (b)(4); (b)(6)

You are being carbon copied ("cc:'d") on an e-mail "To" "Caryl Feldacker" cfeld@uw.edu
CC: bmakunike@itech-zimbabwe.org, mmholec@uw.edu, bochner@uw.edu, arstep@uw.edu,
Redacted by agreement peter.kilmarx@nih.gov, bjy2@cdc.gov, yih0@cdc.gov,
Redacted by agreement chitimbire@zach.org.zw, sbht@uw.edu

(b)(4); (b)(6)

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Caryl Feldacker <cfeld@uw.edu>; Scott Barnhart <sbht@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Marrianne M. Holec <mmholec@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>
Sent Date:	2017/04/14 14:43:56
Delivered Date:	2017/04/14 14:43:00

From:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
To:	Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Subject:	Re: URGENT FW: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA
Date:	2017/04/05 10:19:18
Priority:	Normal
Type:	Note

Thanks very much Ann. I trust you are crunching this into a message.

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On Apr 5, 2017, at 9:47 AM, Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>wrote:

Here's what Barbara dug up so far…

From: Sina, Barbara (NIH/FIC) [E]
Sent: Monday, April 03, 2017 2:58 PM
To: Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Cc: Potash, Shana (NIH/FIC) [E] <Shana.Potash@nih.gov>
Subject: RE: URGENT FW: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA

He's had a grant from NIAID/DAIDS for Sao Paulo Clinical Trials Unit from 2008-2014- a pretty good outcome for a trainee &NIAID. He could not get any more support from FIC or be a faculty member in an HIV training program after 2012 because we eliminated Brazil as a country eligible for training grants.

From: Puderbaugh, Ann (NIH/FIC) [E]
Sent: Monday, April 03, 2017 2:28 PM
To: Sina, Barbara (NIH/FIC) [E] <sinab@mail.nih.gov>
Subject: RE: URGENT FW: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA

Very helpful—thanks so much!
Ann

From: Sina, Barbara (NIH/FIC) [E]
Sent: Monday, April 03, 2017 2:25 PM
To: Potash, Shana (NIH/FIC) [E] <Shana.Potash@nih.gov>

Cc: Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Subject: RE: URGENT FW: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA

From King Holmes's FY2007 progress report in which Casapia is listed as a new scholar:
"Martin Casapia, MD, is Co-Principal Investigator for the HIV Vaccine Preparedness Study and several other related studies under the HIV Prevention Trials Network in Iquitos, Peru. Dr. Casapia received specialty training in Infectious and Tropical Diseases from the Universidad Peruana Cayetano Heredia and post-graduate training in epidemiology in Mexico and Brazil. He entered the MPH degree program in the Department of Epidemiology in September 2005 with Dr. Connie Celum as his faculty mentor."

From Carey Farquhar" FY 2007 progress report in which Casapia is listed as a continuing MS/MPH student:
"Title: Sexual risk and lack of circumcision associated with HIV and HSV-2 infection in men who have sex with men in Peru
Country: Peru (Casapia)
FWA number of foreign site: FWA 0000 1941
Date of foreign IRB approval: 6/14/06
UW Human Subjects number and approval date: 06-1416-E/A 01, 6/09/06"

"Continuing Scholar Martin Casapia MD training period 9/05-9/07"

"Martin Casapia. MD, is Co-Principal Investigator for the HIV Vaccine Preparedness Study and several other related studies under the HIV Prevention Trials Network in Iquitos, Peru. He entered the MPH degree program in the Department of Epidemiology in September 2005 with Dr. Connie Celum as his faculty mentor. In June 2006 he returned to Peru to conduct his study, "Sexual risk and lack of circumcision associated with HIV and HSV-2 infection in men who have sex with men in Peru," and returned to Seattle in March 2007 to complete his thesis and graduate."

He was not mentioned in the FY2008 renewal application.

Here are the papers I found that he published with Connie Celum, his UW mentor:
Effect of aciclovir on HIV-1 acquisition in herpes simplex virus 2 seropositive women and men who have sex with men: a randomised, double-blind, placebo-controlled trial Prof Connie Celum, MDa, b, c, Prof Anna Wald, MDb, c, d, f, Prof James Hughes, PhDe, Jorge Sanchez, MDg, Stewart Reid, MDh, i, Sinead Delany-Moretlwe, MDj, Frances Cowan, MDk, Martin Casapia, MDg, Lancet Volume 371, Issue 9630, 21–27 June 2008, Pages 2109–2119

Male Circumcision and Risk of HIV Acquisition among Men who have Sex with Men from the United States and Peru
Jorge Sánchez,1,3 Victor G. Sal y Rosas,2 James P. Hughes,2 Jared M. Baeten,3 Jonathan Fuchs,5 Susan P. Buchbinder,5 Beryl A. Koblin,6 Martín Casapia,7 Abner Ortiz,8 and Connie Celum3,4 AIDS. 2011 Feb 20; 25(4): 519–523.

Before the UW AITRP program it appears that he worked with Gotuzzo in Peru (these are co-authored papers I found):

Clustered local transmission and asymptomatic Plasmodium falciparum and Plasmodium vivax malaria infections in a recently emerged, hypoendemic Peruvian Amazon community OraLee Branch, W Martin Casapia, Dionicia V Gamboa, Jean N Hernandez, Freddy F Alava, Norma oncal,
Eugenia Alvarez, Enrique J Perez and Eduardo Gotuzzo Malaria Journal 2005 4:27

RELATIONSHIP BETWEEN INTENSITY OF SOIL-TRANSMITTED HELMINTH INFECTIONS AND ANEMIA DURING PREGNANCY
Authors: RENEE LAROCQUE1, MARTIN CASAPIA1, EDUARDO GOTUZZO1, THERESA W. GYORKOS / The American Journal of Tropical Medicine and Hygiene Volume 73, Issue 4 Oct 2005, p. 783 - 789

A double-blind randomized controlled trial of antenatal mebendazole to reduce low birthweight in a hookworm-endemic area of Peru Renée Larocque, Martin Casapia, Eduardo Gotuzzo, J. Dick MacLean, Julio C. Soto, Elham Rahme, Theresa W. Gyorkos Trop Med &Intrnl Health Volume 11, Issue 10 October 2006 Pages 1485–1495

Lack of Risk of Adverse Birth Outcomes After Deworming in Pregnant Women Gyorkos, Theresa W. PhD*; Larocque, Renee MSc*; Casapia, Martin MD†; Gotuzzo, Eduardo MD‡ Pediatric Infectious Disease Journal: September 2006 - Volume 25 - Issue 9 - pp 791-794

According to his publications, in 2005-6 he was affiliated with Asociacio´n Civil Selva Amazo´nica, Iquitos, Peru. In 2007 he is listed as with the Dirección Regional de Salud Loreto, Ministerio de Salud del Peru, Lima, Peru as well as his previous institution. In 2008 he was affiliated with Asociación Civil Salud y Educación, Impacta, Lima, Peru. Recently he was back with Asociación Civil Selva Amazónica, Iquitos, Peru (according to papers published in 2010-2017) where he continued to work on helminth and HIV infections including clinical trials with a variety of U.S. groups working in Peru (including several who had FIC HIV training grants but I didn't try to find out if he was a faculty in any of these programs- let me kwno if you want this information).

Medicines for Malaria Venture (MMV) published an interview (&photo) with him related to an anti-malaria drug trial: https://www.mmv.org/newsroom/interviews/dsm265

He's listed as faculty for Global Health Fellows Northern Pacific Global Health Research Fellows Training Consortium: http://fogartyfellows.org/program-overview/peru/

He's the PI of a NIAID P50 grant 4P50AI098574
Soil-Transmitted Helminthiases (STH) and Deworming 2012-2016 (copy attached- includes biosketch)
DESCRIPTION (provided by applicant): The essential goal of the proposed Tropical Medicine Center is to improve the health of populations, especially those in neglected tropical disease-endemic regions of the world, by undertaking and promoting interdisciplinary research excellence. Its specific objectives include: i) the promotion and conduct of high quality basic, clinical and epidemiological research in tropical medicine; ii) engagement in collaborative research with local, national and international researchers; and iii) commitment to the training and mentoring of students and junior investigators. The first concrete examples of this mission and objectives are illustrated in the three proposed research projects which focus on three diseases causing the highest burden of disease among the neglected tropical diseases, i.e., the soil-transmitted helminthiases of ascariasis, hookworm disease and trichuriasis. These diseases are highly endemic in the Amazon region of Peru where the proposed Tropical Medicine Center will be situated. Each research project addresses important research gaps in a

high-risk group (i.e., preschool-age children, school-age children and women of reproductive age) such that results will be able to be used immediately by global agencies like the World Health Organization and national authorities (and their partners) to inform health policy and intervention strategy on deworming. Ultimately, this research will contribute to reducing the morbidity, mortality and disability caused by the soil-transmitted helminthiases which currently are estimated to affect two billion people living in resource-poor communities around the world. RELEVANCE: The proposed Tropical Medicine Center will be based in the Amazon region of Peru and will be a center of research excellence in basic, clinical and epidemiological research focusing on neglected tropical diseases. Because of the high burden of disease caused by the soil-transmitted helminthiases, this cluster of diseases will constitute the inaugural research focus of the new Center. Project 1: Improving Childhood Growth and Development in Resource-Poor LMICs with Deworming by Incorporating Deworming in Integrated Child Health Care Project Leader (PL): Casapia, M. DESCRIPTION (provided by applicant): Preschool-age children are one of the three high risk groups for morbidity attributable to soil-transmitted helminth infections (STH). At this age, the STH infections of most importance are Ascaris and Trichuris infections. WHO recommends deworming of preschool-age children as of 12 months of age, but there is no empirical evidence on what deworming exposure (in terms of age at administration and frequency of administration) has the most beneficial impact on health. This research project therefore proposes to follow a cohort of preschool-age children who are known to have had different deworming exposure histories between 12 and 24 months of age. By following these children up to five years of age, cumulative health benefits will be measured and the optimal deworming strategy identified. It is expected that these health benefits will extend into later childhood and beyond. Research results will also be used to inform deworming health policy and strategies in STH-endemic regions globally. RELEVANCE: An important window of opportunity exists between 12 and 24 months of age when health and nutrition interventions play a vital role in both short and long term health. It is important to measure this health impact, not only because it fills a research gap, but also because it is useful feedback for program managers, and other partners. In following children up to five years of age, this cohort study will provide key empirical evidence on the health impact of different deworming strategies targeted to this high risk age.

From: Wolfman, Celia (NIH/FIC) [E]
Sent: Monday, April 03, 2017 10:09 AM
To: Katz, Flora (NIH/FIC) [E] <katzf@mail.nih.gov>; FIC DITR <ditr@ficod.fic.nih.gov>
Cc: Anand, Nalini (NIH/FIC) [E] <anandn@mail.nih.gov>; Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Subject: RE: URGENT FW: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA

I found two of the individuals involved in the Zika Trial in CareerTrac:

- 1. ASCA CRS Iquitos (Iquitos, Peru);
- Principal investigator: **Dr. Martin Casapia Morales**
- *****In CareerTrac his name is MARTIN CASAPIA but the email is the exact same. He was an AITRP trainee of Carey Farquhar (D43TW7) from 2005-2007 who got funded for a Masters at Univ of Washington.
- 2. Centro de Pesquisas Clinicas do Instituto Central da FMUSP/University of São Paulo;

- Principal investigator: **Dr. Esper Kallas**
- *****In CareerTrac, he is shown as an AITRP trainee of Arthur Reingold (D43TW3). However there is no in-training information.
-

From: Katz, Flora (NIH/FIC) [E]
Sent: Saturday, April 01, 2017 9:42 AM
To: FIC DITR <ditr@ficod.fic.nih.gov>; Wolfman, Celia (NIH/FIC) [E] <celia.wolfman@nih.gov>
Cc: Anand, Nalini (NIH/FIC) [E] <anandn@mail.nih.gov>
Subject: Fwd: URGENT FW: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA

We are looking into whether any of those involved with the zika vaccine trials had any association with fogarty. Please let me know if you recognize any of these names. Celia, can you do a check in careertrac? Thanks, flora

---

From: Stover, Kathy (NIH/NIAID) [E]
Sent: Friday, March 31, 2017 2:12 PM
To: Puderbaugh, Ann (NIH/FIC) [E] <puderba@mail.nih.gov>
Subject: RE: query from Fogarty re: PHASE 2 ZIKA VACCINE TRIAL BEGINS IN U.S., CENTRAL AND SOUTH AMERICA

Hi Ann,
Here you go. Hope it helps:

- Puerto Rico Clinical and Tranlational Research Consoritum (PRCTRC) (PI Dr. Clemente Diaz- Clemente.Diaz@upr.edu
- San Juan City Hospital Research Unit (San Juan, Puerto Rico); Principal investigator: Dr. Nicolas Rosario - nrosario@sanjuanciudadpatria.com
- Fundación de Investigación de Diego (San Juan, Puerto Rico); Principal investigator: Dr. Grisell Ortiz-Lasanta - mrt@fdipr.com / info@fdipr.com
- ASCA CRS Iquitos (Iquitos, Peru); Principal investigator: Dr. Martin Casapia Morales - Redacted by agreement
- Centro de Pesquisas Clinicas do Instituto Central da FMUSP/University of São Paulo (São Paulo, Brazil); Principal investigator: Dr. Esper Kallas - esper.kallas@usp.br
- Fundación Inciensa or FUNIN (Santa Cruz, Costa Rica); Principal investigator: Dr. Paula Gonzalez - pgonzalez@proyectoguanacaste.com

- Costa Rican Center of Medical Research (Puntarenas, Costa Rica); Principal investigator: Dr. Gisela Herrera - gherrera@racsa.co.cr

- Hospital Civil de Guadalajara "Fray Antonio Alcalde" (Guadalajara, Mexico); Principal investigator: Dr. Rayo Mortin Otero - Redacted by agreement

- Instituto Conmemorativo Gorgas de Estudios de la Salud (Panama City, Panama); Dr. Nestor Sosa: Redacted by agreement ; Dr. Israel Cedeño (Director of Epidemiology) - cedeno@minsa.gob.pa

.gov/cgi-bin/wa.exe?A0=nihpress>.

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
Recipient:	Puderbaugh, Ann (NIH/FIC) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=903639684fe84ad48c32e9447c951460-puderba <puderba@mail.nih.gov>
Sent Date:	2017/04/05 10:19:17
Delivered Date:	2017/04/05 10:19:18

From:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
To:	Scott Barnhart <sbht@uw.edu>
Subject:	Re: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia
Date:	2017/03/22 10:09:16
Priority:	Normal
Type:	Note

Right. Congress decides.

On Mar 22, 2017, at 10:04 AM, Scott Barnhart <sbht@uw.edu>wrote:

Thanks Peter. It is rough on so many fronts just anticipating the fall out (b)(6) (b)(6) reminded me the President doesn't have the power of the purse. Nonetheless I'm on the board of a small ngo that helps first gen students go to college and we are at risk of losing our 30 AmeriCorps staffers- what a loss. Hopefully it won't happen. Best, Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Wednesday, March 22, 2017 6:53 AM
To: Scott Barnhart
Subject: Re: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

I will do. With our Center slated for elimination in the president's budget, is a busy time. Between us, it's a lot quicker to clear something that is really ready for clearance. After a couple iterations of careful review and substantive input, it's hard to maintain my usual rapid turnaround time.
Best,
PK

On Mar 22, 2017, at 9:45 AM, Scott Barnhart <sbht@uw.edu>wrote:

Thx. We are all pumped. Also, if you can send your concurrence on the HIV+ that would be great. We are trying to clear the table to look at new projects.

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Wednesday, March 22, 2017 6:37 AM
To: Scott Barnhart
Subject: Re: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

Woot woot!

On Mar 22, 2017, at 9:20 AM, Scott Barnhart <sbht@uw.edu>wrote:

Hi Peter: That would be great. I'm not sure whether we'll get to that in this cycle. I just heard we got our highest numbers this week. 2600 this past week. Zach and Zichire are on fire and filling the gap from loss of doing prepex (which had been up to 30% of our numbers). Thx. Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Wednesday, March 22, 2017 5:35 AM
To: Scott Barnhart
Subject: Re: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

Thanks Scott.
I'd be happy to be involved in any overall evaluation of PDF in Zim. No clearance needed at NIH :)
Cheers,
PK

On Mar 22, 2017, at 7:56 AM, Scott Barnhart <sbht@uw.edu>wrote:

Yes, it's interesting. The modeling done by CHAI and others suggests the benefits, prevalence of HIV being equal, is greatest in district with lower penetration (better impact to get from 10%-20% than from 70% to 80%). So pushing in districts which are the same as ART scale up may not make that much sense but the differences are modest and there are some benefits to have a smaller geographic area. We'll see that the future brings. As always, thanks for your early and persistent support. It's been a good project and hard to believe we are almost done with Year 4.

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Wednesday, March 22, 2017 3:06 AM
To: Scott Barnhart
Subject: Re: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

Oh right, I understand. I always thought we'd get more done on the steep part of the sigmoid curve in more districts rather than pushing to the top in fewer districts. Efficiency, equity, those things.
Cheers,
PK

On Mar 21, 2017, at 10:56 PM, Scott Barnhart <sbht@uw.edu>wrote:

Hi Peter: Thanks. We have a great team there and here. With the COP 15 Pivot we went from 21 to 10 districts. So, we have been intensively focused on fewer districts though we'd rather have more districts to broaden our target pool. Best, Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Tuesday, March 21, 2017 5:48 PM
To: Scott Barnhart
Subject: Re: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

Hi Scott,
Thanks for your reply.
What do you mean scaling up in half the districts?
I'll let you know if I have any good ideas after reading.
Congratulations on your successes in Zimbabwe.
All the best,
PK

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On Mar 21, 2017, at 8:40 PM, Scott Barnhart <sbht@uw.edu>wrote:

Hi Peter:

Thanks. We are glad to get into press. As you can see it is a mixed bag. Bottom line is it works. We've scaled up even now in half the districts. As we have done so we are having to rely

more on mobile teams as we outstripped the local clinic's capacity to take up more work. We have no good strategy to mitigate the downsides of PBF. I'd love suggestions. We have wanted to move this forward in Namibia - the only other place where we are an IP. The structure there is much more rigid and so far we have not gotten traction. Nor, have we gotten much in the way of numbers (annual target is 8,000 and we struggle to get there). I hope the "Integration" paper gets accepted. its been under review since August. I think the combination of using local capacity and PBF is a good one but has many challenges in rapid scale up as with VMMC and also COP 15 pivot. Hope you are doing well. Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: [redacted]
Facsimile: +1 206-221-4945
Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Tuesday, March 21, 2017 4:50 PM
To: Scott Barnhart
Subject: Fwd: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

Hi Scott, I'm very interested to see this paper on performance-based financing and look forward to reading. Are there any plans to modify the program in Zimbabwe or implement in other countries?
Cheers,
PK

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

Begin forwarded message:

From: Brian Morris <brian.morris@sydney.edu.au>
Date: March 21, 2017 at 7:26:16 PM EDT
To: Brian Morris <brian.morris@sydney.edu.au>
Subject: Male circ pubs this week: Proof of no adverse psychological effect; VMMC; Circ rates for Australia

https://www.ncbi.nlm.nih.gov/pubmed/28291263

Transl Psychiatry. 2017 Mar 14;7(3):e1063. doi: 10.1038/tp.2017.23.

Circumcision does not alter long-term glucocorticoids accumulation or psychological effects associated with trauma- and stressor-related disorders.

Ullmann E1,2, Licinio J3, Barthel A1,4, Petrowski K5, Oratovski B1, Stalder T6,7, Kirschbaum C6, Bornstein SR1,8.

Author information

1 Department of Medicine, TU Dresden, Carl Gustav Carus, Dresden, Germany.

2 Department for Child and Adolescent Psychiatry, Psychotherapy, and Psychosomatics, University of Leipzig, Leipzig, Germany.

3 Mind and Brain Theme, South Australian Health and Medical Research Institute, Flinders University, Adelaide, SA, Australia.

4 Endokrinologikum RUHR, Bochum, Germany.

5 German Sport University, Cologne, Germany.

6 Department of Psychology, TU Dresden, Dresden, Germany.

7 Clinical Psychology, University of Siegen, Siegen, Germany.

8 Faculty of Life Sciences &Medicine, Endocrinology and Diabetes, Kings College London, London, UK.

Abstract

Male infants and boys through early adolescence can undergo circumcision either for the sake of upholding religious traditions or for medical reasons. According to both, Jewish as well as Islamic tenets, circumcision is a religious rite symbolizing the bond with God. The World Health Organization (WHO), the United Nations Council (UNC) as well as the American Academy of Pediatrics (AAP), and the Centers for Disease Control and Prevention (CDC) strongly recommend circumcision to promote hygiene and prevent disease. This procedure has frequently been criticized by various communities claiming that circumcision in infancy and early adolescence were psychologically traumatizing with medical implications up into old age. Due to the lack of evidence concerning an alleged increase in vulnerability, we measured objective and subjective stress and trauma markers, including glucocorticoids from hair samples, in circumcised and non-circumcised males. We found no differences in long-term limbic-hypothalamic-pituitary-adrenal axis activity, subjective stress perception, anxiety, depressiveness, physical complaints, sense of coherence and resilience. Rather, an increase in the glucocorticoid levels indicated a healthy lifestyle and appropriate functioning. Thus, our findings provide evidence that male circumcision does not promote psychological trauma. Moreover, a qualitative approach, the ambivalence construct, was used for the discussion, aiming at a discourse devoid of biases.

PMID: 28291263 DOI: 10.1038/tp.2017.23

https://www.ncbi.nlm.nih.gov/pubmed/28291049

J Acquir Immune Defic Syndr. 2017 Mar 10. doi: 10.1097/QAI.0000000000001349. [Epub ahead of print]

Social disequilibrium and the risk of HIV acquisition: A multilevel study in rural KwaZulu-Natal Province, South Africa.

Tomita A1, Vandormael AM, Bärnighausen T, de Oliveira T, Tanser F.

Author information

1Nelson R Mandela School of Medicine, University of KwaZulu-Natal 2Africa Health Research Institute, University of KwaZulu-Natal 3Department of Global Health and Population, Harvard T.H. Chan School of Public Health 4Institute for Public Health, University of Heidelberg 5Centre for the AIDS Programme of Research in South Africa (CAPRISA) 6School of Nursing and Public Health, University of KwaZulu-Natal.

Abstract

BACKGROUND:

Few population-based multilevel studies have quantified the risks that social context poses in rural communities with high HIV incidence across South Africa. We investigated the individual, social and community challenges to HIV acquisition risk in areas with high and low incidence of HIV infection (hotspots/coldspots).

METHODS:

The cohort (N=17,376) included all HIV-negative adults enrolled in a population-based HIV surveillance study from 2004-2015 in a rural South African community with a large labor migrancy. Multilevel survival models were fitted to examine the social determinants (i.e. neighborhood migration intensity), community traits (i.e. HIV prevalence), and individual determinants of HIV acquisition risk in identified hotspots/coldspots.

RESULTS:

The HIV acquisition risk (aHR=1.05, 95% CI:1.01-1.09) was greater in hotspots with a higher neighborhood migration intensity amongst men. In women, higher neighborhood migration intensity (aHR=1.02, 95% CI:1.01-1.02) was associated with a greater HIV acquisition risk, irrespective of whether they lived in hotspot/coldspot communities. HIV acquisition risk was greater in communities with a higher prevalence of HIV in both men (aHR=1.07, 95% CI:1.03-1.12) and women (aHR=1.03, 95% CI:1.01-1.05), irrespective of hotspot/coldspot locations.

CONCLUSION:

HIV acquisition risk was strongly influenced by gender (i.e. young women), behavior (i.e. sexual debut, contraception, circumcision) and social determinants. Certain challenges (i.e. community disease prevalence) for HIV acquisition risk impacted both sexes, regardless of residence in hotspot/coldspot communities, while social determinants (i.e. neighborhood migration intensity) were pronounced in hotspots among men. Future intervention scale-up requires addressing the social context that contributes to HIV acquisition risk in rural areas with high migration.

PMID: 28291049 DOI: 10.1097/QAI.0000000000001349

https://www.ncbi.nlm.nih.gov/pubmed/28301588

PLoS One. 2017 Mar 16;12(3):e0174047. doi: 10.1371/journal.pone.0174047. eCollection 2017.

Is it all about the money? A qualitative exploration of the effects of performance-based financial incentives on Zimbabwe's voluntary male medical circumcision program.

Feldacker C1,2, Bochner AF1, Herman-Roloff A3, Holec M1, Murenje V4, Stepaniak A1, Xaba S5, Tshimanga M6, Chitimbire V7, Makaure S6, Hove J7, Barnhart S1,2,8, Makunike B4.

Author information

1 International Training and Education Center for Health (I-TECH), Seattle, WA United States of America.

2 Department of Global Health, University of Washington, Seattle, WA, United States of America.

3 U.S. Centers for Disease Control and Prevention, Harare, Zimbabwe.

4 International Training and Education Center for Health (I-TECH), Harare, Zimbabwe.

5 Ministry of Health and Child Care, Harare, Zimbabwe.

6 Zimbabwe Community Health Intervention Project (ZiCHIRe), Harare, Zimbabwe.

7 Zimbabwe Association of Church-related Hospitals (ZACH), Harare, Zimbabwe.

8 Department of Medicine, University of Washington, Seattle, WA, United States of America.

Abstract

BACKGROUND:

In 2013, Zimbabwe's voluntary medical male circumcision (VMMC) program adopted performance-based financing (PBF) to speed progress towards ambitious VMMC targets. The $25 USD PBF intended to encourage low-paid healthcare workers to remain in the public sector and to strengthen the public healthcare system. The majority of the incentive supports healthcare workers (HCWs) who perform VMMC alongside other routine services; a small portion supports province, district, and facility levels.

METHODS:

This qualitative study assessed the effect of the PBF on HCW motivation, satisfaction, and professional relationships. The study objectives were to: 1) Gain understanding of the advantages and disadvantages of PBF at the HCW level; 2) Gain understanding of the advantages and disadvantages of PBF at the site level; and 3) Inform scale up, modification, or discontinuation of PBF for the national VMMC program. Sixteen focus groups were conducted: eight with HCWs who received PBF for VMMC and eight with HCWs in the same clinics who did not work in VMMC and, therefore, did not receive PBF. Fourteen key informant interviews ascertained administrator opinion.

RESULTS:

Findings suggest that PBF appreciably increased motivation among VMMC teams and helped improve facilities where VMMC services are provided. However, PBF appears to contribute to antagonism at the workplace, creating divisiveness that may reach beyond VMMC. PBF may also cause distortion in the healthcare system: HCWs prioritized incentivized VMMC services over other routine duties. To reduce workplace tension and improve the VMMC program, participants suggested increasing HCW training in VMMC to expand PBF beneficiaries and strengthening integration of VMMC services into routine care.

CONCLUSION:

In the low-resource, short-staffed context of Zimbabwe, PBF enabled rapid VMMC scale up and achievement of ambitious targets; however, side effects make PBF less advantageous and sustainable than envisioned. Careful consideration is warranted in choosing whether, and how, to implement PBF to prioritize a public health program.

PMID: 28301588 DOI: 10.1371/journal.pone.0174047

Free full text

https://www.ncbi.nlm.nih.gov/pubmed/28301626

J Drugs Dermatol. 2017 Mar 1;16(3):285-287.

Zoon Balanitis Revisited: Report of Balanitis Circumscripta Plasmacellularis Resolving With Topical Mupirocin Ointment Monotherapy.

Lee MA, Cohen PR.

Abstract

INTRODUCTION: Zoon balanitis is an idiopathic benign inflammatory condition of the glans penis and prepuce. A patient with biopsy confirmed diagnosis of Zoon balanitis who was successfully treated with topical mupirocin ointment monotherapy is described

METHOD: A search using PubMed database was performed using the following terms: Zoon balanitis (cases, diagnosis, treatment of), balanitis circumscripta plasmacellularis, and mupirocin. Relevant papers and their reference citations were reviewed and evaluated.

RESULTS: The gold standard of treatment for Zoon balanitis has previously been circumcision. More recently, topical calcineurin inhibitors have been shown to be effective. Our patient had successful resolution of his Zoon balanitis after 3 months of mupirocin ointment monotherapy.

DISCUSSION: Zoon balanitis is a benign inflammatory dermatosis. Previous successful treatment modalities include circumcision, phototherapy, laser therapy, and topical calcineurin inhibitors. Topical mupirocin ointment twice daily resulted in resolution of Zoon balanitis in our patient. Additional evaluation of mupirocin ointment as a therapeutic agent should be considered as a potential first-line therapy in patients with Zoon balanitis.

J Drugs Dermatol. 2017;16(3):285-287.

PMID: 28301626

http://helmetorhoodie.weebly.com/home/australian-helmet-and-hoodie-stats-by-year

Latest statistics on circumcision status of men in Australia by year of birth from 1945 through 1998, i.e., age approx. 18 to 71 years.

Circumcision Academy of Australia: http://www.circumcisionaustralia.org

Circumcision Academy of America: http://www.circumcisionamerica.org

-

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Bondi Junction, NSW 2022

Australia

Brian J. Morris, DSc PhD FAHA

Professor Emeritus

School of Medical Sciences and Bosch Institute

Anderson Stuart Building (F13)

Sydney Medical School

The University of Sydney

Sydney, NSW 2006, Australia

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
Recipient:	Scott Barnhart <sbht@uw.edu>
Sent Date:	2017/03/22 10:09:16

From:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
To:	Caryl Feldacker <cfeld@uw.edu>
CC:	Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>; Vernon Murenje <vmurenje@itech-zimbabwe.org>; Marrianne M. Holec <mmholec@uw.edu>
Subject:	Re: REVISED HIV+ AE paper draft
Date:	2017/03/04 15:45:52
Priority:	Normal
Type:	Note

Thanks. I'll look forward to seeing once all the updates you mention below are finalized.

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

On Mar 3, 2017, at 6:04 PM, Caryl Feldacker <cfeld@uw.edu>wrote:

Thanks, Peter. Anyone else wish to review this version? I have no further revisions to make.
Best,
Caryl

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Friday, March 3, 2017 2:20 PM
To: Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>; Vernon Murenje <vmurenje@itech-zimbabwe.org>; Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: REVISED HIV+ AE paper draft

Hi Caryl,
Thanks for your reply. Let me please wait until it is finalized and ready for submission before reviewing again.

Thanks and best to all,
PK

From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Friday, March 03, 2017 2:17 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>; Vernon

Murenje <ymurenje@itech-zimbabwe.org>; Marrianne M. Holec <mmholec@uw.edu>
Subject: RE: REVISED HIV+ AE paper draft
Importance: High

Dear Peter,

Thank you so much for this careful review. The paper is significantly improved. I completed the revisions as fully as I could. The remaining issues on definitions and clinical issues related to AEs will have to be answered by Prof.

I hope you will find this to be ready for submission.

Scott: I think that I will need some help to respond to Peter's and you last questions on the AEs. We can get his last clarifications when this group is happy with the paper.

Also, I did not update the citations or attach the appendices to this draft. I am having some trouble accessing the server. Apologies.

Best,
Caryl

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Saturday, February 25, 2017 12:01 PM
To: Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>
Subject: RE: REVISED HIV+ AE paper draft

Hi Caryl,
Thanks for the chance to review again. I made a number of edits and suggestions. Ideally it should be essentially ready for journal submission before it is submitted for CDC clearance. Please complete the revision before sharing again.

Thanks!
PK

Peter H. Kilmarx, MD, FACP, FIDSA
RADM, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell [Redacted by agreement] Email peter.kilmarx@nih.gov

From: Caryl Feldacker [cfeld@uw.edu]
Sent: Thursday, February 23, 2017 5:23 PM
To: Kilmarx, Peter (NIH/FIC) [E]; Herman-Roloff, Amy (CDC/CGH/DGHT)
Cc: Batsi Makunike; Scott Barnhart
Subject: REVISED HIV+ AE paper draft

Dear Peter and Amy,

This reflects minor revision. If you can, review this version please. If you started on the other, no worries. This has the data updated from the Phase II trial only.

Thank you both so much for making time in your crazy schedules. I really appreciate it!

Best,
Caryl

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Wednesday, February 22, 2017 1:55 PM
To: Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>
Subject: RE: Review of first HIV+ PrexPex Manuscript

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Author information

- [1]Infectious Disease Epidemiology Group, Weill Cornell Medical College in Qatar, Cornell University, Qatar Foundation, Education City, Doha, Qatar.
- [2]Surgo Foundation, Washington, District of Columbia, United States of America.
- [3]Department of Global Health and Population, Harvard T. H. Chan School of Public Health, Boston, Massachusetts, United States of America.
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Abstract

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We used the Age-Structured Mathematical (ASM) model to evaluate, over an intermediate horizon (2010-2025), the effectiveness (number of VMMCs needed to avert one HIV infection) of VMMC scale-up scenarios with varying proportions of HIV-positive males. The model was calibrated by fitting to HIV prevalence time trend data from 1990 to 2014. We assumed that inclusivity of HIV positive males may benefit VMMC programs by increasing VMMC uptake among higher risk males, or by circumcision reducing HIV male-to-female transmission risk. All analyses were generated assuming no further antiretroviral therapy (ART) scale-up. The number of VMMCs needed to avert one HIV infection was projected to increase from 12.2 VMMCs per HIV infection averted, in a program that circumcises only HIV-negative males, to 14.0, in a program that includes HIV-positive males. The proportion of HIV-positive males was based on their representation in the population (e.g. 12.6% of those circumcised in 2010 would be HIV-positive based on HIV prevalence among males of 12.6% in 2010). However, if a program that only reaches out to HIV-negative males is associated with 20% lower uptake among higher-risk males, the effectiveness would be 13.2 VMMCs per infection averted. If improved inclusivity of HIV-positive males is associated with 20% higher uptake among higher-risk males, the effectiveness would be 12.4. As the assumed VMMC efficacy against male-to-female HIV transmission was increased from 0% to 20% and 46%, the effectiveness of circumcising regardless of HIV status improved from 14.0 to 11.5 and 9.1, respectively. The reduction in the HIV incidence rate among females increased accordingly, from 24.7% to 34.8% and 50.4%, respectively.
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5. Paul Feldblum – FHI360 (Amy may know better about this suggestion.)

Hi Scott and Batsi!

Best wishes,
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Caryl – please note my new email address. The CDC affiliations should be used on the paper because that was my affiliation when the work was done. My NIH affiliation may be noted as a footnote if you want to include current author affiliations, but it doesn't matter to me.

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Thanks –
Amy

<image002.jpg>

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH <peter.kilmarx@nih.gov>
Recipient:	Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b54f29f69b2a4157bb12e5a92e33aced-bjy2 <bjy2@cdc.gov>; Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>; Vernon Murenje <vmurenje@itech-zimbabwe.org>; Marrianne M. Holec <mmholec@uw.edu>
Sent Date:	2017/03/04 15:45:51
Delivered Date:	2017/03/04 15:45:52

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
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Subject:	RE: REVISED HIV+ AE paper draft
Date:	2017/03/03 17:19:00
Priority:	Normal
Type:	Note

Hi Caryl,
Thanks for your reply. Let me please wait until it is finalized and ready for submission before reviewing again.

Thanks and best to all,
PK

From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Friday, March 03, 2017 2:17 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
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Subject: RE: REVISED HIV+ AE paper draft
Importance: High

Dear Peter,

Thank you so much for this careful review. The paper is significantly improved. I completed the revisions as fully as I could. The remaining issues on definitions and clinical issues related to AEs will have to be answered by Prof.

I hope you will find this to be ready for submission.

Scott: I think that I will need some help to respond to Peter's and you last questions on the AEs. We can get his last clarifications when this group is happy with the paper.

Also, I did not update the citations or attach the appendices to this draft. I am having some trouble accessing the server. Apologies.

Best,

Caryl

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Saturday, February 25, 2017 12:01 PM
To: Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Batsi Makunike <bmakunike@itech-zimbabwe.org>; Scott Barnhart <sbht@uw.edu>
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Thanks!
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Dear Peter and Amy,

This reflects minor revision. If you can, review this version please. If you started on the other, no worries. This has the data updated from the Phase II trial only.

Thank you both so much for making time in your crazy schedules. I really appreciate it!

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Sent Date:	2017/03/03 17:19:40
Delivered Date:	2017/03/03 17:19:00

35

Treatment failure in Cameroon : problems and current limitations of the health care system

Background:
Although the WHO public health strategy aimed at eliminating the epidemic by 2030 has led to widespread access to antiretroviral therapy in countries in the global South, the emergence of viral resistance related to treatment failures poses a growing threat to individuals and the general public. In Cameroon, various constraints hinder the prevention, detection and case management of treatment failures. The aim of our study was to describe and analyze the context, determinants and modalities related to case management of treatment failure.
Methods:
Between 2010 and 2012, we conducted a survey in four urban sites: the Central Hospital in Yaounde; Laquintinie Hospital in Douala; Nylon District Hospital where an NGO (Médecins Sans Frontières) is involved; and the study site of the 2 Lady research project (ANRS 12169). Semi-structured interviews and observations were conducted at the sites with 85 patients and 53 health and psychosocial care professionals.
Results:
Treatment failure was often detected very late due to lack of routine viral load monitoring. Notification of the failure is often associated with placing blame on patients, who are seen as bearing sole responsibility for it. Capacities for prevention, detection and case management are limited by a lack of procedures. Medical and psychosocial care is focused on starting first-line treatment and switching from first- to second-line treatment, but long-term follow-up does not exist. Treatment failure redefines relationships between caregivers and patients. Caregivers' attitudes vacillate between compassion and condemnation, while the failure reinforces the patients' dependence. Current inaccessibility to third-line treatment makes the possibility of a new failure all the more dramatic.
Conclusion:
Treatment failures are a powerful indicator of the current limitations affecting the health care system. Our observations reflect the health system's current inability to adequately deliver adapted case management of treatment failures due to: unpreparedness of health care professionals and unavailability of diagnostic tools and treatments.

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Examining Heterogeneity in HIV Comprehensive Knowledge among Men and Women in Malawi

Background: There are few studies around socioeconomic determinants of comprehensive HIV knowledge, which provide crucial insights from social and behavioral aspects of HIV and AIDS. These provide insights on inter alia, the distribution and more importantly suggest potential mechanisms through which such knowledge, or lack thereof, ultimately conditions sexual behavior which in turn affect the HIV epidemic. However, there is an evident paucity of empirical literature examining in a more detailed what factors contribute to the gap(difference) in HIV and AIDS comprehensive knowledge. With this in mind,the main objective of this study is to empirically decompose the comprehensive HIV knowledge gap (difference in proportion of people having HIV and AIDS knowledge), between male and female in Malawi. To achieve this, the study first identifies the determinants of comprehensive HIV and AIDS knowledge. Secondly we undertake a decomposition analysis to identify how separate social economic factors contribute to the gap(difference) in comprehensive HIV and AIDS knowledge. The study is important as it combines, a gender, behavior dimension into the social aspects of HIV and AIDS. Not only that, it is a first application of labour economics method in the local context to understand the phenomenon.

Methods: Data for the study was obtained from the 2010 Malawi Demographic Health Survey (MDHS). A logit regression was used to assess factors associated with attainment of comprehensive HIV knowledge. On account of some binary nature and non-linearity of the variable of interest, the study utilized the Fairlie method to decompose the HIV and AIDS knowledge gap into its contributions. The decomposition method divides the rural-urban gap between males and females in attainment of comprehensive HIV knowledge into a part that is "explained" and "unexplained" (a residual part that cannot be accounted for by explanatory variables). This part is often used as a measure for discrimination among groups, but it also subsumes the effects of group differences in unobserved predictors. The Farlie's decomposition allows a detailed decomposition of the separate contribution of each variable to comprehensive HIV knowledge gap.

Results: Findings from this study indicate 39% of women have HIV and AIDS comprehensive knowledge and 52% of men have comprehensive HIV and AIDS knowledge. This entails a difference of 14%. Of the difference, 75% is explained by the differences in social economic factors and behavior of men and women, where by 25% still remain unexplained. Having an HIV test reduces the gap as well as leaving in a high HIV and AIDS prevalence areas .Religion doesn't explain the gap. Exposure to radio and TV reduces the difference in HIV and AIDS knowledge. Being rich explains 25.1% of the difference where as being poorer reduces the gap (2.3%)

Recommendations: The results point to the need for a differentiated approach to HIV awareness taking into account the differences in the factors that mediate attainment of comprehensive HIV knowledge among men and women .Also need for development or review of strategic documents with respect to HIV communication and advocacy.

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Social adversities of HIV-positive adolescents in rural Uganda: a qualitative study

Authors: Scholastic Ashaba1, Christine Cooper-Vince2, 3, Dagmar Vořechovská2, Alexander C. Tsai1, 2, 3

Background

Availability of and increased access to antiretroviral therapy has significantly reduced morbidity and mortality associated with HIV. As a result, perinatally HIV infected children are able to grow into adolescents and young adults. In Uganda approximately 100,000-150,000 children and adolescents aged between 10-19 years of age are living with HIV. Although major strides have been made in the biomedical management of HIV among children and adolescents, there is limited information on the social challenges of HIV-positive adolescents in rural settings in sub-Saharan Africa. Previous work about the social challenges of HIV-positive adolescents has been limited to studies done in high-income countries and/or urban areas in low-income countries. The purpose of this study was to explore social challenges facing adolescents living with HIV in rural Uganda.

Methods

We collected qualitative data using focus group discussions and one-on-one in-depth interviews between February and May 2016. Participants in the focus group discussions included 26 adolescents aged 13-17 years, 14 of whom were HIV-positive and 12 of whom were of unknown serostatus. We conducted a total of 42 in-depth interviews, including 5 interviews with HIV-positive adolescents, 5 interviews with adolescents of unknown HIV status, and 32 interviews with adult caregivers (10 of whom were themselves HIV-positive). HIV-positive participants were recruited from the Mbarara Immune Suppression Syndrome clinic. Participants of unknown serostatus were recruited from Nyakabare Parish, a rural site 20 km from Mbarara town. All interviews were audio-recorded, translated and transcribed into English, and coded using thematic analysis to identify themes related to social challenges.

Results

Social challenges faced by adolescents were categorized under 7 themes: 1) stigma and discrimination; 2) fear of unintended disclosure of HIV status; 3) poverty associated with lack of basic needs and missed schooling; 4) ART adherence challenges; 5) food insecurity; 6) loss of parents; and 7) maltreatment. Stigma/discrimination and poverty were the most frequently mentioned challenges. Data generated from focus group discussions were rich in content than in depth interview data.

Conclusion

HIV-positive adolescents face numerous important challenges that could compromise their engagement in HIV care.

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The potential of advanced mHealth interventions for youth populations: insights from mobile phone use in a mixed rural-urban sub district in South Africa

Background: The ubiquity of mobile phone use in Sub-Saharan Africa is well documented in adult populations. Measures of access to - and utilisation of - mobile phones among adolescents are lacking. Mobile health (mHealth) interventions have begun to explore the potential of using more advanced methods to engage young people in sexual and reproductive health messaging. These include mobi sites, social media, and applications ("apps"). To assess the potential effectiveness of advanced mHealth technologies in adolescent populations, we must first understand how this group engages with mobile phones, and across which platforms.

Methods: To describe mobile phone uptake and user behaviours amongst adolescents residing within a mixed rural-urban health sub district, data were gathered from 1286 participants (10 – 22 years) enrolled in a prospective longitudinal cohort study (Mzantsi Wakho) in the Eastern Cape Province, South Africa. The tablet-based questionnaire collected optional quantitative information regarding: 1) access to and personal ownership of a mobile phone; 2) SIM card ownership; 3) kind of device and operating system; 4) purposes of engagements (e.g. health-seeking); and 5) general usage characteristics (e.g. messaging preferences). Analyses were conducted using SPSS.

Results: Given that responses to all questions were not mandatory, there were variances in response rates (range 1006 – 1229, 78.2% - 95.6%). When disaggregated by indicator, self-reported data show that: 54.4% have access to a mobile device; 47.7% own a SIM card; 34.8% have access to a smart phone; and 25.3%, a basic phone. Possession of a personal phone (not shared) within the sample counted smartphone ownership as higher than basic phones: 33.8% versus 29.2%. Further, 21.1% reported owning a "brand name" phone, such as an iPhone or Blackberry device.

Usage statistics demonstrated that 14.9% of mobile phone engagement was for the purposes of gathering health information (including HIV-specific materials) and job-seeking. 40%, 39.2%, 37.3%, and 31.2% reported using their phones for music, WhatsApp messaging, games, and Facebook, respectively. SMS's remained the dominant mode of communicating, as reported by 44.7% of the sample.

Females reported having more access to mobile phones (61.8%) compared with males (44.7%) ($p \leq 0.001$). Of note, access to cell phones increased with age ($x^2=129.9678$ α 0.5, $df=4$ $p \leq 0.00001$): 29% of those under 12; 42.9% 13-15 years; 66.6% 16-18 years; 78.5% 19-21 years; and 80% 22+ years. Smart phone access also increased accordingly with the exception of those aged 22+, perhaps owing to small sample size (n=5).

Conclusions: These results demonstrate a tangible shift away from basic cell phone use to more sophisticated, smart phone devices. It also highlights gender disparities in terms of access to mobile technologies. Thus, the potential to introduce novel mHealth interventions that target young people, particularly females – who are also most at risk of HIV infection, shows promise. However, these methods should be balanced with existing evidence-based programming to ensure a broader reach. Interventions that do not rely on mobile platforms should be retained with a view to potentially translate them to digital spaces as smartphones become less expensive, and thus more accessible to young people.

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Barriers to ART uptake experienced by healthy clients in Malawi under Test and Treat

Background: Malawi is one of the first countries in sub-Saharan Africa to implement antiretroviral therapy (ART) regardless of clinical stage or CD4 cell count (Test and Treat). We evaluated barriers and facilitators to ART uptake from the perspective of both asymptomatic newly HIV+ clients and HIV service providers during the first 6 weeks of program implementation.

Methods: Routine data from 5 ART clinics were reviewed to identify clients >18 years of age testing HIV+ between July 14-September 23, 2016. Individuals were screened to determine if they were asymptomatic at time of testing. In-depth interviews were conducted with asymptomatic clients. Twelve focus group discussions were completed with ART providers (n=31), HIV counselors (n=19), and community-based support staff (n=29).

Results: One hundred and fifty-three clients tested HIV+ and of those 22% (n=33) were asymptomatic. Ninety-one percent of clients identified as asymptomatic completed in-depth interviews (n=30). The most common barriers to ART uptake identified by clients were fear of disclosure (63%, n=19), fear of experiencing side effects while healthy (57%, n=17), work schedules or other commitments that conflict with clinic hours (33%, n=10), and needing time to accept their diagnosis before initiating ART (30%, n=9). Dominant facilitators to ART initiation included the desire to stay healthy to provide and/or care for family members (70%, n=21), motivation to prevent unwanted disclosure by becoming sick (23%, n=7), the desire to extend one's life (43%, n=13), and personal knowledge of others who died from AIDS due to delayed treatment (37%, n=11). Providers identified fear of disclosure, lack of privacy at ART clinics, and poor knowledge about benefits of early ART as primary barriers to uptake among asymptomatic clients. Additionally, providers raised concern that asymptomatic men may not engage in HIV care.

Conclusions: Concern about HIV disclosure, lack of privacy, fear of side effects, and facility hours may limit ART uptake among asymptomatic clients. Patient- and provider-reported barriers closely align. Interventions that improve privacy, support disclosure, increase patient knowledge, and improve access to ART may facilitate ART uptake among asymptomatic HIV+ individuals under Test and Treat.

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Discordance, Disclosure and Normative gender roles: A triad of barrier to couples HIV self-testing provided through a community-based approach in urban Blantyre, Malawi

Background: Most individuals living in established heterosexual relationships are unaware of their partner's HIV status, and most people with an HIV infected partner are unaware of their own status. Early results from a community-based HIV self-testing study in Malawi demonstrated that not all individuals living in established sexual relationships who self-tested for HIV tested did so their partner, despite an option of getting two test-kits. We describe factors that dissuade individuals living in established heterosexual relationships from self-testing for HIV with a sexual partner.
Method: Data were drawn from a 12-month qualitative longitudinal cohort study exploring the long-term consequences of semi-supervised HIV self-testing within couples in Blantyre Malawi. In-depth interviews were conducted within a month of self-testing with 33 individuals living in established heterosexual relationships who tested without a sexual partner were analysed.
Results: Both men and women who tested alone did so expressed fear of dealing with HIV discordant results within a trusting relationship when given a chance to self-test as couples. The failure to self-test with a partner was gendered with more men overtly declining or unconsciously unable to have joint HIV self-testing than women. Men feared blame and exposure of previous or current infidelity. Men were also often not available at home for economic or work reasons and were usually missed by the HIVST community-based approach.
Conclusions: The socio-structural landscape prohibited men differently from having a joint HIVST when compared to women owing to the normative notions of gender. To contribute towards achieving the UNAIDS 90:90:90 goals, it is important to overcome the structural barriers to couples testing that constrain the realisation of HIVST full potential in couples.

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Impact of Theater for Development and interactive Drama in community awareness and community mobilization of VMMC services

Story Workshop Education Trust (SWET) conducted a baseline study in order to design Social Behavior Change Communication programs on HIV prevention. This was followed by Theater for development (TFD) using Interactive drama. The aim of the study was to assess the knowledge levels on Sexual Reproductive Health and Rights among the youth aged between 15 to 24 years. The study was carried out in Balaka district in Traditional Authority Chanthunya and Amidu. The baseline was carried out through inter personal interview questions. This was followed by TFD sessions and data collection using activity performance forms. The baseline interviewed 52 youth from the two traditional authorities. This revealed that 84% of the youth are knowledgeable about Sexual Reproductive Health and Rights (SRHR), 42% of which were females. Their main sources of information are their peers, making up to 40%. The percentage of youth engaged in sexual activities was found to be 57%. The percentage of youth knowledgeable on Voluntary Medical Male Circumcision (VMMC) was found to be 92%. Males made up 42% of the percentage on VMMC. The percentage of circumcised males was found to be 23%. SWET facilitated Social and Behaviour Change Communication interventions through Theater for Development and interactive drama sessions. A total of 40 Theater for Development and interactive drama sessions were conducted in the area. This resulted into 84,741 youth reached using interpersonal forum discussions on SRHR. The Theater for Development sessions resulted to 1,143 youth demanding VMMC services. TFD and drama communicates information that is not discussed in most community gatherings. Its use should be explored in order to involve different age groups and trigger community discussions on sensitive subjects like HIV and AIDS.

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Scott Barnhart <sbht@uw.edu>
Subject:	RE: Review of first HIV+ PrexPex Manuscript
Date:	2017/02/01 08:41:00
Priority:	Normal
Type:	Note

That sounds like the approach that was recommended at the OGAC scientific advisory meeting I attended last year.

Cheers,
PK

From: Scott Barnhart [mailto:sbht@uw.edu]
Sent: Wednesday, February 01, 2017 8:10 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: Re: Review of first HIV+ PrexPex Manuscript

They are pretty well immunized. There was one case of tetanus with PSI but the pt was 47 and thus immunized (or not) at an earier time when immunization rates were less. We had hoped for a more nuanced risk assessment and perhaps age stratification.

Sent from my BlackBerry 10 smartphone.

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Wednesday, February 1, 2017 07:02
To: Scott Barnhart
Subject: Re: Review of first HIV+ PrexPex Manuscript

Hi Scott,
I'm less closely involved these days, but I assume you are referring to tetanus risk. Are Zimbabweans not well immunized?

Cheers,
PK

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH

On Feb 1, 2017, at 6:43 AM, Scott Barnhart <sbht@uw.edu>wrote:

Thanks Peter- This is quite interesting. I am really sorry to see the turn of events around prepex. We were doing very well with it rising to greater than 30% ov VMMC 's some weeks. Best, Scott

Scott Barnhart, MD, MPH
Professor, Departments of Medicine and Global Health
University of Washington
Telephone: +1 206-685-4875
Mobile: Redacted by agreement
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Skype: scottbarnhart1

"A pessimist makes his opportunities difficult, and an optimist makes his difficulties opportunities."

From: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Sent: Tuesday, January 31, 2017 4:06 PM
To: Caryl Feldacker; Herman-Roloff, Amy (CDC/CGH/DGHT)
Cc: Scott Barnhart; Batsi Makunike
Subject: RE: Review of first HIV+ PrexPex Manuscript

FYI - a reference of interest:

https://www.ncbi.nlm.nih.gov/pubmed/28118387

Could Circumcision of HIV-Positive Males Benefit Voluntary Medical Male Circumcision Programs in Africa? Mathematical Modeling Analysis. - PubMed - NCBI

www.ncbi.nlm.nih.gov

PLoS One. 2017 Jan 24;12(1):e0170641. doi: 10.1371/journal.pone.0170641. eCollection 2017.

PLoS One. 2017 Jan 24;12(1):e0170641. doi: 10.1371/journal.pone.0170641. eCollection 2017.
Could Circumcision of HIV-Positive Males Benefit Voluntary Medical Male Circumcision Programs in Africa? Mathematical Modeling Analysis.

Awad SF[1], Sgaier SK[2,3,4], Lau FK[2], Mohamoud YA[1], Tambatamba BC[5], Kripke KE[6], Thomas AG[7], Bock N[8], Reed JB[9], Njeuhmeli E[10], Abu-Raddad LJ[1,11,12].

Author information

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Abstract

BACKGROUND:

The epidemiological and programmatic implications of inclusivity of HIV-positive males in voluntary medical male circumcision (VMMC) programs are uncertain. We modeled these implications using Zambia as an illustrative example.

METHODS AND FINDINGS:

We used the Age-Structured Mathematical (ASM) model to evaluate, over an intermediate horizon (2010-2025), the effectiveness (number of VMMCs needed to avert one HIV infection) of VMMC scale-up scenarios with varying proportions of HIV-positive males. The model was calibrated by fitting to HIV prevalence time trend data from 1990 to 2014. We assumed that inclusivity of HIV positive males may benefit VMMC programs by increasing VMMC uptake among higher risk males, or by circumcision reducing HIV male-to-female transmission risk. All analyses were generated assuming no further antiretroviral therapy (ART) scale-up. The number of VMMCs needed to avert one HIV infection was projected to increase from 12.2 VMMCs per HIV infection averted, in a program that circumcises only HIV-negative males, to 14.0, in a program that includes HIV-positive males. The proportion of HIV-positive males was based on their representation in the population (e.g. 12.6% of those circumcised in 2010 would be HIV-positive based on HIV prevalence among males of 12.6% in 2010). However, if a program that only reaches out to HIV-negative males is associated with 20% lower uptake among higher-risk males, the effectiveness would be 13.2 VMMCs per infection averted. If improved inclusivity of HIV-positive males is associated with 20% higher uptake among higher-risk males, the effectiveness would be 12.4. As the assumed VMMC efficacy against male-to-female HIV transmission was increased from 0% to 20% and 46%, the effectiveness of circumcising regardless of HIV status improved from 14.0

to 11.5 and 9.1, respectively. The reduction in the HIV incidence rate among females increased accordingly, from 24.7% to 34.8% and 50.4%, respectively.

CONCLUSION:

Improving inclusivity of males in VMMC programs regardless of HIV status increases VMMC effectiveness, if there is moderate increase in VMMC uptake among higher-risk males and/or if there is moderate efficacy for VMMC against male-to-female transmission. In these circumstances, VMMC programs can reduce the HIV incidence rate in males by nearly as much as expected by some ART programs, and additionally, females can benefit from the intervention nearly as much as males.

PMID: 28118387
DOI: 10.1371/journal.pone.0170641
[PubMed - in process]

Free full text

Peter H. Kilmarx, MD, FACP, FIDSA
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From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Monday, January 23, 2017 12:30 PM
To: Caryl Feldacker; Herman-Roloff, Amy (CDC/CGH/DGHT)
Cc: Scott Barnhart; Batsi Makunike
Subject: RE: Review of first HIV+ PrexPex Manuscript

Hi Caryl,
This is a great start on this paper. Please see my comments attached. I look forward to seeing the next draft.

Suggested reviewers:

1. Naomi Bock – CDC
2. Jason Reed – JHPIEGO (formerly CDC)
3. Cate Hankins – AIGHD
4. Jeffrey Klausner – UCLA
5. Paul Feldblum – FHI360 (Amy may know better about this suggestion.)

Hi Scott and Batsi!

Best wishes,
PK

Peter H. Kilmarx, MD, FACP, FIDSA
RADM, U.S. Public Health Service
Deputy Director, Fogarty International Center

U.S. National Institutes of Health
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From: Caryl Feldacker [mailto:cfeld@uw.edu]
Sent: Friday, January 20, 2017 5:00 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Cc: Scott Barnhart <sbht@uw.edu>; Batsi Makunike <bmakunike@itech-zimbabwe.org>
Subject: RE: Review of first HIV+ PrexPex Manuscript

Hi Peter,

Glad to be back in touch with some good progress! I look forward to your comments in the HIV+ Prepex paper. I also hope to hear some good news from WHO Bulletin about the integration paper someday soon when they can find reviewers. On that note, do you have anyone that you can think of who might look with interest and favor on our paper about the VMMC integrated model? WHO is having a hard time finding reviewers. It is significantly slowing the process.

Best,
Caryl

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Thursday, January 19, 2017 2:08 PM
To: Caryl Feldacker <cfeld@uw.edu>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>
Subject: RE: Review of first HIV+ PrexPex Manuscript

Hi and thanks Caryl and Amy. I'll aim to review carefully and provide comments this weekend.

Caryl – please note my new email address. The CDC affiliations should be used on the paper because that was my affiliation when the work was done. My NIH affiliation may be noted as a footnote if you want to include current author affiliations, but it doesn't matter to me.

Thanks,
PK

Peter H. Kilmarx, MD, FACP, FIDSA
RADM, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell Redacted by agreement Email peter.kilmarx@nih.gov

From: Caryl Feldacker [mailto:cfeld@UW.EDU]
Sent: Thursday, January 19, 2017 12:10 PM

To: Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: RE: Review of first HIV+ PrexPex Manuscript

Thank you, Amy! Hello, Peter!

I'd appreciate any comments, Peter, at your earliest convenience. It has one or two sections that are a work in progress – mostly on the sample size/design issues that we will face – but it is almost ready for CDC review.

Hopefully, it will have a speedy CDC review for submission to PLOS One by early February.

Best,
Caryl

From: Herman-Roloff, Amy (CDC/CGH/DGHT) [mailto:bjy2@cdc.gov]
Sent: Thursday, January 19, 2017 5:43 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Cc: Caryl Feldacker <cfeld@uw.edu>
Subject: Review of first HIV+ PrexPex Manuscript

Hi Peter –

It was nice to chat with you today. As discussed, I am in the midst of reviewing the second draft of the first paper coming out of the HIV+ PrePex study. You are listed as an author, and your in-depth review would be most appreciated. Caryl is coordinating the writing and responses, and I've copied her here. (Caryl – please note Peter's NIH's email address.)

Thanks –
Amy

<image002.jpg>

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Scott Barnhart <sbht@uw.edu>
Sent Date:	2017/02/01 08:41:34
Delivered Date:	2017/02/01 08:41:00

From:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
To:	Barr, Beth (CDC/CGH/DGHT) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=HKC5 <hkc5@CDC.GOV>
Subject:	FW: MC pubs this week: Roll-out for HIV prevention; Anesthesia; Penile cancer; Nurse practitioners to lower costs
Date:	2017/01/31 19:10:08
Priority:	Normal
Type:	Note

FYI - one might have expected a CDC author?
Cheers,
PK
https://www.ncbi.nlm.nih.gov/pubmed/28132009
BMJ Open. 2017 Jan 27;7(1):e013562. doi: 10.1136/bmjopen-2016-013562.

Challenges in data quality: the influence of data quality assessments on data availability and completeness in a voluntary medical male circumcision programme in Zimbabwe.

Xiao Y[1,2], Bochner AF[2], Makunike B[3], Holec M[2], Xaba S[4], Tshimanga M[5], Chitimbire V[6], Barnhart S[2,7,8], Feldacker C[2,8].

Author information

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- [6]Zimbabwe Association of Church-related Hospitals (ZACH), Harare, Zimbabwe.
- [7]Department of Medicine, University of Washington, Seattle, Washington, USA.
- [8]Department of Global Health, University of Washington, Seattle, Washington, USA.

Abstract

OBJECTIVES:

To assess availability and completeness of data collected before and after a data quality audit (DQA) in voluntary medical male circumcision (VMMC) sites in Zimbabwe to determine the effect of this process on data quality.

SETTING:

4 of 10 VMMC sites in Zimbabwe that received a DQA in February, 2015 selected by convenience sampling.

PARTICIPANTS:

Retrospective reviews of all client intake forms (CIFs) from November, 2014 and May, 2015. A total of 1400 CIFs were included from those 2 months across four sites.

PRIMARY AND SECONDARY OUTCOMES:

Data availability was measured as the percentage of VMMC clients whose CIF was on file at each site. A data evaluation tool measured the completeness of 34 key CIF variables. A comparison of pre-DQA and post-DQA results was conducted using χ^2 and t-tests.

RESULTS:

After the DQA, high record availability of over 98% was maintained by sites 3 and 4. For sites 1 and 2, record availability increased by 8.0% (p=0.001) and 9.7% (p=0.02), respectively. After the DQA, sites 1, 2 and 3 improved significantly in data completeness across 34 key indicators, increasing by 8.6% (p<0.001), 2.7% (p=0.003) and 3.8% (p<0.001), respectively. For site 4, CIF data completeness decreased by 1.7% (p<0.01) after the DQA.

CONCLUSIONS:

Our findings suggest that CIF data availability and completeness generally improved after the DQA. However, gaps in documentation of vital signs and adverse events signal areas for improvement. Additional emphasis on data completeness would help support high-quality programme implementation and availability of reliable data for decision-making.

KEYWORDS:

Data quality; Monitoring and Evaluation; Zimbabwe; operations research; voluntary medical male circumcision

PMID: 28132009

DOI: 10.1136/bmjopen-2016-013562

[PubMed - in process]

Free full text

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From: Brian Morris [brian.morris@sydney.edu.au]
Sent: Tuesday, January 31, 2017 6:49 PM
To: Brian Morris
Subject: MC pubs this week: Roll-out for HIV prevention; Anesthesia; Penile cancer; Nurse practitioners to lower costs

https://www.ncbi.nlm.nih.gov/pubmed/28121914

Medicine (Baltimore). 2017 Jan;96(4):e5328. doi: 10.1097/MD.0000000000005328.

Obtaining a male circumcision prevalence rate of 80% among adults in a short time: An observational prospective intervention study in the Orange Farm township of South Africa.

Marshall E[1], Rain-Taljaard R, Tsepe M, Monkwe C, Taljaard D, Hlatswayo F, Xaba D, Molomo T, Lissouba P, Puren A, Auvert B.

Author information

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Abstract

World Health Organization recommends a target for the male circumcision prevalence rate of 80%. This rate will have a substantial impact on the human immunodeficiency virus-acquired immunodeficiency syndrome epidemic in Eastern and Southern Africa. The objective of the study was to assess whether an innovative intervention can lead to an increased voluntary male medical circumcision (VMMC) uptake among adults in a short time. This prospective observational study of a demand generation intervention was conducted in the township of Orange Farm (South Africa) in August to November 2015. In this community male circumcision prevalence rate among adults was stable between 2010 and 2015 at 55% and 57%, despite regular VMMC campaigns at community level and the presence of a VMMC clinic that offered free VMMC. The intervention took place in a random sample of 981 households where 522 men aged 18 to 49 years accepted to participate in the study. Among the 226 uncircumcised men, 212 accepted to be enrolled in the intervention study. A personal male circumcision adviser trained in interpersonal communication skills was assigned to each uncircumcised participant. The male circumcision advisers were trained to explain the risks and benefits of VMMC, and to discuss 24 possible reasons given by men for not being circumcised. Participants were then followed for 9 weeks. Each participant had a maximum of 3 motivational interviews at home. Participants who decided to be circumcised received financial compensation for their time equivalent to 2.5 days of work at the minimum South African salary rate. Among the 212 uncircumcised men enrolled in the intervention, 69.8% (148/212; 95% confidence interval [CI]; 63.4%-75.7%) agreed to be circumcised, which defines the uptake of the intervention. The male circumcision prevalence rate of the sample increased from 56.7% (296/522) to 81.4% (425/522; 77.9%-84.6%), $P<0.001$, corresponding to a relative increase of 43.6% (95% CI: 35.4%-53.7%). The reported reasons for accepting circumcision were motivational interviews with the male circumcision adviser (83.1%), and time compensation (39.4%).Increased uptake of VMMC uptake can be obtained in a short time among adult males but requires an intense intervention centered on uncircumcised men at an individual level and time compensation.

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Could Circumcision of HIV-Positive Males Benefit Voluntary Medical Male Circumcision Programs in Africa? Mathematical Modeling Analysis.

Awad SF[1], Sgaier SK[2,3,4], Lau FK[2], Mohamoud YA[1], Tambatamba BC[5], Kripke KE[6], Thomas AG[7], Bock N[8], Reed JB[9], Njeuhmeli E[10], Abu-Raddad LJ[1,11,12].

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Abstract

BACKGROUND:

The epidemiological and programmatic implications of inclusivity of HIV-positive males in voluntary medical male circumcision (VMMC) programs are uncertain. We modeled these implications using Zambia as an illustrative example.

METHODS AND FINDINGS:

We used the Age-Structured Mathematical (ASM) model to evaluate, over an intermediate horizon (2010-2025), the effectiveness (number of VMMCs needed to avert one HIV infection) of VMMC scale-up scenarios with varying proportions of HIV-positive males. The model was calibrated by fitting to HIV prevalence time trend data from 1990 to 2014. We assumed that inclusivity of HIV positive males may benefit VMMC programs by increasing VMMC uptake among higher risk males, or by circumcision reducing HIV male-to-female transmission risk. All analyses were generated assuming no further antiretroviral therapy (ART) scale-up. The number of VMMCs needed to avert one HIV infection was projected to increase from 12.2 VMMCs per HIV infection averted, in a program that circumcises only HIV-negative males, to 14.0, in a program that includes HIV-positive males. The proportion of HIV-positive males was based on their representation in the population (e.g. 12.6% of those circumcised in 2010 would be HIV-positive based on HIV prevalence among males of 12.6% in 2010). However, if a program that only reaches out to HIV-negative males is associated with 20% lower uptake among higher-risk males, the effectiveness would be 13.2 VMMCs per infection averted. If improved inclusivity of HIV-positive males is associated with 20% higher uptake among higher-risk males, the effectiveness would be 12.4. As the assumed VMMC efficacy against male-to-female HIV transmission was increased from 0% to 20% and 46%, the effectiveness of circumcising regardless of HIV status improved from 14.0 to 11.5 and 9.1, respectively. The reduction in the HIV incidence rate among females increased accordingly, from 24.7% to 34.8% and 50.4%, respectively.

CONCLUSION:

Improving inclusivity of males in VMMC programs regardless of HIV status increases VMMC effectiveness, if there is moderate increase in VMMC uptake among higher-risk males and/or if there is moderate efficacy for VMMC against male-to-female transmission. In these circumstances, VMMC programs can reduce the HIV incidence rate in males by nearly as much as expected by some ART programs, and additionally, females can benefit from the intervention nearly as much as males.

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Sex Transm Infect. 2017 Jan 27. pii: sextrans-2016-052930. doi: 10.1136/sextrans-2016-052930. [Epub ahead of print]

A national evaluation using standardised patient actors to assess STI services in public sector clinical sentinel surveillance facilities in South Africa.

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Abstract

OBJECTIVES:

Quality concerns in STI service delivery and missed opportunities for integration with HIV testing and prevention services in South Africa have been well documented. This national evaluation aimed to evaluate current utilisation and adherence to national STI guidelines, including partner notification and integration with HIV services, for diagnosis and management of STIs.

METHODS:

Facility surveys assessed infrastructure and resource availability, and standardised patient (SP) assessments evaluated quality of STI care in 50 public clinics in nine provinces in South Africa. The primary outcome was the proportion of SPs receiving essential STI care, defined as: offered an HIV test, condoms, partner notification counselling and correct syndromic treatment. Weighted proportions were generated, and SP findings were compared by gender using χ^2 tests with Rao-Scott correction.

RESULTS:

More than 80% of facilities reported medications in stock, with the exceptions of oral cefixime (48.3%), oral erythromycin (75.1%) and paediatric syrups. Among 195 SP encounters, 18.7% (95% CI 10.7% to 30.5%) received all hypothesised essential STI services: offered HIV test (67.1%), offered condoms (31.4%), partner notification counselling (70.2%) and recommended syndromic treatment (60.7%). Men were more likely than women to be offered all services (25.1% vs 12.3%, p=0.023), recommended treatment (70.7% vs 50.9%, p=0.013) and partner notification counselling (79.9% vs 60.6%, p=0.020). Only 6.3% of providers discussed male circumcision with male SPs, and 26.3% discussed family planning with female SPs.

CONCLUSIONS:

This evaluation of STI services across South Africa found gaps in the availability of medications, adherence to STI guidelines, condom provision and prevention messaging. Limited integration with HIV services for this high-risk population was a missed opportunity. Quality of STI care should continue to be monitored, and interventions to improve quality should be prioritised as part of national strategic HIV and primary healthcare agendas.

KEYWORDS:
AFRICA; HEALTH SERV RESEARCH; IMPLEMENTATION SCIENCE; PUBLIC HEALTH; SERVICE DELIVERY
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BMC Med Inform Decis Mak. 2017 Jan 23;17(1):14. doi: 10.1186/s12911-017-0409-5.

The use of multi-criteria decision making models in evaluating anesthesia method options in circumcision surgery.

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Abstract

BACKGROUND:

Determining the most suitable anesthesia method for circumcision surgery plays a fundamental role in pediatric surgery. This study is aimed to present pediatric surgeons' perspective on the relative importance of the criteria for selecting anesthesia method for circumcision surgery by utilizing the multi-criteria decision making methods.

METHODS:

Fuzzy set theory offers a useful tool for transforming linguistic terms into numerical assessments. Since the evaluation of anesthesia methods requires linguistic terms, we utilize the fuzzy Analytic Hierarchy Process (AHP) and fuzzy Technique for Order Preference by Similarity to Ideal Solution (TOPSIS). Both mathematical decision-making methods are originated from individual judgements for qualitative factors utilizing the pair-wise comparison matrix. Our model uses four main criteria, eight sub-criteria as well as three alternatives. To assess the relative priorities, an online questionnaire was completed by three experts, pediatric surgeons, who had experience with circumcision surgery.

RESULTS:

Discussion of the results with the experts indicates that time-related factors are the most important criteria, followed by psychology, convenience and duration. Moreover, general anesthesia with penile block for circumcision surgery is the preferred choice of anesthesia compared to general anesthesia without penile block, which has a greater priority compared to local anesthesia under the discussed main-criteria and sub-criteria.

CONCLUSIONS:

The results presented in this study highlight the need to integrate surgeons' criteria into the decision making process for selecting anesthesia methods. This is the first study in which multi-criteria decision

making tools, specifically fuzzy AHP and fuzzy TOPSIS, are used to evaluate anesthesia methods for a pediatric surgical procedure.

KEYWORDS:
AHP; Anesthesia methods; Circumcision surgery procedure; Fuzzy; Health care; Multi-criteria; TOPSIS
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BMJ Open. 2017 Jan 27;7(1):e013562. doi: 10.1136/bmjopen-2016-013562.

Challenges in data quality: the influence of data quality assessments on data availability and completeness in a voluntary medical male circumcision programme in Zimbabwe.

Xiao Y[1,2], Bochner AF[2], Makunike B[3], Holec M[2], Xaba S[4], Tshimanga M[5], Chitimbire V[6], Barnhart S[2,7,8], Feldacker C[2,8].

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Abstract

OBJECTIVES:
To assess availability and completeness of data collected before and after a data quality audit (DQA) in voluntary medical male circumcision (VMMC) sites in Zimbabwe to determine the effect of this process on data quality.

SETTING:
4 of 10 VMMC sites in Zimbabwe that received a DQA in February, 2015 selected by convenience sampling.

PARTICIPANTS:
Retrospective reviews of all client intake forms (CIFs) from November, 2014 and May, 2015. A total of 1400 CIFs were included from those 2 months across four sites.

PRIMARY AND SECONDARY OUTCOMES:
Data availability was measured as the percentage of VMMC clients whose CIF was on file at each site. A data evaluation tool measured the completeness of 34 key CIF variables. A comparison of pre-DQA and post-DQA results was conducted using χ^2 and t-tests.

RESULTS:
After the DQA, high record availability of over 98% was maintained by sites 3 and 4. For sites 1 and 2, record availability increased by 8.0% (p=0.001) and 9.7% (p=0.02), respectively. After the DQA, sites 1, 2 and 3 improved significantly in data completeness across 34 key indicators, increasing by 8.6% (p<0.001), 2.7% (p=0.003) and 3.8% (p<0.001), respectively. For site 4, CIF data completeness decreased by 1.7% (p<0.01) after the DQA.

CONCLUSIONS:
Our findings suggest that CIF data availability and completeness generally improved after the DQA. However, gaps in documentation of vital signs and adverse events signal areas for improvement. Additional emphasis on data completeness would help support high-quality programme implementation and availability of reliable data for decision-making.

KEYWORDS:
Data quality; Monitoring and Evaluation; Zimbabwe; operations research; voluntary medical male circumcision
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Cent European J Urol. 2016;69(4):377-383. doi: 10.5173/ceju.2016.890. Epub 2016 Oct 17.
Primary penile cancer organ sparing treatment.
Sosnowski R[1], Kuligowski M[1], Kuczkiewicz O[2], Moskal K[2], Wolski JK[1], Bjurlin MA[3], Wysock JS[4], Pęczkowski P[5], Protzel C[6], Demkow T[1].
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Abstract
INTRODUCTION:
Surgical treatment of penile cancer is usually associated with mutilation; alterations in self-esteem and body image; affecting sexual and urinary functions; and declined health-related quality of life. Recently, organ sparing treatment has appeared and led to limiting these complications.
MATERIAL AND METHODS:
An extensive review of the literature concerning penile-preserving strategies was conducted. The focus was put on indications, general principles of management, surgical options and reconstructive techniques, the most common complications, as well as functional and oncological outcomes.
RESULTS:

Analyzed methods, e.g.: topical chemotherapy, laser ablation therapy, radiotherapy, Moh's microscopic surgery, circumcision, wide local excision, glans resurfacing and glansectomy are indicated in low-stage tumors (Tis, Ta-T2). After glansectomy, reconstruction is also possible.

CONCLUSIONS:

Organ sparing techniques may achieve good anatomical, functional, and psychological outcomes without compromising local cancer control, which depends on early diagnosis and treatment. Penile sparing strategies are acceptable treatment approaches in selected patients with low-stage penile cancer after establishing disease-risk and should be considered in this population.

KEYWORDS:

QoL; organ sparing treatment; penile cancer

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PMCID: PMC5260461

DOI: 10.5173/ceju.2016.890

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Int Braz J Urol. 2017 Jan-Feb;43(1):7-9. doi: 10.1590/S1677-5538.IBJU.2017.01.03.

Should routine neonatal circumcision be a polic[y] to prevent penile cancer? | Opinion: Yes.

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KEYWORDS:

Circumcision, Male; Penile Neoplasms; Phimosis

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https://www.ncbi.nlm.nih.gov/pubmed/28124520

Int Braz J Urol. 2017 Jan-Feb;43(1):10-12. doi: 10.1590/S1677-5538.IBJU.2017.01.04.

Should routine neonatal circumcision be a policy to prevent penile cancer? | Opinion: No.

Tang DH[1], Spiess PE[1].

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KEYWORDS:

Circumcision, Male; Penile Neoplasms; Phimosis

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[PubMed - in process]

https://www.ncbi.nlm.nih.gov/pubmed/28133698

Saudi Med J. 2017 Feb;38(2):213-214. doi: 10.15537/smj.2017.2.18065.

Non-therapeutic infant male circumcision. evidence, ethics and international law perspective.

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Abstract

[No Avaliable Abstract].

PMID: 28133698

DOI: 10.15537/smj.2017.2.18065

[PubMed - in process]

Free full text

http://www.news8000.com/health/mayo-study-proposes-method-to-lower-circumcision-costs/291188898

Mayo study proposes method to lower circumcision costs

Switch from specialists to [nurse practitioners] could save millions

Posted: Jan 24, 2017 07:35 PM CST

Updated: Jan 24, 2017 07:35 PM CST

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Recipient:	Barr, Beth (CDC/CGH/DGHT) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=HKC5 <hkc5@CDC.GOV>
Sent Date:	2017/01/31 19:10:08

Comments from Peter Kilmarx – January 23, 2017

Safety and Efficacy of the PrePex™ Device among HIV-positive men in Zimbabwe

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Background

Zimbabwe has reached ~~about~~ approximately 50% of ~~its~~ the national 1.3 million voluntary medical male circumcision (VMMC) target for 2018 [1] with a national VMMC program adverse event (AE) rate of 0.35% [2]. Non-surgical male circumcision (MC) devices, such as Pre ex, have the potential to accelerate adult VMMC programme scale up. In pilot studies and controlled trials in sub-Saharan Africa, moderate and severe AE rates from device-based MC range from 0-5.9% [3-9] with few severe AEs resulting in permanent impairment.

Pre ex ~~may be~~has been shown to be faster, ~~simpler~~more simple to implement, and more cost effective ~~as~~ when compared to surgical ~~circumcision~~ MC [10-12] and may be safely applied by less highly trained~~lower~~ cadres of nurses and clinicians [7, 13, 14]. In some contexts, ~~D~~devices, such as PrePex, ~~also~~ appear more acceptable than surgical MC as they do not cause prolonged pain [6] nor interrupt activities of daily living for most clients [5]. Pre ex has also proven safe and effective [3-5]. For these reasons, PrePex offers an important tool to accelerate VMMC programs to meet targets especially in men over age 15 years. Zimbabwe piloted the Pre ex device in a series of clinical trials from October 2011 to establish its safety and efficacy for VMMC among HIV-negative adults [15] and adolescents [16]. To date, WHO pre-qualification supports PrePex for circumcision of HIV negative adult men [17].

Stigma associated with identification as HIV-positive is a major barrier to the scale up of VMMC ~~in Zimbabwe~~, including the use of PrePex. While HIV testing is usually not a precondition to being circumcised in national VMMC policies, in practice virtually all men are HIV tested prior to circumcision, and some men report~~may~~ avoiding VMMC because they do not want to be HIV tested~~of the strong suggestion to~~perception that ~~HIV testing as part of VMMC counseling by both MC clients and providers~~ [18, 19]. If PrePex is shown to be safe among HIV-positive men, ~~promotion of~~provider initiated HIV testing would continue, but messaging about the perceived mandate for HIV testing before the procedure would be adapted, and the importance of this practice would diminish. Moreover, as VMMC scales up, excluding HIV-positive men in VMMC programs could increase stigmatization. To avoid indirect identification, HIV-positive men might seek MC surgery from potentially unsafe sources to mask their sero-status. ~~Similarly, cHIV-uninfected men might use their circumcision status to negotiate unsafe sex.~~ Therefore, establishment of the safety of use of PrePex for VMMC of HIV-positive men would be advantageous ~~in Zimbabwe and the region~~.

There is some evidence to support the safety of surgical VMMC in healthy, HIV-positive men [20-22], but ~~MC~~ research on the safety of MC among HIV-positive adults is limited, especially in the context of MC devices. This lack of evidence is most acute in countries in the African region where rapid expansion of male circumcision programmes is most urgent. Therefore, we conducted a one-arm, open-label, prospective, cohort field study to assess the safety, acceptability and feasibility of the PrePex device among HIV-positive adult men. The primary objective was to assess the safety of the PrePex device as measured through moderate or severe AEs among HIV-positive men in order to. ~~The results will~~ inform policy and clinical practice pertaining to HIV testing among men seeking circumcision.

Methods

(b)(5)

(b)(5)

Comments from P Kilmarx – January 23, 2017

(b)(5)

HIV + STUDY ADVERSE EVENTS

Device-related Adverse Events

Participant 1: Self-removal

The participant was an informal vendor, 35 years of age and was of WHO clinical stage 1. His CD4 count on day of device placement was 497c/µl and was referred to the OI clinic since he was not on ART. The participant had a size E device applied on him on 26 October 2015 after all the study processes and procedures were met. On day 7 after device placement (2 November 2015), the participant did not turn up for the scheduled visit and so was followed up. It was discovered that the participant was in Mozambique and had removed the device on day 3 after device placement. On 3 November 2015, the client came at the site. On examination, swelling and necrotic of distal foreskin was noted. Debridement and secondary suturing was done. He was encouraged to come for daily G&I dressing. He was given Cloxacillin and Ibuprofen for pain. On the second day after suturing, the participant did not turn up for bandage removal. He was picked up from home and was seen by a doctor who ordered dressing with Betadine and was given Ciprofloxacin. After two days he came and bandage was removed and wound cleaned with Betadine solution. Client was instructed to do saline baths and to abstain from sexual intercourse. Complete wound healing was noted on day 37 after device placement. This event was reported to MRCZ.

Participant 2: Device Displacement

The participant, an unmarried man 39 years of age, had device size A applied on 2 November 2015. All the vital signs were fine on day of screening. He was of WHO clinical stage 2 and had a CD4 count of 172 c/µl. He was on first line of ARVs and was taking Tenolam E and Cotrimoxazole. He had been on ART for one year eleven months. Before device placement, he underwent a psychosocial interview and portrayed some good understanding of the procedure. The participant did not turn up for device removal on the scheduled day. On day 8, the participant was visited at home but he was not there. A message was left for him to visit the clinic. The participant was picked up from home on day 9 post placement. He said the device had been completely displaced on day 1 but had only noticed it the following morning. On examination the device displacement resulted in partial necrosis of the foreskin with gross oedema. There was no ulceration or evidence of sepsis noted. Dorsal slit circumcision was done and closed with 3/0 vicryl on a cutting, dressed with paraffin gauze. Participant came for weekly review visits and seen to be completely healed on day 28. This event was reported to MRCZ.

Participant 3: Device Displacement

All vital signs were normal on day of placement. He was on clinical stage 2 and had a CD4 count of 164 c/µl. He was on first line of ARVs and was taking Tenolam E. He had been on ART since 9 November 2009. The participant had size C device placed on 18 March 2016. The adverse event occurred while he was at home with the device on. The device had displaced on fifth day

after placement. Participant said the device moved while scratching the penis which was itchy post placement. On examination of the site, foreskin was in full retraction and swollen distal to the device. Swelling of shaft and glands could be seen. No septic sores were noted. Surgical circumcision using the sleeve method was done. Sutured with 2/0 Vicryl and dressed with paraffin gauze. On day 7, the participant came for review. Sutureline was septic and graying in the frenular area. Swelling subsided, discolouring of the skin L 0.5cm between the ring line and swollen line (Black band) was noted. Participant was advised on cleaning the wound with salty water. On day 42, client was completely healed. This event was reported to MRCZ.

Participant 4: Device Displacement

The participant was a 32 year old married man who had size C device placed on 24 March 2016. On day of device placement, the participant had a CD4 count of 283 c/µl, was of WHO clinical stage 1 and was taking first line ARVs, Tenolam E and Cotrimoxazole. He had been initiated on ART on 20 March 2016. The adverse event occurred while the participant was at home with the device on. The participant came on the 28th of March reporting that the device came off on third day after placement while taking a shower. On examination of the site, foreskin was in full retraction. Gross swelling of the penile shaft was noted but was not septic. Dorsal slit was done under local anaesthetic Lignocaine 2% and Bupivacaine 0.5%. Haemosthasis was achieved and suturing with 3.0 Vicryl done. Dressing of the wound was done and participant instructed to return on day 2 post operatively. Participant was given some Ciprofloxacin and Brufen. On day 9 post device placement, participant came for review and bandage was removed and participant was encouraged to start salt baths. Sutures were intact. On day 12 post device placement, the wound area had no sutures and was septic. The doctor ordered daily G&I dressings and was given Cloxacillin 500mg. Participant was completely healed on day 52 post device placement. This event was reported to MRCZ.

Adverse Events not related to the device

(b)(5)

Participant 5:

The participant a married 45 years of age man was of WHO clinical stage 2 and on first line of ARVs taking Tenolam E. He had been initiated on ART on 30 October 2012. His CD4 count on day of device placement was 361 c/µl. The participant had size C device applied on 1 February 2016. The device was successfully removed on day 7 post placement and experienced pain level VAS 2 when the device was being removed. The participant came for all scheduled visits and did not report any pain. On day 37 post device placement, the participant came for a review visit but complained of difficulty in passing urine and was referred to the doctor. Upon further investigations, the problem had started in September 2015 before he came for circumcision. He had complete obstruction about 28 days post device placement. Upon realizing his problem, he had gone to Karanda Mission Hospital where catherisation was unsuccessful but urine started coming out. He was experiencing pain towards the meatal opening when passing urine. On examination the bladder was not full but had some suprapubic tenderness. USS done at a private hospital showed significant urine retention of about 59%. There were no stones seen. The diagnosis was urethral stricture with unknown immediate cause. An ultrasound was done and participant was referred to Parirenyatwa OPD urology. Participant was completely healed on day 49 post device placement. This event was reported to MRCZ.

Participant 6:

The participant was a 33 year old man who had a size C device applied on 4 April 2016 after all the study processes and procedures were met. On day of device placement, the participant had a CD4 count of 256 c/µl, was of WHO clinical stage 1 and was taking first line ARVs, Tenolam E. He had been on ART for about four and a half years. Participant healed on 9 May 2016, 35 days after device placement. The adverse event occurred while participant was killed in a road traffic accident at home on the 5th of June 2016, nearly 60 days after circumcision. The study team only got to know about it on the 4th of July after trying to contact the participant to remind him of the last review visit which had been scheduled for that day. This event was reported to MRCZ.

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Caryl Feldacker <cfeld@UW.EDU>
Subject:	RE: BLT/2016/184218 Acknowledgment of Manuscript
Date:	2017/01/19 17:21:00
Priority:	Normal
Type:	Note

Thanks Amy.

Caryl - I'm now back in the loop on this.

Cheers,
PK

-----Original Message-----
From: Herman-Roloff, Amy (CDC/CGH/DGHT) [mailto:bjy2@cdc.gov]
Sent: Thursday, January 19, 2017 8:33 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: BLT/2016/184218 Acknowledgment of Manuscript

For your records...

-----Original Message-----
From: bulletin.submit.ask@who.int [mailto:bulletin.submit.ask@who.int]
Sent: Monday, August 29, 2016 12:22 PM
To: Caryl Feldacker <cfeld@uw.edu>
Cc: Batsirai Makunike <bmakunike@itech-zimbabwe.org>; Marrianne Holec <mmholec@uw.edu>; Aaron Bochner <bochner@uw.edu>; Abby Stepaniak <arstep@uw.edu>; Robert Nyanga [Redacted by agreement]; Sinokathemba Xaba [Redacted by agreement]; Peter Kilmarx <pbk4@cdc.gov>; Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Taurayi Tafuma <yih0@cdc.gov>; Mufata Tshimanga [Redacted by agreement]; Vuyelwa Chitimbire <chitimbire@zach.org.zw>; Scott Barnhart <sbht@uw.edu>
Subject: BLT/2016/184218 Acknowledgment of Manuscript

Dear Dr. Feldacker

MS ID#: BLT/2016/184218
MS TITLE: Implementing voluntary medical male circumcision using an integrated, health systems approach: Experience from 21 districts in Zimbabwe

Thank you for the manuscript you have submitted to the Bulletin of the World Health Organization.

This manuscript is being considered. To follow the progress of your paper please go to: http://submit.bwho.org and log in to your Author Area.

If you have not registered with the system please click on 'Create a new account'.
If you require any assistance with the registration process, please contact the editorial office at bulletin.submit.ask@who.int.

We thank you for your interest in the World Health Organization and the Bulletin.

Yours sincerely
Bulletin of the World Health Organization

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Herman-Roloff, Amy (CDC/CGH/DGHT) <bjy2@cdc.gov>; Caryl Feldacker <cfeld@UW.EDU>
Sent Date:	2017/01/19 17:21:46

Delivered Date:	2017/01/19 17:21:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Herman-Roloff, Amy (CDC/CGH/DGHT) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=bjy2 <bjy2@cdc.gov>
Subject:	RE: PLOS ONE: Notification of co-authorship on manuscript - [EMID:bcb3e5dd9b59e1a9]
Date:	2017/01/17 17:36:00
Priority:	Normal
Type:	Note

Hi Amy,
Greetings from Bethesda!

I'm updating my papers-in-progress list.

Do you know what happened to this one - Feldacker?

I've asked others about them, but would also be interested if you have any news about TASP or ZIMPHIA - the world AIDS day results were exciting, but interested in status of manuscripts (and authorship).

I hope all is well with you guys.

PK

From: PLOS ONE <em@editorialmanager.com>
Sent: Tuesday, October 6, 2015 12:25 PM
To: Peter Kilmarx
Reply To: PLOS ONE
Subject: PLOS ONE: Notification of co-authorship on manuscript - [EMID:bcb3e5dd9b59e1a9]

PONE-D-15-43969
Implementing voluntary medical male circumcision using an integrated, health systems approach: Experience from 21 districts in Zimbabwe
Dr. Caryl Feldacker

Dear Peter Kilmarx,

You are receiving this email because you have been listed as an author on a manuscript recently submitted to PLOS ONE and entitled "Implementing voluntary medical male circumcision using an integrated, health systems approach: Experience from 21 districts in Zimbabwe".

The corresponding author for the submission process is: Dr. Caryl Feldacker

The full author list for the submission is: Caryl Feldacker, PhD; Batsirai Makunike; Marrianne

Holec; Aaron Bochner; Abby Stepaniak; Robert Nyanga; Sinokuthemba Xaba; Peter Kilmarx; Amy Herman-Roloff; Taurayi Tafuma; Mufuta Tshimanga; Vuyelwa Chitimbire; Scott Barnhart

If you are not aware of this submission, or if you should not be listed as a co-author, then please contact the journal office at plosone@plos.org.

Kind regards,
PLOS ONE
http://pone.edmgr.com/

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Herman-Roloff, Amy (CDC/CGH/DGHT) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=bjy2 <bjy2@cdc.gov>
Sent Date:	2017/01/17 17:36:53
Delivered Date:	2017/01/17 17:36:00

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Katz, Flora (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=katzf <katzf@mail.nih.gov>
Subject:	FW: FW: New projects in Kenya, Tanzania, and more from intrahealth.org
Date:	2016/10/31 15:48:00
Priority:	Normal
Type:	Note

FYI – attachment.

From: Ariel Pablos-Mendez [mailto:apablos@usaid.gov]
Sent: Monday, October 31, 2016 11:14 AM
To: Glass, Roger (NIH/FIC) [E] <glassr@mail.nih.gov>
Cc: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>; Frymus, Diana (GH/OHA/SPER) <dfrymus@usaid.gov>
Subject: Re: FW: New projects in Kenya, Tanzania, and more from intrahealth.org

Dear Roger,

Our USAID Kenya Mission has had extensive investments in HRH. The new award builds on previous ones and other ongoing awards. Intrahealth has been a key partner in Kenya. More information on the work supported in HRIS, Human Resource Management including an emergency hiring plan for health workers, Pre-Service Education can be found here. Also attaching a briefer with more information.

HIV funding is a major component of our HRH programs. Unfortunately, there hasn't been NIH participation on the PEPFAR HRH TWG for over a year which has limited our engagement.There are many ongoing discussions with OGAC regarding funding approvals for all agency HRH HOP activities and ensuring coordination and preventing duplication. I am looping in Diane Frymus, our POC in this area and quite involved with global HRH strategy as well. Our missions would appreciate more engagement with MEPI.

Cheers,,

Ariel

Ariel Pablos-Méndez, MD, MPH
Assistant Administrator for Global Health
Child and Maternal Survival Coordinator
U.S. Agency for International Development
Washington, D.C.
Tel: +1 (571) 551-7060
Email: apablos@usaid.gov

On Sun, Oct 30, 2016 at 2:22 AM, Glass, Roger (NIH/FIC) [E] <glassr@mail.nih.gov>wrote:
Hello Ariel,

We just learned around this amazing investment by USAID in Kenya and Tanzania. Could you tell us more and see how this interacts or might interact with our MEPI activities in these countries. One big difference is that the MEPI grants went directly to the schools in Africa which has really empowered their leadership to do amazing things together. I wonder if there might be some real scope or though to link these activities in the field. towards a common vision.

Best.

Roger

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Friday, October 28, 2016 11:38 AM
To: McDermott, Jeanne (NIH/FIC) [E]; Katz, Flora (NIH/FIC) [E]
Cc: Glass, Roger (NIH/FIC) [E]; Wallick, Stacy (NIH/FIC) [E]
Subject: RE: New projects in Kenya, Tanzania, and more from intrahealth.org

Thanks Jeanne. That's a significant investment by USAID.

Through a new five-year, $37.8 million award from the US Agency for International Development, IntraHealth International and its partners will strengthen health professional training programs and health workforce management systems throughout Kenya to help the country improve the health of its citizens.

PK

From: McDermott, Jeanne (NIH/FIC) [E]
Sent: Friday, October 28, 2016 11:11 AM
To: Katz, Flora (NIH/FIC) [E] <katzf@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: New projects in Kenya, Tanzania, and more from intrahealth.org

See new award to INTRAH for Kenya to "...work with our local partners to increase the number of students graduating from Kenya's health training institutions and improve the quality and applicability of their training to the country's disease burden. We will also work with national and county-level leaders to improve health workforce management and leadership and to strengthen the ability of health sector leaders to access and use health workforce and epidemiological data to make informed and effective decisions.

More details at https://www.intrahealth.org/page/new-project-in-kenya-will-bring-health-care-to-the-countrys-most-vulnerable-

Jeanne McDermott MPH PhD
Program Officer, Div of Training and Research
Fogarty International Center, NIH
Bldg 31 Rm B2 C39 , 31 Center Dr. MSC 2220
Bethesda MD 20892-2220 USA
301 496-1492, 301 402-0779 (FAX)
jeanne.mcdermott@nih.gov
I telework on Fridays and can be reached via email

From: IntraHealth International [mailto:intrahealth=intrahealth.org@mail83.suw17.mcsv.net] **On Behalf Of** IntraHealth International
Sent: Friday, October 28, 2016 10:16 AM
To: McDermott, Jeanne (NIH/FIC) [E] <mcdermoj@mail.nih.gov>
Subject: New projects in Kenya, Tanzania, and more from intrahealth.org

IntraHealth Awarded $123 Million to Improve Health Care and Fight Disease around the World

Major new awards from the US government, foundations, and the private sector are expanding IntraHealth's impact globally as it strengthens health systems, addresses the health worker shortage, and fights disease around the world.

NEWS &FEATURES

New Project in Kenya Will Bring Health Care to the Country's Most Vulnerable

With a new five-year, $37.8 million award from USAID, IntraHealth will help counties build the health worforces they need to expand health services and reach more people in need.

Tohara *Plus* to Provide HIV-Prevention Services to More than 412,000 Tanzanians

Through a new five-year award from the US Centers for Disease Control and Prevention, IntraHealth will strengthen and scale up a comprehensive package of high-quality, safe services for voluntary

INTRAHEALTH ON TUMBLR

INTRAHEALTH BLOG POSTS

Out-of-School Youth: Often Forgotten in Reproductive Health Programs

Under a Shade Tree in Mali, Women with Fistula Recover Together

WASH Works, So What Are We Waiting For?

A Death in Durham Stirs Drive to Prevent Intimate Partner Violence

medical male circumcision among adolescents and adult men in Tanzania.

Turkana County: The Face of Kenya's Health Worker Boom

It used to be where Kenyan health workers who stepped out of line were sent as punishment. But today, Turkana County has become the go-to place for health workers. Here's how it happened.

UN Security Council Should Take Immediate Action to Protect Health Workers and Health Care in Conflict

Recently the United Nations Security Council held a briefing on Resolution 2286, which it passed in May 2016 to condemn attacks on health care. Yet despite the resolution, such attacks continue at an alarming rate, including airstrikes in September in Aleppo, Syria, that destroyed the two largest remaining hospitals.

It only takes $300 to train 10 health workers to use mSakhi. Donate today through CaringCrowd and your donation will be matched up to $250.

Interested in what you've read and want to help us do more? Investing in health workers, especially those on the front lines of care, is one of the most cost-effective and sustainable ways to improve health and save lives. Consider making a donation today.

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Katz, Flora (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=katzf <katzf@mail.nih.gov>
Sent Date:	2016/10/31 15:49:00
Delivered Date:	2016/10/31 15:48:00

COUNTRY BRIEF

IntraHealth INTERNATIONAL
Because Health Workers Save Lives.

KENYA

The Government of Kenya has set ambitious targets for providing essential health services to all its citizens. It has a plan to slash the country's persistently high maternal, child, and newborn mortality rates by 2030, combat infectious and noncommunicable diseases as well as expand the use of reproductive health and family planning services. Kenya is also committed to accelerating its progress combatting HIV and AIDS.

To meet these goals, Kenya must ramp up and improve access to and quality of health care throughout the country. Kenya needs to produce and retain more health workers; update the skills and support the performance management system of its existing health workforce; and build capacity at the county level for planning, deploying, and managing an effective health workforce.

IntraHealth International has worked in Kenya for over 30 years strengthening health workforce systems at the national and county levels to align Kenya's health workforce with the most pressing health care needs of its citizens. Our work has focused on improving the availability and quality of family planning, HIV/AIDS, and maternal, newborn, and child health (MNCH) services.

FUNZOKenya (2012–2017)

Through the USAID-funded FUNZOKenya project, IntraHealth works with the Kenyan government to strengthen preservice education of health workers, improve access to and quality of in-service training, build capacities of training institutions and faculty, and link licensure to professional development across the health system. For example, we:

- Establish regional training hubs that have updated 8,000+ health workers in critical areas such as HIV, family planning, and MNCH.
- Improve the supply of health workers by forecasting the number of new health workers required and working with training institutions to increase their admissions capacities.

47 counties are strengthening human resources for health policies, guidelines, and management systems.

8,000+ health workers received in-service training on topics such as HIV, MNCH, and family planning at eight regional training hubs.

5,000+ students received loans making their schooling to become health workers possible.

- Develop scholarship and loan programs to increase the supply of health workers through the Afya Elimu Fund. To date, 341 students have benefited from scholarships and more than 5,000 students have accessed loans.
- Harness technology to support 15 training institutions to develop and deliver up-to-date technical content and curricula through new teaching modalities as well as eLearning and mLearning.
- Improve service delivery by strengthening regulatory agencies' abilities to identify performance gaps, review curricula, and reinforce the link between continuing professional development and registration/relicensure.
- Develop the iHRIS Train database, which contains records for nearly 12,000 health workers, to provide data for improving efficiencies and filling training gaps.

Human Resources for Health (HRH) Capacity Bridge Project (2014–2015)

The USAID-funded project builds on the successes of the previous Capacity Kenya project by strengthening HRH systems at the national and county levels. We partner with county governments, USAID implementing partners, the public and private sectors, and faith-based organizations to build an adequate, skilled, and equitably distributed health workforce. The project's multilevel interventions improve health workforce management through strengthening national- and county-level HRH functions and rolling out an HRH information system based on IntraHealth's iHRIS software. For example, we:

- Provide HRH leadership by convening donor and partner coordination meetings and establishing an HRH technical working group.
- Provide technical assistance to develop HRH policies and guidelines at the national and county levels.
- Establish five functional HRH Inter-Agency Coordination Committees involving 34 counties.
- Develop interoperability between iHRIS and the AfyaInfo District Health Information Systems (DHIS-2) to link facility-level workload indicators to service delivery statistics.
- Provide iHRIS training to county health personnel to improve human resources data and use of iHRIS for decision-making.
- Facilitate the transition of 837 health workers originally deployed under Capacity Kenya to 43 county government payrolls.

Improving Reproductive Health Commodity Management (2015–2016)

Through an Innovation Fund grant awarded by the Reproductive Health Supplies Coalition, IntraHealth is improving reproductive health commodity management in the North Rift Region. This project is developing an eLearning course, building the capacities of supply chain managers through eTraining and mentoring, and strengthening county capacity to budget for commodities and monitor supply chain management performance.

Measurement Learning and Evaluation (2013–2015)

IntraHealth partners with the University of North Carolina at Chapel Hill on this Bill & Melinda Gates Foundation-funded project to promote evidence-based decision-making in designing urban family planning and reproductive health interventions.

CapacityPlus (2009–2015)

Through the USAID-funded, IntraHealth-led CapacityPlus project, IntraHealth analyzes Kenya's existing social welfare workforce relative to the needs of the country's vulnerable children. The analysis identifies gaps in service delivery and technical skills and provides a roadmap to inform the government as it plans, designs, and supports a more robust social welfare workforce.

Pfizer Global Health Fellows Program

Since 2006, IntraHealth has partnered with Pfizer's international corporate volunteer program, which places Pfizer employees in short-term assignments with leading international development organizations.

Past projects and funders

- Capacity Kenya 2009–2014 (USAID)
- Capacity Project 2004–2009 (USAID)
- APHIA II North Eastern Province 2007-2012, sub to Pathfinder International (USAID)
- PRIME II 1999–2004 (USAID)

CONTACT

Meshack Ndolo
Country Director, Kenya
Chief of Party, HRH Kenya Project
mndolo@intrahealth.org
+254-203746845

IntraHealth INTERNATIONAL
Because Health Workers Save Lives.

www.intrahealth.org/page/kenya

August 2015

From:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
To:	Dominguez, Ken (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:kld0@CDC.GOV>
Subject:	Fwd: Critical Evaluation of Adler¹s Challenge to the CDC¹s Male Circumcision Recommendations
Date:	2016/08/01 20:34:59
Priority:	Normal
Type:	Note

Hi Ken,
Greetings from Bethesda!

Here's a publication of interest. Do you know when the CDC recommendations will be finalized? August is always a good time for it.

Best wishes, PK

Peter Kilmarx
Fogarty International Center, NIH

Begin forwarded message:

From: Brian Morris <brian.morris@sydney.edu.au>
Date: August 1, 2016 at 20:03:38 EDT
To: Brian Morris <brian.morris@sydney.edu.au>
Subject: Critical Evaluation of Adler¹s Challenge to the CDC¹s Male Circumcision Recommendations

http://booksandjournals.brillonline.com/content/journals/10.1163/15718182-02402004;jsessionid=1dcgw13ijubvm.x-brill-live-02

Critical Evaluation of Adler's Challenge to the CDC's Male Circumcision Recommendations

image of The International Journal of Children's Rights

• **Authors:** Beth E. Rivin[1]; Douglas S. Diekema[2]; Anna C. Mastroianni[3]; John N. Krieger[4]; Jeffrey D. Klausner[4] **and** Brian J. Morris[5]
• **Source:** The International Journal of Children's Rights, Volume 24, Issue 2,**pages** 265 – 303 **Publication Year :** 2016
• **DOI:** 10.1163/15718182-02402004
• **ISSN:** 0927-5568 **E-ISSN:** 1571-8182
• **Document Type:** Research Article
• **Subjects:** Human Rights &Humanitarian Law
• **Keywords:** policy; male circumcision; critical perspective; Centers for Disease Control and Prevention; children's rights
• Subscription and article submission information

We evaluate Peter Adler's challenge to the Centers for Disease Control and Prevention (CDC) draft recommendations on male circumcision (this issue, see pp. 237–262). The CDC advocates elective male circumcision (MC) to improve public health in the USAbased on strong scientific evidence. In marked contrast to the CDC, Adler's criticisms depend on speculative claims and obfuscation of the scientific data. Adler's central argument that circumcision in infancy should be delayed to allow a boy to make up his own mind as an adult fails to appreciate that circumcision later in life is a more complex operation, entails higher risk, is more likely to involve general anaesthesia and presents financial, psychological and organisational barriers. These limitations are avoided by circumcision early in infancy, when it is convenient, safe, quick, low risk, usually involves local anaesthesia and provides benefits immediately. Benefits of male circumcision include: protection against: urinary tract infections that are ten times higher in uncircumcised infants; inflammatory skin conditions; other foreskin problems; sexually transmitted infections and genital cancers in the male and his female sexual partners. Circumcision during infancy is also associated with faster healing and improved cosmetic outcomes. Circumcision does not impair sexual function or pleasure. Some authorities regard the failure to offer circumcision as unethical, just as it would be unethical to fail to encourage paediatric vaccination. Since the benefits vastly outweigh the risks, each intervention is in the best interests of the child. In conclusion, Adler's criticisms of the CDC's evidence-based male circumcision policy are flawed scientifically, ethically and legally, and should be dismissed as endangering public health and individual well-being.

Affiliations: 1: University of Washington School of Law, Seattle, Washington, USA brivin@uw.edu ; 2: Treuman Katz Center for Pediatric Bioethics, Seattle Children's Hospital, Seattle, Washington, USA diek@uw.edu ; 3: Section of Urology, VA Puget Sound Health Care System and School of Medicine, University of Washington, Seattle, Washington, USA amastroi@uw.edu ; 4: Division of Infectious Diseases, Department of Medicine, David Geffen School of Medicine, University of California Los Angeles, California, USA, jkrieger@uw.edu; jdklausner@mednet.ucla.edu ; 5: *Brian J. Morris* DSc PhD, Professor Emeritus, School of Medical Sciences, Building F13, University of Sydney, New South Wales 2006, Australia

Introduction

GO TO SECTION

We evaluate an article by Peter Adler (Adler, 2016), a legal advisor for an anti-circumcision organisation. His article attempts to undermine draft recommendations favouring male circumcision

(mc) in the United States that were developed by the Centers for Disease Control and Prevention (cdc) after a thorough evaluation of the scientific evidence (Centers, 2014). The cdc's document supports the policy statement on infant mc (imc) from the American Academy of Pediatrics (aap) in 2012 which found that the benefits of imc outweigh the risks (American, 2012a).

Adler claims, 'the draft cdc recommendations are not medically correct, ethically sound, legally permissible, or procedurally valid'. He goes on to say, 'accordingly they should not be implemented and would be legally invalid if they are'. His statement that the cdc's draft recommendations, 'provide erroneous and misleading advice to physicians that exposes them to the threat of lawsuits [1] by men and parents', is based on fallacious arguments propagated by the anti-circumcision lobby. Adler refers to, 'thousands of official [?] comments [that] have been filed opposed to the cdc proposal', and, 'public protests against it'. This simply reflects the efficient use of social media by anti-mc groups to mobilise their members, most of whom are lay activists whose *modus operandi* is akin to childhood vaccination opponents. Almost all of those comments were short, repetitious and lacked scientific merit or legal foundation for us policy. Policy should be decided on scientific evidence and current law, not public protests by fringe groups. Adler's conclusion is that, the cdc must revise its draft guidelines to comport with the prevailing view that circumcision is on balance deleterious to health; that men have the right to make the "circumcision decision" for themselves; that physicians are not permitted to circumcise healthy boys; and that Medicaid cannot be used to pay for unnecessary surgery.

Below, we summarise the scientific and legal evidence that contradicts each of Adler's arguments.

1 Medically Justified?

GO TO SECTION

1.1 Unscientific and Isolated Medical Opinion?

1.1.1 Undisclosed and Unaddressed Criticisms?

Adler cites, 'a group of 38 distinguished physicians from Europe and Canada' [2] (Frisch *et al.*, 2013) who criticised the aap's imc policy, that the cdc supported. He fails to mention that the aap responded at the time, arguing convincingly that a cultural bias against imc is more likely to exist in Europe than cultural bias favouring imc in the usa, since the usa comprises similar

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Balachandra, Shirish (CDC/CGH/DGHT) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=ymx1 <ymx1@cdc.gov>
Subject:	RE: your thoughts?
Date:	2016/06/24 11:14:51
Priority:	Normal
Type:	Note

Hi Shirish,
Nice to hear from you.

I like it! A few suggestions attached.

AIDS Care or AIDS Behavior are good choices for this. You could start higher and at least hope for quick responses.

Thanks for inviting me to join. As you know, I already have a number of ongoing interests/papers in Zimbabwe and probably would be best not to add to that. I don't think my inclusion would change the journal outcomes.

Sorry won't see you in DUR. Get in touch if you are here when I am.

Cheers,
PK

From: Balachandra, Shirish (CDC/CGH/DGHT)
Sent: Tuesday, June 21, 2016 5:37 PM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: your thoughts?

Hi Peter!
I hope you're well. DGHT Annual Meeting a couple weeks back was a very good experience, but I kept thinking I'd run into you there. Anyway, as I alluded to before, I wanted your eyes and ideas on something… take a look at the attached. The authors will be myself, Beth, Nicola Willis and Joseph Murungu. I'm just waiting for Beth's input, but otherwise I think it's nearly final. Please tell me what you think… I'm not sure about where to submit. Beth was checking into this thing called JANE that gives guidance on manuscript submissions, and its suggestion was AIDS Care, because stigma was a central theme. This may be best. But I guess I was naively thinking that we could get a larger readership given the Ministry's co-authorship… but I don't know if Lancet, BMJ, etc. welcome "uninvited commentary." What say you? And, it goes without saying that you're welcome to jump aboard if you have significant suggestions on content and/or if your co-authorship can bump us into a higher weight class ☺

Many thanks,
Shirish

Shirish Balachandra, MD
Branch Chief, HIV Services
U.S. Centers for Disease Control and Prevention, Zimbabwe
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38 Samora Machel Avenue
Harare, Zimbabwe
Tel +263-4-796-040
Cell [redacted]

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Sent Date:	2016/06/24 11:14:50
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Page 402 of 561 to Page 404 of 561

Withheld pursuant to exemption

(b)(4) ; (b)(6)

of the Freedom of Information and Privacy Act

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
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Subject:	Integrated health care innovations in Africa!
Date:	2016/06/17 14:38:44
Priority:	Normal
Type:	Note

John and Roger – thought you would appreciate this photo from Zimbabwe. Actually, the Indian Avarind Eye Care System has trained male circumcision providers.

Best,
PK

https://scontent.xx.fbcdn.net/v/t1.0-9/13418999_10207969229762186_5713791870906831678_n.jpg?oh=d7b8006d696844781c4325c9a771be2b&oe=57E2795E

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Sent Date:	2016/06/17 14:38:43
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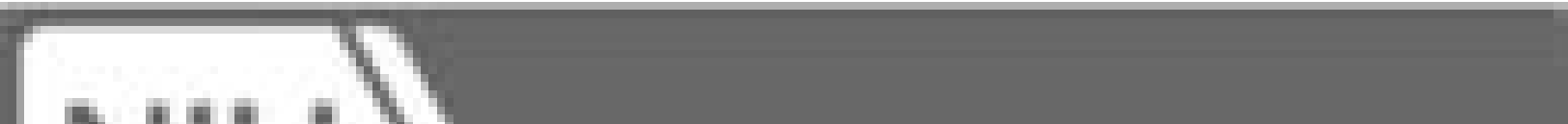
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CC:	Brandon O'Dell <b.odell@joeplangeinstitute.org>
Subject:	RE: Manuscript about INTEREST 10
Date:	2016/06/06 13:36:24
Priority:	Normal
Type:	Note

Thanks Cate for outstanding report, remarkably quickly produced.

My few comments attached. If you need to shorten a little, the emerging infections part could be reduced or cut since it is not strictly related to the overall theme of ending AIDS as a public health threat by 2030.

Best to all!

PK

Peter H. Kilmarx, MD, FACP, FIDSA
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From: Catherine Hankins
Sent: Saturday, May 28, 2016 2:54 AM
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Anna Laura Ross Redacted by agreement ; Kenly Sikwese Redacted by agreement ; Mauro Schechter
Redacted by agreement ; Charles Boucher Redacted by agreement coumba kane
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Cc: Brandon O'Dell <b.odell@joeplangeinstitute.org>
Subject: Manuscript about INTEREST 10

Hi everyone,
Trust this finds you all fine as May comes to a close. The long report for the 10th INTEREST Workshop will have links to all the presentations that will be posted on the http://interestworkshop.org/ website. In the meantime, attached is a draft scientific manuscript that I have edited from a preliminary draft based on the long report.

We are asking all international and scientific organizing committee members who attended INTEREST 2016 if they would like to be a co-author. If you are interested, you will need to read the manuscript and provide comments. I have approached the editors but have not heard back yet on whether this might need to be shortened so if you see areas that could be shortened, please feel free to let me know. It would be helpful if you could get back to me by June 15th about whether you would like to be co-author and any changes that you propose.
All the best,
Cate

Catherine Hankins MD PhD FRCPC CM
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Sent Date:	2016/06/06 13:36:24

Comments – PK – June 6, 2016

The 10th International Workshop on HIV Treatment, Pathogenesis and Prevention Research in Resource-Limited Settings (INTEREST) in Yaoundé, Cameroon

Authors: to be determined

The goal to end AIDS as a public health threat by 2030(1) was the underpinning theme of the 10th International Workshop on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Limited Settings (INTEREST) held in Yaoundé, Cameroon, 3-6 May 2016[1]. Spirited debates on the UNAIDS 90-90-90[2] treatment cascade goal for 2020(2) and on the place of antiretroviral pre-exposure prophylaxis (PrEP) took place along with presentations on treatment optimisation, acquired drug resistance, care of children and adolescents, laboratory monitoring and diagnostics, implementation challenges, HIV prevention, key populations, vaccine and cure, hepatitis C, mHealth, financing the HIV response, and emerging pathogens(3). Presentations and videos are available at www.interestworkshop.org.

(b)(5)

The meeting attracted 509 registrants and 369 active delegates from 22 African countries, Cameroon, South Africa, Nigeria, Cote D'Ivoire, Kenya, Uganda, Zambia, Zimbabwe, Botswana, Ghana, Senegal, Tanzania, Benin, Burkina Faso, Congo, Gabon, Guinea, Liberia, Malawi, Namibia, and Rwanda, and Swaziland, along with participants from the Netherlands, the USA, the United Kingdom, France, Switzerland, Germany, Italy, India, Brazil, Turkey, Canada, and Singapore, a total of 34 countries.

In addition to 8 oral abstract presentations and 18 poster discussion presentations (mini-orals) in the main programme, the 10th INTEREST Workshop offered parallel early morning sessions on three mornings. The Joep Lange research career guidance sessions saw mid-career and senior investigators explain how they got started on a research career and give advice on how to get funded, choose a mentor, and get published. Research grantspersonship sessions were presented by the ANRS (France Recherche Nord & Sud Sida-hepatites), the Fogarty International Center, U.S. National Institutes of Health\Fogarty), and the EDCTP (European & Developing Countries Clinical Trials Partnership.

HIV in Cameroon

Following the opening of the meeting by the Cameroon Minister of Public Health, André Mama Fouda, the Permanent Secretary of the National AIDS Programme, Dr. JB Elat, presented an overview of HIV in Cameroon. With a population currently estimated at 22.2 million, HIV prevalence in 2011 was 4.3%, with urban populations and women disproportionately affected: 5.6% of women vs. 2.9% of men. In 2014, 34,158 people died of AIDS. An estimated 320,000 children have been orphaned by HIV. Comparing HIV prevalence in key populations to the general population, men who have sex with men (MSM) have 8-14 times higher (24-44%), truck drivers have five times higher (16%), and female sex workers (FSW) have six times higher (36%) HIV prevalence. Clients of FSW account for

[1]Please see www.interestworkshop.org

[2]90-90-90 refers to the targets of 90% of people living with HIV knowing their serostatus, 90% of those who know they are HIV-positive being on antiretroviral treatment (ART), and 90% of those on ART achieving viral suppression. This translates into 70% of all people living with HIV being virally suppressed.

36% of new HIV infections annually. The Cameroon national AIDS programme was established a year after the first case of HIV infection was identified in 1985. After the antiretroviral treatment (ART) programme began in 2000, HIV prevalence fell by 20% between 2004 and 2011 from 5.5% to 4.3%. Prenatal consultations for prevention of mother-to-child transmission (PMTCT) have increased steadily since 2009, with attendance reaching 74% in 2015. Between 2005 and 2015, the number of people on ART increased ten-fold and approximately 7000 children now receive ART. In 2015, 882,639 Cameroonians were tested for HIV. Cameroon is working towards the UNAIDS 90-90-90 goals by increasing access to HIV testing and treatment services, reducing stigma, strengthening the supply chain, tailoring HIV prevention for key populations, and building civil society capacity.

(b)(5)

Achieving the UNAIDS 90-90-90 targets by 2020

The passionate debate that took place about whether the targets can be achieved addressed factors that may prevent this such as insufficient resources (human, infrastructure, financial), inability to reach all people living with HIV (PLHIV) and retain them in care, the risk of emerging drug resistance, and international donor fatigue. Optimists highlighted the tremendous achievements in the past decade to provide ART to 15 million PLHIV, the opportunity to halt the HIV epidemic now, and data from several countries that are close to achieving the target of 73% viral suppression. Although the majority of delegates at the end of the debate continued to believe that achieving the targets is desirable, more people became convinced that the proposed timeframe is too short.

The first 90: HIV Testing

More than 150 million HIV tests are conducted in low- and middle-income countries annually and although the goal of diagnosing 90% of PLHIV is achievable, testing must be done with 100% accuracy because misdiagnosis has profound consequences at both the individual and population level. Outreach programs are necessary for key populations who are marginalised, stigmatized, often criminalised, and hard to reach.

The second 90: antiretroviral treatment

The World Health Organisation recommends an immediate offer of ART to all those diagnosed with HIV infection, regardless of their CD4 count that measures immune status(4). By mid-2015, 15.8 million people were on ART, representing an estimated 41% of people living with HIV (PLHIV) globally. ART optimisation is crucial to achieve the 90% treatment target and it must be effective, well tolerated, and quality assured. Increased access to ART in resource-limited settings has been made possible through voluntary licensing that enables generic companies to manufacture antiretroviral (ARV) drugs in individual or combination formulations. Generic combinations can provide ART for US$100-130 per year. Voluntary licensing of drugs such as dolutegravir and tenofovir alafenamide may reduce this cost to US$60/year in the near future, however, more efficacy and safety data in pregnant women and in HIV/TB co-infected patients are needed before these drug can be rolled out globally. Robust supply chains are essential to prevent stock-outs and ensure continuity of ART. Increasing domestic healthcare funding in sub-Saharan Africa to reach the Abuja target of 15% of annual government budgets will reduce donor dependency and facilitate sustainable programs. Building on the global success of generic ART, generic versions of drugs for tuberculosis, cancer, and hepatitis B and C could facilitate drug access for people in resource-limited settings around the world at very affordable prices.

(b)(5)

The third 90: Viral suppression

Rapid scale up of viral load (VL) monitoring is essential to track the third 90 and know how many patients achieve viral suppression. This will require improved efficiencies across the VL testing spectrum, from sample collection and transportation to laboratory performance and ensuring that results are sent to clinics and patients and are acted upon appropriately. A major barrier to achieving the 90% viral suppression target is poor adherence, which leads to the emergence of drug resistance. Because retention in care and adherence support are key to achieving virological suppression, the design of effective interventions must be anchored in a comprehensive understanding of the multiple barriers at different levels that people on ART face.

The WHO recommends that ART scale up is accompanied by high quality surveillance of HIV drug resistance, which requires investment in human and laboratory resources, innovative and efficient technical approaches, robust supply chains, and quality assurance measures, as well as community and political commitment. Limited laboratory capacity in sub Saharan Africa (SSA) is hampering drug resistance monitoring. Specific studies can identify suitable ARV options, such as the ultra-deep pyrosequencing work at the Chantal Biya International Reference Centre in Yaoundé, Cameroon that has shown that protease inhibitors and maraviroc are likely to be effective in young Cameroonian children(5). The author of this abstract received the Joep Lange award for the top-scoring abstract by an African scientist at the 10th INTEREST Workshop.

HIV Prevention

More than 10 million voluntary medical male circumcisions (VMMC) have been performed(6) in sub-Saharan Africa since WHO/UNAIDS recommended male circumcision for HIV prevention in settings with predominant heterosexual transmission(7). Countries are moving forward to establish sustainable VMMC programs focused on early infant and early adolescent male circumcision as they achieve a high prevalence of adult male circumcision.

In Africa, pre-exposure prophylaxis (PrEP) with antiretroviral drugs has achieved regulatory approval in South Africa and Kenya, following clinical trials among serodiscordant couples, men who have sex with men, and heterosexual men and women. Lessons learned from follow-on studies and demonstration projects of oral PrEP in tablet form have shown that adherence is higher than in trial settings, possibly because people know that they are taking an effective product. Novel products and delivery options under investigation include injectables that would be taken every 2 to 3 months, vaginal gel and ring formulations, and monoclonal antibodies. PrEP is not for everyone all the time. Serodiscordant couples can use PrEP until the partner starting on ART is virally suppressed and it works for anyone experiencing a high risk of HIV exposure during a specific time of his or her life. A debate on whether Africa was ready for pre-exposure prophylaxis, following on a similar debate at INTEREST 2015 in Harare, Zimbabwe, persuaded some that had been sure that Africa was ready to wonder whether the regulatory, logistical, equity, and other issues had all been adequately addressed.

Vaccine and Cure

The search for a vaccine, following the promising results of RV 144(8), includes active and passive approaches to HIV prevention. Clade-specific trials in South Africa and elsewhere are part of the pox-protein public-private partnership (P5) evaluating pox-protein candidates. Hypothesis-generating Phase 2b trials are underway of passive vaccine strategies involving monoclonal antibodies using trivalent and tetravalent vectors to obtain broader coverage against HIV. Research to understand viral reservoirs with the goal of an eventual cure has found that Ugandans without HIV infection have increased immune activation and lymph node pathology that resembles early HIV infection among patients in Minnesota, USA. If they acquire HIV, they may develop a larger HIV reservoir with persistent immune activation This can lead to lymph node fibrosis that damages mechanisms to maintain CD4 counts(9) and may limit the diffusion of therapeutic agents to reduce the reservoir.

Key Populations

Alongside success stories in bringing down HIV prevalence among sex workers in countries such as Rwanda, Burkina Faso, Kenya, and Namibia, there is a paucity of data on successful interventions among men involved in sex work, regular partners of female sex workers, and girls under 18 years who receive money or goods in exchange for sexual services. Exciting new developments include studies of PrEP use, integration of HIV and sexual and reproductive health services, and use of mobile technology, social media and biometric measures to assist in studying the often mobile sex work population. Striking data on the use of heroin, tramadol, and other opioids have led to the African Union Plan of Action on Drug Control that recognises the burden of HIV and hepatitis C among people who inject drugs in Africa. Political barriers to holistic harm reduction remain for illicit drugs and for alcohol, a psychoactive substance with dependence-producing properties that has been strongly linked to HIV risk in Africa and around the world. As a key population, men who have sex with men have high HIV risks and continue to be criminalised in many African countries, making it difficult to reach them with services. In 8 African countries, between 25 and 65% of these men aged 18-19 years are meeting male sexual partners on line, suggesting that social media and mobile platforms could help increase access to HIV prevention and treatment.

Emerging pathogens – lessons learned for and from HIV

Lessons were drawn from the Ebola epidemic of 2014-2015 for HIV and for emerging and re-emerging pathogens such as Zika and Lassa Fever. Developing and running Ebola clinical trials proved to be very challenging in Guinea, Liberia, and Sierra Leone. In Guinea, an adaptive trial 'ring vaccination' design was used to evaluate vaccine candidate, with real time modifications to take account of the rapidly changing epidemic and logistical issues(8). The impact of favipiravir on Ebola virus disease was evaluated in a single arm, proof of concept trial that found it well-tolerated and possibly more effective in a subset of patients(9).

It proved possible to run high-quality studies alongside the response during an outbreak, but healthcare systems must be strengthened before another epidemic occurs. Ideally outbreaks of emerging and re-emerging pathogens should be anticipated and potential drugs and vaccines for them investigated on an ongoing basis so that efficacy trials can be initiated quickly when an outbreak occurs. Engaging stakeholders, including community stakeholders, at all stages of a clinical trial contributes to robust trial design, facilities trial conduct by addressing rumours and enhancing participant retention, and helps ensure ownership of the results for action. The 2011 UNAIDS/AVAC Good Participatory Practices (GPP) guidelines for biomedical HIV prevention trials(10) are currently being adapted for emerging pathogens. Addressing ethical issues is key to ensuring that studies are conducted ethically, communities support them, and post-trial legacies are assured. Robust public health infrastructure, appropriate legislation, and community involvement were key in containing an Ebola outbreak of 20 cases in Nigeria. Subsequent investments in the healthcare system have upgraded disease surveillance, research infrastructure, and treatment facilities, with lessons learned from Ebola being applied to Lassa fever.

Worldwide, infectious diseases remain among the leading causes of death, despite tremendous progress in treating and preventing them. New pathogens are emerging and known pathogens are re-emerging in the 21st century, with climate change and the interconnectedness of the world increasing the risk that humans will be exposed to zoonosis. This underscores the need for early warning surveillance, quick action responses by public health authorities, and timely research to develop effective treatments and vaccines, alongside vector control and behaviour change.

Conclusions

b)(5)

Although new HIV infections declined in sub-Saharan Africa by 41% between 2000 and 2014, in 2014 alone there were an estimated 1.4 million new HIV infections. An estimated 25.8 people are living with HIV in sub-Saharan Africa, with women accounting for more than half.

Over 10.7 million people were accessing ART, 41% of all people living with HIV in the region, up from fewer than 100,000 people in 2002 (36% of men and 47% of women living with HIV)(11). Although there has been a 48% decline in new HIV infections among children in the 21 priority countries of the Global Plan to eliminate new HIV infections among children and keeping their mothers alive in Africa(12), 190,000 African children became infected with HIV infections in 2014(13). Late diagnosis of HIV infection is the most substantial barrier to scaling up HIV treatment, with 790 000 people dying of AIDS-related causes in sub-Saharan Africa in 2014.

The 10th INTEREST Workshop heard a call for leadership and activism among HIV investigators and physicians to show global solidarity with PLHIV worldwide and to ensure that resources are used effectively. Africa loses US$150 billion/year through illicit financial flows, corruption, and money laundering. This money could replace international donations and fund healthcare throughout the continent. At the closing ceremony, the Yaoundé Declaration(14) was read out, calling on African governments; UNAIDS; development, bilateral, and multilateral partners; and civil society to adopt urgent and sustained approaches to end HIV by 2030(15)(11).

2428 words

References

1. Piot P, Abdool Karim SS, Hecht R, Legido-Quigley H, Buse K, Stover J, et al. Defeating AIDS—advancing global health. The Lancet [Internet]. 2015 Jul [cited 2015 Oct 14];386(9989):171–218. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673615606584

2. UNAIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic [Internet]. 2014. Available from: http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf

3. International Workshop on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Limited Settings (INTEREST) [Internet]. Available from: www.interestworkshop.org

4. World Health Organization. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. [Internet]. 2015 [cited 2015 Oct 17]. Available from: http://apps.who.int/iris/bitstream/10665/186275/1/9789241509565_eng.pdf

5. Fokam J. Ultra-Deep Pyrosequencing of HIV-1 Protease-RT Drug Resistance and Coreceptors in Cameroonian Children. 10th International Workshop on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Limited Settings (INTEREST); 2016 May 3; Yaoundé, Cameroon.

6. UNAIDS. Fast-Tracking Combination Prevention: Towards reducing new HIV Infections to fewer than 500 000 by 2020. Joint United Nations Programme on HIV/AIDS; 2015.

7. WHO | New data on male circumcision and HIV prevention: Policy and programme implications [Internet]. WHO. 2007 [cited 2013 Jul 19]. Available from: http://www.who.int/hiv/pub/malecircumcision/research_implications/en/index.html

8. Henao-Restrepo AM, Longini IM, Egger M, Dean NE, Edmunds WJ, Camacho A, et al. Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial.

The Lancet [Internet]. 2015 Aug [cited 2016 Mar 27];386(9996):857–66. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673615611175

9. Sissoko D, Laouenan C, Folkesson E, M'Lebing A-B, Beavogui A-H, Baize S, et al. Experimental Treatment with Favipiravir for Ebola Virus Disease (the JIKI Trial): A Historically Controlled, Single-Arm Proof-of-Concept Trial in Guinea. Lipsitch M, editor. PLOS Med [Internet]. 2016 Mar 1 [cited 2016 Mar 24];13(3):e1001967. Available from: http://dx.plos.org/10.1371/journal.pmed.1001967

10. UNAIDS/AVAC. Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials 2011 [Internet]. Joint United Nations Programme on HIV/AIDS; 2011 [cited 2013 Aug 7]. Available from: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf

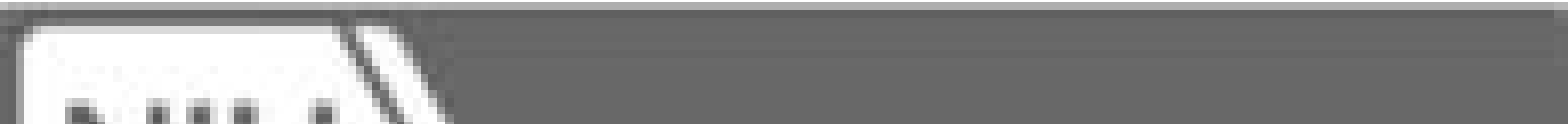
11. UNAIDS. On the Fast-Track to end AIDS by 2030: Focus on location and population [World AIDS Day Report 2015] [Internet]. 2015 [cited 2016 Apr 4]. Available from: http://www.unaids.org/sites/default/files/media_asset/WAD2015_report_en_part01.pdf

12. UNAIDS. 2014 Progress Report on the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive [Internet]. 2014 [cited 2015 Oct 12]. Available from: http://www.unaids.org/en/resources/documents/2014/JC2681_2014-Global-Plan-progress

13. UNAIDS. Fact Sheet 2015 [Internet]. Available from: http://www.unaids.org/sites/default/files/media_asset/20150901_FactSheet_2015_en.pdf

14. Yaoundé Declaration [Internet]. [cited 2016 May 24]. Available from: http://interestworkshop.org/2016/05/06/539/

15. UNAIDS. Fast Track: Ending the AIDS Epidemic by 2030 [Internet]. 2014 [cited 2015 Oct 1]. Available from: http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf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To:	Timothy Mastro <TMastro@fhi360.org>
Subject:	Re: Circumcision of male infants and children as a public health measure in... - Academia.edu
Date:	2016/06/04 22:05:44
Priority:	Normal
Type:	Note

Hi,
Did you see the paper? Would be interested if it adds anything.
I hope the recommendations will finally be published this summer, 6.5 years after starting clearance.
Hope you are off to a good start to summer.
PK
Peter Kilmarx, MD, FACP, FIDSA
Fogarty International Center, NIH
Redacted by agreement

From: Timothy Mastro
Sent: Saturday, June 4, 2016 9:44 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: FW: Circumcision of male infants and children as a public health measure in... - Academia.edu

This beat goes on.....

From: Academia.edu Weekly Digest [mailto:noreply@academia-mail.com]
Sent: Saturday, June 04, 2016 9:30 PM
To: Timothy Mastro <TMastro@fhi360.org>
Subject: Circumcision of male infants and children as a public health measure in... - Academia.edu

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Brian D. Earp

Brian D. Earp
University of Oxford, Philosophy, Department Member

Circumcision of male infants and children as a public health measure in developed countries: A critical assessment of recent evidence

In December of 2014, an anonymous working group under the United States' Centers for Disease Control and Prevention (CDC)

issued a draft of the first-ever federal recommendations regarding male circumcision. In accordance with the American Academy of Pediatrics' circumcision policy from 2012 - but in contrast to the more recent 2015 policy from the Canadian Paediatric Society as well as prior policies (still in force) from medical associations in Europe and Australasia - the CDC suggested that the benefits of the surgery outweigh the risks. In this article, we provide a brief scientific and...

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Roula Choueiri

Early Intervention for Children With Autism Spectrum Disorder Under 3 Years of Age: Recommendations for Practice and Research

This article reviews current evidence for autism spectrum disorder (ASD) interventions for children aged <3 years, based on peer-reviewed articles published up to December 2013. Several groups have adapted treatments initially designed for older, preschool-aged children with ASD, integrating best practice in behavioral teaching methods into a developmental framework based on current scientific understanding of how infants and toddlers learn. The central role of parents has been emphasized, and interventions are designed to incorporate learning opportunities into everyday activities,...

VIEW PAPER

Jorge UrbÃ¡n

Jorge Urbán
Universidad Autonoma de Baja California Sur (UABCS), Departamento Academico de Biología Marina, Faculty Member

Bioacoustics: Only male fin whales sing loud songs

VIEW PAPER

Fasoro Ayodeji Akinwande

Fasoro Ayodeji Akinwande
Afe Babalola University, Ado-Ekiti, Community Medicine, Faculty Member

Assessment of Food Safety Practices in a Rural Community in Southwest Nigeria

Food safety has been a major health challenge in both developed and developing countries. Ensuring food safety is key to preventing food borne illnesses which are contracted through consumption of unsafe foods. The aim of this study was to identify the food safety practices of residents of a rural community in Southwest, Nigeria. The study design was cross-sectional. Five clusters were selected by simple random sampling from the sampling frame. All households in the clusters were sampled to achieve a sample size of 216 households. Data were collected using a semi-structured questionnaire....

VIEW PAPER

Luca Colucci-D'Amato
Seconda Università di Napoli, Dipartimento di Scienze e Tecnologie Ambientali, Biologiche e Farmaceutiche, Faculty Member

Secretome profiling of differentiated neural mes-c-myc A1 cell line endowed with stem cell properties

VIEW PAPER

Carlos Vale

Hepatic proteome changes in Solea senegalensis exposed to contaminated estuarine sediments: a laboratory and in situ survey

VIEW PAPER

Mathias Uhlén
KTH Royal Institute of Technology, Science for Life Lab, Faculty Member

A single fixation protocol for proteome-wide immunofluorescence localization studies

VIEW PAPER

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
Recipient:	Timothy Mastro <TMastro@fhi360.org>
Sent Date:	2016/06/04 22:05:43
Delivered Date:	2016/06/04 22:05:44

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Qualls, Michael (CDC/CGH/DGHT) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:muq1@CDC.GOV>
Subject:	RE: HIV Prevention (HIP) Literature Digest--2nd Edition
Date:	2016/05/18 11:27:10
Priority:	Normal
Type:	Note

Thanks Michael. The Malawi 90-90-90 paper is impressive.

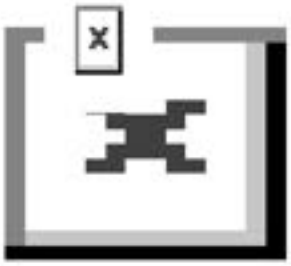
Best,
PK

From: Qualls, Michael (CDC/CGH/DGHT)
Sent: Wednesday, May 18, 2016 8:58 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: FW: HIV Prevention (HIP) Literature Digest--2nd Edition

Greetings from Atlanta! Just a FYI in case you are interested. Best regards.

MLQ

From: Chevalier, Michelle (CDC/CGH/DGHT)
Sent: Wednesday, May 18, 2016 8:55 AM
To: CDCL-DGHT-PREVLIT@LISTSERV.CDC.GOV
Subject: HIV Prevention (HIP) Literature Digest--2nd Edition



Dear Field and Headquarters HIV Prevention Colleagues and Supporters,

We are pleased to share our second collection of prevention and prevention-related publications. Thanks much to HiP (
scientific insights and innovations.

Please stay tuned for further HiP communications coming out soon as we are preparing some exciting prevention works
combination prevention, pre-exposure prophylaxis and more, as part of the up-coming CGH &DGHT Annual Meeting fro

You will have received earlier announcements but just a quick reminder, that we are offering the one-day "Gender &Se
xka3@cdc.gov to register. Both HQ and field staff are invited. Of note to supervisors, as an additional bonus, this trainir

I am looking forward to seeing many of you in Atlanta soon. Happy reading,

Irene

Irene Benech
DGHT HIV Prevention Branch Chief

Title	Introduction
Closer to 90–90–90. The cascade of care after 10 years of ART scale-up in rural Malawi: a population study. Journal of the International AIDS Society 19.1 (2016).	Empirical data on population-level coverage is important to assess an estimates to help track progress on achieving UNAIDS 90-90-90 target colleagues conducted a cross-sectional household survey in the Chira evaluate after 10 years of available ART services: (1) HIV prevalence a HIV status and ART coverage, and (3) population viral load. The overa was 17.0% (95% CI 16.1%-17.9%). Of HIV-infected participants, 76.7% diagnosed, 71.2% were in HIV care, 65.8% were receiving ART, and 61 suppressed. The authors concluded that high population coverage of with low HIV incidence, can be achieved in resource-limited settings.

The Impact of Methadone Maintenance Treatment on HIV Risk Behaviors among High-Risk Injection Drug Users: A Systematic Review Evidence Based Med Public Health (2016)	This systematic review explores relevant literature for evidence of me treatment (MMT) on HIV risk behaviors among high-risk injection drug studies conducted between 2005 and 2015 associate MMT with a sig drug use and sharing of injecting equipment. Limited evidence on sex- that MMT is associated with a lower incidence of multiple sex partner literature also finds that the most significant factor in reducing these adherence.
Findings of Phlebotomy Practices in Kenya in 2010: Need for Action Journal of Infectious Diseases J Infect Dis. 2016 Apr 15;213 Suppl 2:S53-8	This article presents findings of a cross-sectional observational study i Kenya on compliance with safe, accurate phlebotomy techniques. Key practices that could adversely affect patient and healthcare worker sa quality. None of the blood collection procedures in this study adhered phlebotomy procedure as described by WHO, and the majority of dev could compromise patient safety, including hand hygiene, gloves use, identification, and sample labeling.
Supervised Oral HIV Self-Testing is Accurate in Rural KwaZulu Natal, South Africa Trop Med Int Health. doi:10.1111/tmi.12703	The authors describe implementation of supervised HIV self-testing us prevalence rural area in South Africa, with the specific aims of determ to correctly perform, read, and interpret the rapid HIV test under cou diagnostic accuracy of the oral self-testing method. Only two particip OraQuick test as they accidentally spilled the developer solution vial. agreement was 99.8% (Kappa 0.9925). Sensitivity for the oral self-test 99.6) and specificity was 100% (95%CI 99.8-100). Oral self-testing has uptake of HIV testing and could be offered at clinics and community t Africa.
HIV Transmission Risk Persists During the First 6 Months of Antiretroviral Therapy JAIDS Journal of Acquired Immune Deficiency Syndromes Publish Ahead of Print DOI: 10.1097/QAI.0000000000001019	The protective value of pre-exposure prophylaxis for HIV-serodiscorda data from the Partners PrEP Study, a prospective cohort study of 4747 serodiscordant couples in Kenya and Uganda. Findings show cumulati blood viral suppression (<80 copies/ml) 3, 6 and 9-months after ART i and 89.1%, respectively. Among initially uninfected partners, HIV inci 100 person-years (55 infections; 2644 person-years), 1.79 for 0-6 mon infections; 168 person-years), and 0 with >6 months of ART (0 infectio obviously good news for uninfected partners whose likelihood of prot with the corresponding viral suppression of their HIV-positive partner
Influence of parental factors on adolescents' transition to first sexual intercourse in Nairobi, Kenya: a longitudinal study Reproductive Health (2015) 12:73	While the overall global HIV mortality rate has been declining, the HIV adolescents is rising. In this article, Okigbo et al. assessed the influenc communication and discipline on the transition to first sexual intercou adolescents, aged 12-19, and living in urban slums of Kenya. The study gender communication, i.e., mothers talking to sons and fathers talkin with a delay in the onset of sexual intercourse; accordingly, targeted reproductive health interventions that include parents, may be highly choice to delay sexual debut, and may reduce sexual risk behaviors an high risk settings such as urban slums.

The Relationship Between Distance and Post-operative Visit Attendance Following Medical Male Circumcision in Nyanza Province, Kenya AIDS Behav. 2015 Sep 30.	This study used VMMC client demographic information, clinical data, a the relationship between distance to a VMMC facility and attendance visit. Among 1437 participants, 46.7 % attended follow-up. We found distance beyond which follow-up attendance significantly dropped. Th distance is an important predictor of attending follow-up, and this rela modified by facility type.
Tetanus Cases After Voluntary Medical Male Circumcision for HIV Prevention — Eastern and Southern Africa, 2012–2015 MMWR / January 22, 2016 / Vol. 65 / No. 2	This report summarizes 12 tetanus cases from five sub-Saharan Africa PEPFAR from April 2012 – November 2015. Eight patients received cou four were circumcised via PrePex, a nonsurgical male circumcision dev Health Organization case definition, five of the eight cases were deter associated with VMMC; three were determined to be indeterminate c insufficient data. PEPFAR is working with implementing partners and M strengthen national surveillance systems for VMMC-related adverse e reported adverse events, and support the implementation of tetanus accordance with WHO tetanus prevention recommendations for VMM wound care for VMMC clients.

If you received this email message directly from CDCL-DGHT-PREVLIT@LISTSERV.CDC.GOV , you are already a subscribin and supporters of prevention compiled at DGHT headquarters. Please encourage any new CDC prevention colleagues or the list by sending the following command, from the email account they will be using, to List@cdc.gov

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If you wish to unsubscribe, please follow the instructions available at the bottom of each message. Do not hesitate to re (xde1@cdc.gov), Jonathan Grund (iha3@cdc.gov), Arielle Lasry (ftn9@cdc.gov), Dan Rutz (dwr1@cdc.gov) and Irene Ber

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Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Qualls, Michael (CDC/CGH/DGHT) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:muq1@CDC.GOV>
Sent Date:	2016/05/18 11:27:10

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Wallick, Stacy (NIH/FIC) [E] /O=NIH/OU=Nihexchange/cn=nibib/cn=wallicks <wallicks@mail.nih.gov>
CC:	Bridbord, Ken (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=bridbork <bridbork@ficod.fic.nih.gov>
Subject:	FW: Research career capacity building in Zambia
Date:	2016/03/21 15:23:27
Priority:	Normal
Type:	Note

FYI – background on Holmes/CIDRZ. Will likely host him for brownbag next month. Shannon is communicating with him.

PK

From: Charles Holmes [mailto:Charles.Holmes@cidrz.org]
Sent: Thursday, March 17, 2016 2:12 AM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: Research career capacity building in Zambia

Dear Peter,
I hope this message finds you well. Congratulations on your position at NIH! I have been meaning to reach out to you for some time to see if I could come by and update you, and potentially Roger as well, on the work we've done to morph CIDRZ into a strong Zambian organization (2014 Annual Report attached). With our new Deputy Director, Dr. Izukanji Sikazwe, our new Scientific Director, Dr. Roma Chilengi, and numerous other local leaders in place, we have overcome some difficult institutional challenges of historical making, and have built a foundation for successfully meeting our research, program and training goals. At the moment, we are completely research/program grant funded, and we are finding it particularly difficult to support the capacity building and other elements that are needed to recruit, nurture and retain in science, junior Zambian investigators. We have started talking with a number of funders, including the Bill and Melinda Gates Foundation about ways to support this broader goal of building solid career pathways in science for Zambians, and it would be great if you would have some time to talk about the same.

I will be in the Washington area for the last 2 weeks of April, and it would be great if you might have time to connect.

Many thanks,
Charles

Charles B. Holmes, MD, MPH
Director and CEO
Centre for Infectious Disease Research in Zambia
5032 Great North Road, Lusaka, ZAMBIA|Lusaka Cell Redacted by agreement | US Cell Redacted by agreement
Redacted charles.holmes@cidrz.org|www.cidrz.org

CIDRZ is an independent Zambian organisation with a mission to "improve access to quality healthcare in Zambia through capacity development, exceptional implementation science and research, and impactful sustainable public health programmes." We are governed by a majority Zambian Board of Directors and a 14-member Leadership Team. CIDRZ has collaborations with

numerous renowned local and international universities and other partners that enable the organisation to stay at the cutting edge of science, programme delivery and training.

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Wallick, Stacy (NIH/FIC) [E] /O=NIH/OU=Nihexchange/cn=nibib/cn=wallicks <wallicks@mail.nih.gov>; Bridbord, Ken (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=bridbork <bridbork@ficod.fic.nih.gov>
Sent Date:	2016/03/21 15:23:27

CIDRZ

2014

ANNUAL REPORT

Centre for Infectious Disease Research in Zambia

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About CIDRZ

Established in 2001, and recognised as an independent Zambian organisation in 2011, CIDRZ has a strong commitment to answering key research questions relevant to Zambia; supporting the financial and technical local ownership of high-quality complementary and integrated healthcare services within the public health system; and facilitating clinical, research and professional development training.

Since inception, CIDRZ has been an active partner of the Government of the Republic of Zambia (GRZ) through our collaboration with multiple Ministries, including the Ministry of Health, the Ministry of Community Development Mother and Child Health, the Ministry of Home Affairs, the Ministry of Local Government and Housing, and other line Ministries, as well as key stakeholders and institutions such as the Zambian Prisons Services, University of Zambia - School of Medicine, and Cancer Diseases Hospital, among others.

CIDRZ programmes support healthcare-related activities in all 10 Zambian Provinces as we focus on strengthening primary healthcare provision systems in the following areas:

- HIV/AIDS Prevention, Care & Treatment
- Tuberculosis Diagnosis & Treatment
- Primary Care & Health Systems Strengthening
- Newborn & Child Health
- Women's Health, including Cancer
- Hepatitis & other Infectious Disease

Think CIDRZ... for a healthier Zambia

Message from the CIDRZ Board Chair, Mr Bradford Machila

I am privileged to welcome you to the 2014 CIDRZ annual report.

This is our second annual report as a local Zambian organisation, and I hope you will find it informative and inspiring. What continues to motivate, drive and inspire the Board more than anything else, is the prospect of and opportunity to contribute to CIDRZ's realisation of its Mission and Vision. I am confident that this desire is shared with our hundreds of staff members, who are and remain key to this aspiration.

As you will read in the message that follows from Drs Holmes and Sikazwe, management faced some difficult challenges of historical making in 2014. My perspective as Board Chair, and that of my fellow Board Members, is that the new leadership has dealt with these issues in an exceptionally fine manner, replacing them with positive developments that have put CIDRZ on track for a long and productive future.

During the course of 2014 we also embarked on building a Board of Directors of highly committed individuals that bring leadership and skills at the top of their professions to the service of CIDRZ, and we will continue this process into 2015. We have also worked with management to put into place world-class governance procedures and controls that have allowed CIDRZ to not only excel at its core mission, but to do so in an accountable fashion that is valued by our donors, partners and beneficiaries.

Lastly, CIDRZ has truly become a significant partner to the government of the Republic of Zambia, as evidenced by the recently signed Memoranda of Understanding with three of the critical Ministries relating to health. My fellow Board Members and I will continue to work with the dedicated CIDRZ management team to ensure that the organisation is in complete alignment with Zambian national health priorities as CIDRZ contributes to improving health in our country through innovative service delivery, locally-relevant research, and training of the next generation of Zambian health leaders.

Bradford Machila

Board of Directors as of 30th September 2014

1

2

3

6

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5

In 2014, CIDRZ initiated a Board recruitment exercise to actively seek experienced and dedicated finance, business, governance and controls, and science leaders to join our Board of Directors. Following best governance practices, our target is a ten-member, 75%-majority Zambian board, that meets quarterly and ad hoc as required. *As of the date of publication a full board has been constituted. Membership can be found at: http://www.cidrz.org/about-us/board-of-directors/

Over the last year we are gratified that four exceptional new members have joined our board to contribute their experience and expertise to furthering the CIDRZ mission.

"I was delighted to be asked to join the board of CIDRZ because during 30 years' of living and being involved in research in Africa I have been committed to the development of local institutions. I see in the team at CIDRZ great determination and potential to develop a genuinely Zambian institution which will make a real difference." -- Professor Kevin Marsh
Former Director of Kenya Medical Research Institute (KEMRI)

1 **Chair, Mr Bradford Machila** - Former Deputy Minister of Justice, Minister of Lands, and Minister of Livestock and Fisheries Development, Zambia

2 **Member, Dr Chipepo Kankasa** - Consultant Paediatrician, and Director of the UNZA UTH HIV/AIDS Programme and The Paediatric HIV Centre of Excellence, Zambia

3 **Member, Ambassador Dr Eric Goosby** - Former U.S. Global AIDS Coordinator, Distinguished Professor of Medicine at the University of California, San Francisco, and United Nations Special Envoy for TB

4 **Member, Mr Christopher Mubemba** - Director of Transmission Development, ZESCO Ltd., Zambia

5 **Member, Ms Annabelle DeGroot** - Finance Director, Zambian Breweries Plc., National Breweries Plc., Heinrichs Beverages Ltd., Zambia

6 **Member, Professor Kevin Marsh** - Professor of Tropical Medicine, University of Oxford, and Chair of the World Health Organization Malaria Policy Advisory Committee

Message from CIDRZ Leadership

We would like to welcome you to our second annual report!
As you are likely aware, CIDRZ has undergone substantial changes over the last two years. While 2013 was a year of serious challenges, 2014 was a year in which we successfully addressed these challenges head-on.
We are pleased to say that the organisation is nothing short of transformed as we write this letter of introduction.

New additions to our management team have allowed us to bring integrity, smart ideas and hard work to tackle difficult historical problems. We have built systems and controls in response to organisational issues identified in early 2013, overhauled the management of the CIDRZ Central Laboratory and achieved re-accreditation with the National Institutes of Health Clinical Trials Networks, adapted our labour practices to ensure local compliance, become fully compliant with local tax authorities, recruited a merit-based Board of Directors well-versed in organisational governance, re-organised our HIV programmes and dramatically improved performance, obtained substantial new grant funding after achievement of organisational milestones with key donors, and built strong new research links with the University of California, San Francisco and Johns Hopkins University, to complement existing collaborations with the University of Zambia, University of Alabama at Birmingham, the London School of Hygiene and Tropical Medicine and others, along with many other achievements made possible by our talented and committed staff.

What does all of this mean? It means that we now have a strong foundation on which to fulfill our mission of delivering better health for Zambians. Although we collaborate with partners, we are now a completely independent Zambian organisation, with the management and governance needed to face future challenges and to thrive. In the pages that follow, you will see examples of our innovative and impactful healthcare, research, and training programmes. All of this work is done with the closest collaboration with our colleagues in the Government of the Republic of Zambia, whose lead we take, and whose vision for a healthier Zambia we share. Thank you for your support and interest in CIDRZ!

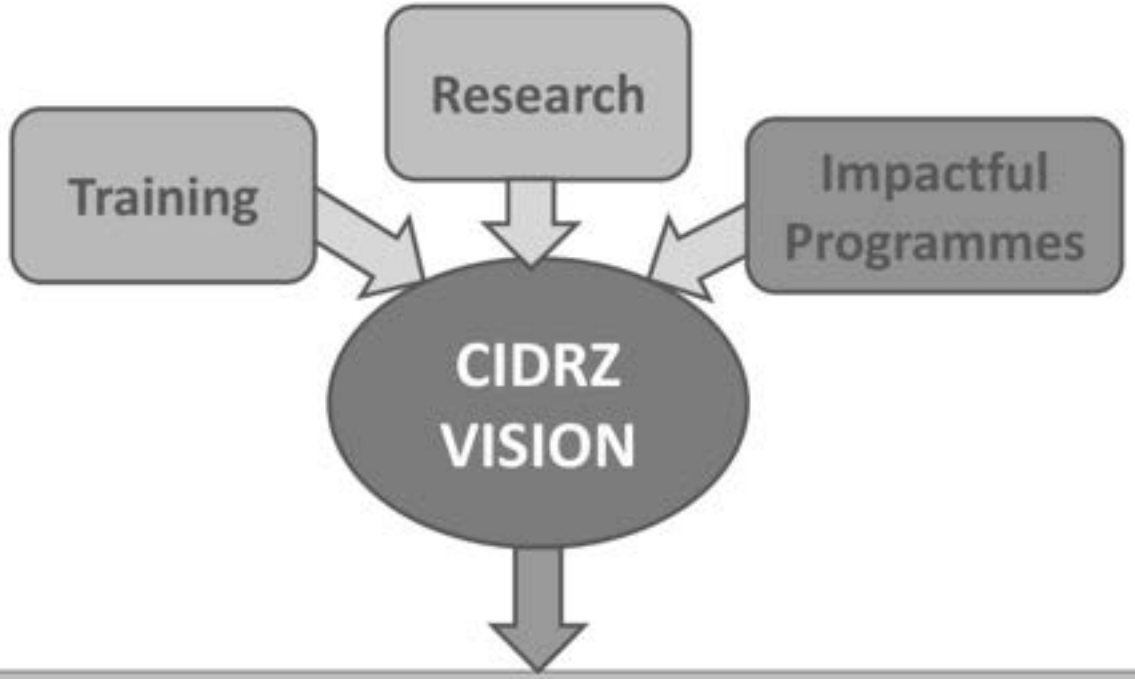
With best regards,
Charles and Izukanji

Dr Charles B. Holmes, MD, MPH

Dr Izukanji Sikazwe, MBChB, MPH

The CIDRZ Mission:

To improve access to quality healthcare in Zambia
through capacity development,
exceptional implementation research,
and impactful sustainable public health programmes.



A Zambia, and a region, in which all people have access to quality healthcare and enjoy the best possible health, including a life free of AIDS

Thank You to the Government of the Republic of Zambia

CIDRZ would not be able to contribute to the development of a strong, responsive and resilient local healthcare system without the close partnership of the Zambian Government.

Since inception, over 14 years ago, CIDRZ has been privileged to collaborate with Zambian health leaders at the District, Provincial and National levels so that we may work together to find effective programmes and interventions that are locally-relevant, culturally-appropriate, and most importantly, acceptable, affordable and sustainable to serve the Zambian people.

We ensure our healthcare services and programmes, logistic, infra-structure and technical support, and research activities align with the Zambian National Health Strategic Plans. We provide, or source partners to provide, training activities that support local capacity-building so that Zambians have the systems, skills and abilities required to implement their development policies and achieve their own economic, social, and environmental goals.

CIDRZ's Zambian Institutional Partners

- Ministry of Health (MOH)
- Ministry of Community Development Mother and Child Health (MCDMCH)
- Ministry of Home Affairs
- Ministry of Chiefs and Traditional Affairs
- Ministry of Education
- Ministry of Gender
- Ministry of Local Government and Housing
- Cancer Diseases Hospital
- Medical Stores Limited
- National TB Programme
- University Teaching Hospital
- University of Zambia – School of Medicine
- Zambian Medicines Regulatory Authority
- Zambian Prisons Services

Thank you to the Government of the United States

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) programme coordinated through the Centers for Disease Control and Prevention (CDC) - Zambia has generously provided significant financial support to CIDRZ without which the organisation could not have contributed to efforts to mitigate the Zambian HIV/AIDS epidemic.

ZAMBIANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

PEPFAR

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

USAID

FROM THE AMERICAN PEOPLE

In 2004, CIDRZ received a PEPFAR/Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)-coordinated grant through its affiliated university for Project HEART. The story of partnership continued in 2011 when CIDRZ - as a newly minted independent local organisation - received its first-ever PEPFAR award as a Prime Recipient for the HIV Integration into Local Ownership (HILO) grant.

HIV Integration into Local Ownership (HILO) - PEPFAR/CDC

Zambia's rapid scale-up of HIV prevention, care and treatment services has been among the most successful programmes in Africa and CIDRZ has been privileged to serve as a key technical and implementing partner in this response.

Supported by PEPFAR, our HILO programmes are aligned to support Zambia's strategic response to the HIV/AIDS epidemic, and our longstanding engagement with local communities and their health systems enable us to support Zambian priorities efficiently, holistically and respectfully. Partnering with the Ministry of Health and Ministry of Community Development Mother and Child Health, we integrate HIV programmes into primary healthcare settings, and build workforce capacity at all levels to ensure sustainable delivery of HIV services to all clients.

As of June 2014, over 400,000 Zambian men, women and children in 336 CIDRZ-supported public clinics are enrolled in long-term HIV ART care.

40,588 clients are newly enrolled.

The primary aim of HILO is to ensure access to quality HIV care and services while progressively transitioning the anti-retroviral treatment (ART), Prevention of Mother-to-Child Transmission of HIV, voluntary medical male circumcision, tuberculosis, cervical cancer, pharmacy, laboratory and data management services we support through HILO to local ownership, ensuring that high-quality, cost-effective HIV-related services are increasingly country-owned and country-driven.

From Emergency Response to Proactive Strategic Planning: CIDRZ Responds to the Changing HIV Epidemic

Significant progress has been made in the fight to tackle HIV and we are now within reach of an AIDS-free generation: access to life-saving ART has been expanded, new infections are being averted, and losses in life expectancy have begun to reverse. In light of these advances, CIDRZ has shifted focus from emergency scale-up of HIV services towards a more comprehensive and sustainable approach of health service delivery by building a well-trained and healthy workforce, that functions within a comprehensive, well-supplied and sustainable healthcare system that is Zambia-owned and Zambia-driven. **CIDRZ is committed to expanding and strengthening the quality of local health services for all Zambians. Here is how...**

Anti-Retroviral Treatment (ART) - HILO PEPFAR/CDC

We Build Local Capacity:

CIDRZ has always invested in developing the capacity of the Zambian healthcare workforce. We train, and support the training of, personnel from all levels of the Ministry of Health and the Ministry of Community Development Mother and Child Health and also serve as an essential resource for the **336 public system health clinics we support**. Our rotating teams of Technical Area Experts conduct joint site visits with Provincial and District Health Officers to provide mentorship and technical assistance to both healthcare facility and district staff.

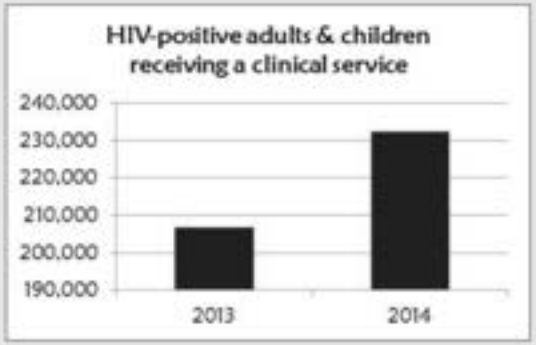
Right: Some of our CIDRZ HILO programme team

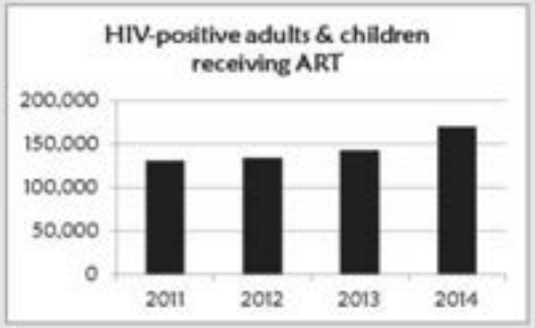
We Invest in Communities:

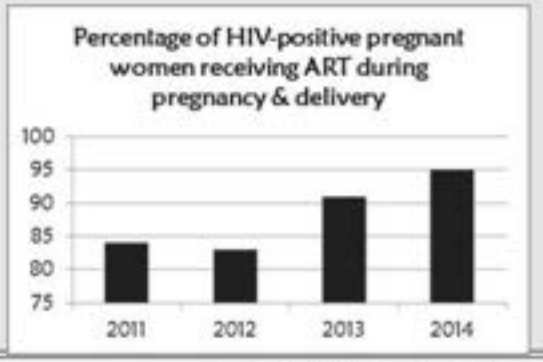
We value a community-centred approach and work to ensure that persons living with and affected by HIV and TB are included in our prevention, care and treatment efforts.

Since the beginning, CIDRZ has been training and supporting community-based volunteers to provide culturally-appropriate health education both in healthcare facilities and the community, to promote healthy behaviour and positive living, and to follow-up clients who have missed appointments. These Peer Educators and Treatment Supporters are invaluable assets to clinic personnel and clients alike. Additionally, we work with the traditional infrastructure and liaise with Traditional Leaders, Faith-based institutions and Neighbourhood Health Committees to reach more people at the community level.

HILO FY 2014 Highlights







Anti-Retroviral Treatment (ART) - HILO PEPFAR/CDC

We Strengthen Health Systems:

Working hand-in-hand with our government counterparts and other partners, we support and strengthen data collection, record-keeping and forecasting of the national supply chain so that pharmacies remain stocked, clinics get the supplies they need and laboratories have the tools required to conduct testing for all clients in the public sector. We are also an instrumental partner in government's push to roll-out a nationwide Peri-natal and Adult HIV Electronic Medical Records system which aims to improve the continuity and quality of care wherever a client seeks healthcare services in the public health sector of Zambia.

We Integrate Healthcare Services:

In all the programmes that we support we integrate comprehensive healthcare services so that HIV, and TB testing and counselling, provision of ART and family planning, referral for cervical cancer screening, and voluntary male circumcision for HIV-uninfected male partners is part of holistic care.

A HILO Success Story:
Building Capacity in Midwives Improves Ante-natal Care and ART Uptake

"This programme has been of great benefit to me as a healthcare provider as well as to my patients. Because I can now provide ART in the Maternal Child Health clinic my pregnant patients don't have to wait a long time to be seen to receive their ART care. They are no longer 'lost-referrals' to the ART clinic." -- Margaret Chitenge, Nurse Midwife

In Zambia's public sector health facilities, HIV-infected pregnant women are usually referred to separate HIV Prevention, Care and Treatment clinics to access ART care. However, these clinics are under-staffed and overwhelmed by the high demand and as a result, only a small proportion of pregnant women who need this healthcare actually access these services, thus delaying their initiation on the recommended ART. To address this critical issue, **CIDRZ piloted an 'ART in Maternal Child Health' mentorship programme in 10 ante-natal care clinics.** Midwives from the ante-natal clinics completed an intensive on- and off-site mentorship programme with CIDRZ Clinical Mentors. Upon completion, the mentored midwives reported feeling more confident in their ability to provide quality services to both HIV-infected and uninfected mothers, and there was a significant increase in the uptake of ART among HIV-infected pregnant women at their ante-natal care visits.

Prevention of Mother –To- Child Transmission of HIV (PMTCT) - HILO PEPFAR/CDC

In 2014, we supported 336 facilities providing PMTCT services in 3 provinces. 100% of infants born to HIV-infected women received a virologic HIV test within 12 months of birth.

In 2013, the World Health Organization recommended that National PMTCT programmes begin providing life-long anti-retroviral treatment (ART) to pregnant and breastfeeding women living with HIV, regardless of their CD4 T - cell count or their WHO AIDS Clinical Stage in a programme called OPTION B+.

Zambia adopted this strategy and beginning in 2014, CIDRZ through the PEPFAR/CDC- funded HILO Programme has been supporting the Ministry of Health and the Ministry of Community Development Mother and Child Health's efforts to promptly roll-out Option B+ in health facilities across Zambia.

Working hand-in-hand with counterparts in the Ministry, Provincial and District Health Offices, in health facilities and with Neighbourhood Health Committees, we are building the capacity of new cadres of health workers to provide ART to all HIV-infected pregnant and breastfeeding women, and strengthening the health systems that make efficient delivery of these life-saving services possible.

⇒ We trained 181 healthcare workers and 100 lay counsellors in Option B+ and the PMTCT minimum package

⇒ Introduced the Option B+ programme into 115 facilities

⇒ Supported initiation of 7,740 HIV-infected pregnant women on lifelong ART treatment

Voluntary Medical Male Circumcision - **HILO PEPFAR/CDC**

As a local organisation, our research and programme activities are driven by the priorities determined by the Zambian national health agenda.

In 2014, MC providers in 23 static & mobile clinics **circumcised** 19,951 men **(105% of our target).**

Trained 12 government providers **in surgical circumcision skills.**

The Zambian government recently expanded the Voluntary Medical Male Circumcision (VMMC) for HIV Prevention Programme, as the WHO recommends it for countries like Zambia with high HIV prevalence (12.5% UNAIDS 2013) coupled with low rates of circumcision as VMMC is a safe, effective prevention strategy to reduce the risk of sexual transmission of HIV. However, male circumcision is not widely practiced in some areas of Zambia and as a result uptake is low in several rural areas, especially in Eastern Province.

Above CIDRZ VMMC staff sensitising the Chief's Indunas (Advisors) in Western Province

To tackle this we increased our engagement and sensitisation of rural traditional rulers and local leaders, and as a result we saw an increase of VMMC acceptance in Eastern Province, including some Chiefs who themselves 'took the step' to become circumcised and become MC Champions encouraging others to do the same. This approach enabled us to correct misconceptions and gain the trust of local leadership. In turn, community members trust the messages of their local leadership. This model was so successful in increasing male circumcisions that we replicated it with traditional leaders in other CIDRZ-served provinces with similar success.

The CIDRZ HILO - supported VMMC programme also is an active partner in the government-led National MC campaigns. In addition to providing actual services, throughout the year we supported sensitisation via rural radio call-in programmes, community awareness and mobilisation via megaphone and flier distribution, and gave awareness and Questions & Answers talks to students, teachers, and at workplaces.

Community COMPACT: Community-Led HIV Prevention Programme

The PEPFAR/CDC- funded Community COMPACT Programme puts the community in charge of its HIV/AIDS response by identifying the drivers of infection and taking action to combat them.

Active in rural Kalabo in Western Province and over 870 km (600 miles) away in urban Kanyama, a congested shanty compound in the capital Lusaka - the focus of COMPACT is to increase the number of people who are aware of their HIV status and accessing HIV prevention, care & treatment. **A key activity is to train** Community Volunteers **in HIV/AIDS basics, Prevention with Positives, and psychosocial & couples Counselling so they can support health facility-based Voluntary Counselling and Testing (VCT) departments and also take part in quarterly community-based VCT drives.** In 2014, COMPACT Kanyama volunteers were trained in PMTCT, while Kalabo volunteers were trained in rapid HIV testing. Both groups received training on how to test vulnerable populations such as commercial sex workers (CSW) or men who have sex with men (MSM). Because of this and previous training, more counsellors were available this year and able to reach more community members during door-to-door outreach activities.

In FY14:

54, 979 Adults and Children received VCT
(Includes 25, 232 couples, 59 CSW, and 61 MSM)
359, 118 Condoms distributed
114, 462 Language-appropriate education materials distributed

COMPACT volunteers are now recognised and respected as key sources of information on HIV prevention, care and treatment in their communities.

Another COMPACT activity is to try to reduce barriers to care at the local health facilities by working with partners and stakeholders. In Kalabo, there are only two CD4 -T cell testing machines in the entire district. HIV-infected clients identified in the field must travel long distances to the mission or district hospital for CD4 testing to learn of the health of their immune system and if they need to start ART. In some cases clients have waited at the facility for over a week and have to return home without seeing a clinician because their food has run out. Therefore, CIDRZ is working with the District Community Health Office in Kalabo to ensure that clients who test positive can have their CD4 T-cell count determined as quickly as possible.

Cervical Cancer Screening Programme



The PEPFAR/CDC and Pink Ribbon Red Ribbon - funded Screen & Treat Visual Inspection with Acetic Acid (VIA) programme features a nurse-led, low-cost, efficient & effective technique where nurses are trained to wash the cervix with a dilute vinegar, take a photo with a digital camera, and freeze any pre-cancerous lesions with carbon dioxide or nitrous oxide gas. Real time, remote digital consultation is available, and women with advanced lesions are referred to Loop Electrosurgical Excision Procedure (LEEP) clinics or tertiary centres for comprehensive care.

By September 2014, 168, 617 women have been screened at 33 screening sites or received treatment at 21 LEEP sites. Services are available in all 10 Provinces.

In Zambia, VIA Screening & Treatment prevents 1 DEATH from cervical cancer for every 46 HIV-infected women SCREENED

In FY14 in addition to clinics being refurbished and opened, cervical cancer screening sensitisation also reached new audiences in rural areas, at the mines on the Copperbelt, and with the visually-impaired community in Lusaka.

As well as providing training to teams from other countries, a free DVD and Provider Training manual was developed and an e-learning platform launched.

See more at **el.acewcc.org.**

In the Cervical Cancer Programme Pipeline for 2015

⇒ Continue to train staff and introduce new cervical cancer screening and LEEP services throughout Zambia

⇒ With funding from Susan G. Komen introduce breast cancer screening services

Saving Mothers Giving Life (SMGL)

Known locally as the Accelerating Maternal care Access Initiative (AMAI), this PEPFAR/CDC - funded programme aims to rapidly reduce maternal & neonatal mortality in the CIDRZ- supported Lundazi and Nyimba districts of the Eastern Province of Zambia.

AMAI Phase 1 aimed to improve maternal and neo-natal outcomes by increasing the demand for and access to local quality obstetric care. This was done by sensitisation of key stakeholders, including health facility staff, and community members about the importance of early care-seeking in pregnancy and the benefit of health facility deliveries. In addition to better equipping local health facilities (left: 5 ambulances were purchased to serve Lundazi and Nyimba Districts), we supported Community Health Workers and Clinic Support Workers to spread health messages to seek early ante-natal care as well as to deliver at health facilities.

AMAI Phase 2 began in July 2014 and monitored and evaluated existing SMGL interventions, as well as performed baseline assessments in a third underserved district, Chipata. After development of data collection tools to extract data from clinic registers and government Health Management Information Systems and training on best data collection practices, teams collected data on **31 SMGL indicators** including: the number of basic & comprehensive Emergency Obstetric and Neo-natal Care trained and equipped health facilities; the number of vaginal and caesarean deliveries; maternal complications and deaths, stillbirths and neo-natal deaths from **over 109 health facilities** in Lundazi and Nyimba ranging from small rural health posts to district hospitals. In Chipata, **47 health facility assessments** were done to quantify staff, infrastructure, and available maternal and newborn healthcare services.

In the SMGL- AMAI Programme Pipeline for 2015

- ⇒ Purchase and distribution of basic Ante-natal care supplies
- ⇒ Provide Emergency Obstetric & Neo-natal Care (EmONC) trainings for healthcare staff in Lundazi, Nyimba & Chipata districts
- ⇒ Mentor Training of Trainers (TOT) participants for programme sustainability
- ⇒ Sensitise Chipata district traditional leaders about SMGL activities
- ⇒ Purchase and distribute incentives for community-based Safe Motherhood Action Groups (SMAGs)
- ⇒ Print back-up Health Management Information System tools

Eastern Province - Improving Maternal Outcomes

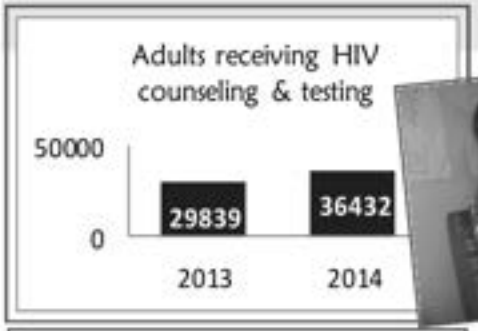
This PEPFAR/CDC- funded programme supports the provision of high-quality, comprehensive, integrated health services to the underserved population of Zambia's Eastern Province through support of PMTCT activities in 54 facilities in Chadiza and Lundazi districts; and TB activities in 43 facilities in Chipata district.

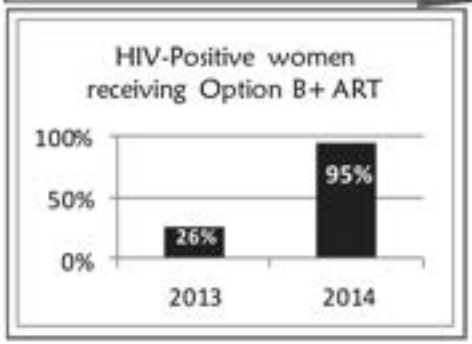
The aim is to build healthcare worker capacity & strengthen health systems that promote improved health, sustainability, and local ownership. Working through the District & Provincial Health Offices, we provide technical support through on-site training, mentorship, and supervision. We also establish Quality Assurance/Quality Improvement systems and conduct data quality audits.

In FY14, we trained 25 healthcare workers & 25 lay counsellors in PMTCT; and 126 healthcare workers, 9 lay counsellors, 42 traditional birth attendants and 56 classified daily employees in Option B+.

We also held 15 Option B+ **'Community Conversations'** and provided blood draw, syphilis testing and infant HIV testing supplies, cooler boxes, transport for CD4 T-cell count testing, and bicycles for mother-infant follow-up in the community.

We aim to eliminate paediatric HIV by enhancing implementation of Option B+ to provide lifelong ART to HIV-infected pregnant women.





"I am Precious Sakala of Chadiza, Eastern Province and a mother of two children. During my first pregnancy I tested HIV-negative so I knew my baby was safe, but during my second I tested HIV-positive. I couldn't accept my status and did not take ART; and my twin babies died. During my third pregnancy, after intense counselling from the healthcare workers, I finally accepted my HIV status. My hubby also asked to be tested, and he was negative. When I reported to ante-natal care I was 5 months pregnant and had already started ART. I was advised not to miss any doses so that I did not weaken my immune system. When my baby son was born he was given Nevirapine syrup while I continued with my ART. I was instructed to give him the syrup every day and also to exclusively breastfeed him for 6 months to try to prevent him getting HIV from me. He was tested for HIV at 6 weeks, and 6, 12 and 18 months. Thankfully he was HIV-negative! These results made me extremely happy as it meant that I did not pass the HIV virus to my innocent baby. In order to help other women like me I have started talking to women in my village about the benefits of counselling and testing, and also about adhering to ART as it not only saves the lives of our unborn babies, but also benefits the mother's health. I am eternally grateful to the nurses and lay counsellors at Chanjowe clinic who made it possible for me to accept my status, to start medication and so save the life of my unborn baby." -- Precious Sakala

Eastern Province - TB Programme

The goal of the Eastern Province TB Programme - also funded by PEPFAR/CDC - is to reduce morbidity & mortality by improving diagnosis and co-management of TB & HIV co-infected patients; and by reducing the spread of TB, particularly in HIV clinics.

Previously, an HIV-infected patient suspected of having TB was referred to the TB clinic and had to wait in another long queue to be screened. This lead to patients being 'lost to referral' and meant that HIV patients with active TB might not be screened and receive treatment, risking their own health and spreading TB to others. The same was true for TB patients suspected of also having HIV infection. To integrate TB & HIV care and capacitate District health facility staff to provide holistic services we supported the training of Provider Initiated Testing and Counseling (PITC). This means that now HIV counseling & testing is available at the TB Corner, and TB screening is available in the ART & Maternal Child Health clinics. The Eastern Province TB Programme also focused on improving infection control procedures to reduce the airborne spread of TB, particularly in HIV Care & Treatment Clinics.

"My name is Moses N'gombe. I am 32 years old and am married and have three children. In May 2013, I developed a cough, fever, difficulties in breathing, night sweats and loss of appetite. I was admitted to the clinic because of the fever and was treated for malaria. But the fever did not stop, so sputum and blood was collected and I was diagnosed with both TB and HIV. This was the second time I suffered with TB; the first was in 2008. I was put on TB treatment – pills and injections for months - the nurses encouraged me to take the drugs every day and the community volunteers were also helpful. When I started treatment I weighed 38 kg (84 lbs) and after 3 months I was 50 kg (110 lbs). Though I was gaining weight, I still had problems so the nurse from the TB Corner took me to the ART Department and on the same day I was put on ART as well as continuing on my TB drugs. I finally finished my TB treatment in October 2014 and am still on the ART – I will take ART for the rest of my life. I thank the clinic staff for their hard work and the care they showed me, and I also want to thank the cooperating partners for the assistance rendered to health facilities that help our healthcare workers better manage patients like me so we can get healthy again and take care of our families. It is my prayer that they continue with the good works."-- Moses N'gombe

TB Training

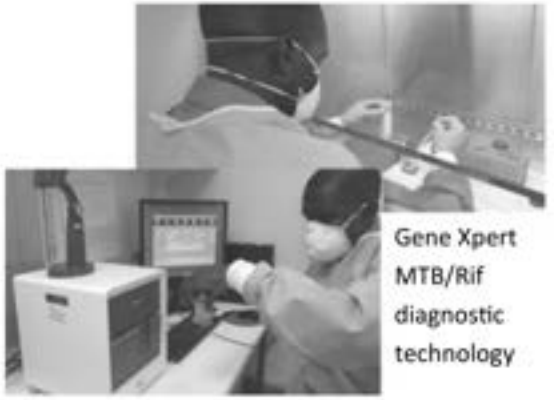
⇒ Infection control to 25 healthcare workers
⇒ PITC training to 25 Trainer of Trainers
⇒ Fixed sputum smear slide preparation for 25 Laboratory staff

TB Commodity Support

⇒ Distribution of HIV & TB Diagnosis and Treatment Guidelines
⇒ Printing of Diagnostic Algorithms
⇒ Provision of 20 cooler boxes, 5,000 sputum containers, and 20 bicycles for sample transportation to TB Diagnostic Centres

Tuberculosis Programme Highlights

Our CIDRZ CDC- funded healthcare service and TB & HIV training programme assists the MOH to reduce the burden of TB in 4 provinces, 12 districts and 337 sites. We also focus on TB & HIV healthcare service integration and completed evaluation of a pilot HIV & TB care integration at 2 TB clinics in Lusaka which demonstrated an increase in the proportion of co-infected patients enrolling into care, and initiating ART.

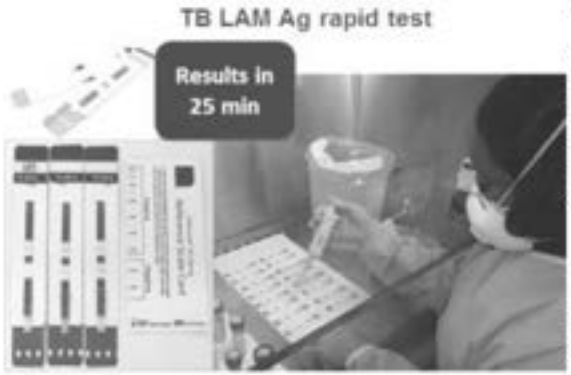


Gene Xpert MTB/Rif diagnostic technology

TB Plus-Up 3 I's strategy of Intensified Case Finding, Isoniazid Preventive Therapy, & Improved Infection Control

In 2014 we implemented this CDC- funded initiative in **29 health facilities and 8 prisons in 4 provinces**. This laboratory 'hub' and clinic or prison based 'satellite' model uses **Gene Xpert MTB/Rif TB testing** (top right) to improve accuracy; decrease time to TB diagnosis thereby enabling earlier patient initiation on TB and ART treatment; decrease the number of patients lost to follow-up; and ultimately provide better TB treatment outcomes. TB Plus-Up will end in 2015.

TB Op-X: Optimizing Clinical Outcomes in HIV-Infected Adults & Children Using Xpert MTB/Rif in Zambia



Another CDC- funded initiative has been implementation of the Xpert MTB/Rif diagnostic capability in HIV-infected patients at **3 peri-urban sites in Chongwe and Kafue districts**. Identifying concurrent TB and HIV infection is important as it can shorten time to initiate necessary TB and ART treatment, thereby improving a patient's clinical outcome. This implementation study is comparing the performance of Xpert MTB/Rif to the existing standard of care of culturing sputum for TB - the 'gold standard' - for TB diagnosis.

In addition, lipoarabinoman or LAM (left) is being tested for accuracy and utility as a novel point-of-care TB diagnostic test that uses urine instead of sputum. Results are expected in late 2016.

Prisons Work

In 2013, we implemented the successful and high profile WHO - funded **TB REACH TB and HIV Screening in Zambian Prisons Programme** which highlighted the extremely high prevalence of both TB and HIV in Zambian prisons and the threat this posed to community public health ***outside*** prison walls. This experience helped us source additional funding from the European Union to build capacity within the Zambian Prisons Services.

Hon. Deputy Minister of Home Affairs (in yellow), **Prisons & CIDRZ leadership at the ZaPHSS Stake-holders Meeting**

This 3-year Zambian Prisons Health Systems Strengthening (ZaPHSS) project aims to capacitate the Zambian Prisons Service Health Directorate to plan, manage, and implement improved and sustainable health services in Zambian Prison facilities.
This project is being conducted in **11 prisons** and includes conducting a qualitative study to better understand inmate health and access to health care, as well as creating facility-based Prison Health Committees of inmates and prisons staff and training them on health needs assessment, peer education, TB and HIV screening, and monitoring and evaluation.

Right: A training for a Prisons Health Committee comprising of inmates & staff

In the TB Programme Pipeline for 2015

⇒ With funding from GlaxoSmithKline and Aeras, prepare to conduct the international multi-centre protective immunity TB Vaccine Clinical Trial, TB-018

⇒ With funding from Global TB Alliance for TB Drug Development, prepare to conduct the Shortening Treatment by Advancing Novel Drugs (STAND) multi-centre international clinical trial to test a treatment-shortening, novel drug combination including an investigational new drug, PA-824. Both of these studies will start in mid-2015 and will help build capacity in both our laboratory and clinical staff

Programme for the Awareness and Elimination of Diarrhoea (PAED)

The Ark and Comic Relief - funded PAED Programme is a comprehensive, sustainable and scalable diarrhoea prevention and treatment programme designed to decrease post neo-natal Under-5 child mortality in Lusaka Province.

MCDMCH Hon. Minister Katema speaking at the National Rotavirus Vaccine launch

After a successful pilot in Lusaka Province and training 561 frontline health workers on the Improved Management of Childhood Illnesses (IMCI), we worked through the Ministry of Community Development Mother and Child Health to successfully roll-out the Rotarix ™ oral rotavirus vaccine nationally in November 2013 as part of the national Expanded Program for Immunisation (EPI).

In June 2014, CIDRZ PAED hosted the 8th African Rotavirus Symposium in Livingstone, the first time this scientific event was held in Zambia.

Over 130 leading researchers and scientists from 35 countries -- 28 from across Africa -- attended to discuss current research results and epidemiological trends of the rotavirus. A total of 70 abstracts were accepted and 35 oral presentations were made during the 2-day symposium.

Above : VIPs at the 8th ARS. Back row: Dr Umesh Parashar CDC-Atlanta; Dr Evans Mpabalwani University Teaching Hospital Zambia; Dr Duncan Steele Bill & Melinda Gates Foundation; Dr Roma Chilengi CIDRZ; Dr George Armah University of Ghana; Cheryl Rudd CIDRZ. Front row: Dr Penelope Kalesha MCDMCH; Dr Jason Mwenda WHO AFRO; Hon. Minister MCDMCH Emerine Kabanshi; and Dr Roger Glass U.S. National Institutes of Health.

"The African Rotavirus group began as a simple training grant which has provided critical data on the burden of rotavirus disease in Africa leading to the rollout of vaccination programmes in more than 14 countries in the region. This 8th African Rotavirus Symposium organised by CIDRZ provided the first documentation of the impact of these vaccines and so was really a highlight of many years of training, support and investment." -- Dr Roger I. Glass, Director of the Fogarty International Center and NIH Associate Director for International Research

The Komboni Housewives: A Behavioural Change Campaign

PAED also launched a Lusaka Province - wide behaviour change campaign and research study to promote the prevention, management and treatment of childhood diarrhoea.

Partnering with the London School of Hygiene and Tropical Medicine, funded by Ark and Comic Relief, the Komboni Housewives (gossiping "Compound Housewives") was an innovative and edu-taining ensemble of women, accompanied by popular Zambian musician Afunika that conducted community events, radio programmes and contests that trained parents and caregivers in the proper technique and times for hand-washing with soap, the importance of exclusive breastfeeding up to 6 months of age, and the correct method to constitute and use Oral Rehydration Salts (ORS) and oral Zinc to treat childhood diarrhoea. Our PAED's Komboni Housewives initiative advocated for a Zambian company to produce Zinc locally, thus improving access and price competition for this life-saving commodity. An evaluation of the campaign impact is ongoing.

Above: Zambian music artist Afunika - encouraging audience participation in the Komboni Housewives campaign song of "Tiku Checking Ani" (Checking Up On You!) Above right: The Komboni Housewives in action.

In the PAED Pipeline for 2015

⇒ With funding from Ark and Comic Relief, complete the PAED Programme Monitoring and Evaluation

⇒ With support from the ELMA Vaccine and Immunizations Foundation, strengthen the vaccine cold chain at the District and Health Facility levels so that life-saving vaccines can reach every child in Zambia, including those that live in distant rural areas

Water, Sanitation and Hygiene Activities (WASH)

3 Million People Sanitation Programme: A Community-Led Total Sanitation Success Story!

In July 2014, CIDRZ and WaterAid Zambia - both implementing partners - joined the Ministry of Local Government and Housing, and funders UNICEF and DFID, to celebrate an important milestone in the 3 Million People Sanitation Programme. This Community-Led Total Sanitation (CLTS) programme promotes improvement in community-wide sanitation in rural Zambia through providing awareness to promote the end of open defecation. After appropriate sensitisation, the community itself must truly take the lead in this accomplishment by constructing latrines and 'tippy tap' hand-washing stations supplied with soap, or ash, to attain WASH Open Defecation Free (ODF) status in order to reduce diarrhoeal disease and improve general well-being of the community.

The celebration of **1,000,000 New Sanitation Users** was held in tiny Mupapa Village in Kafue district just outside of the capital Lusaka. The Mupapa village effort towards attaining ODF status was triggered by a Community Champion in August 2013 and the village was verified to be ODF - status in March 2014. Villagers like Josephine Aisam (below right with her new latrine and tippy tap) were ecstatic to be recognised as a model village and chosen to host the celebrations. The Honourable Deputy Minister of Local Government and Housing Nicholas Banda presented an ODF certificate to the Village Headman (above). At the event, 15-year old Catherine Isam expressed her joy at finally having a latrine that provided privacy, and how shameful it was before when she and members of her household practiced open defecation. She wholeheartedly encouraged other villages to emulate Mupapa's achievement!

In the WASH Programme Pipeline for 2015

⇒ With support from DFID through UNICEF continue to improve Water, Sanitation and Hygiene through Community-Led Total Sanitation (CLTS) and initiate School-Led Total Sanitation (SLTS) in CIDRZ-responsible districts in Lusaka Province.

Better Health Outcomes through Mentoring and Assessment

The BHOMA 1 Project - in the 6th year of funding from the Doris Duke Charitable Foundation under the Population Health Initiative and Training African Health Initiative - is a collaboration with MOH, MCDMCH and Zambart focusing on 5 rural districts of Lusaka Province. The overall aim is to accelerate a shift from disease-specific to sustainable, integrated primary healthcare programmes that strengthen health systems and achieve measureable significant health improvements. Another aim is to increase use of evidence-based health delivery and health systems planning by supporting implementation research. In 2014 the BHOMA 1 team completed implementations at **40 rural clinic sites** by setting up sustainable electronic data systems with **over 1 million individual patient visit records entered.** Clinic staff received ongoing mentoring and supportive visits, and 500 volunteers in 20 facilities received trainings in safe motherhood through 'Community Conversations.'

Above: A BHOMA 'Community Conversation' meeting

BHOMA 2 Project

In 2013, Comic Relief provided funding for 20 existing BHOMA sites to focus intensively on implementation of adapted best practices for maternal newborn care packages at the community and clinic level. Titled BHOMA 2, this project is promoting establishment of community-led and community-owned maternal support activities as well as implementation of incentive-based traditional birth attendant activities to improve Ante-natal care attendance, facility deliveries and family planning use.

In the BHOMA Programme Pipeline for 2015

⇒ Scale-down mentoring support to BHOMA 1 sites

⇒ Collect and map BHOMA 2 baseline implementation data around Sexual Reproductive Health (SRH) issues affecting target communities; conduct sensitisations and 'Community Conversations' to address barriers to access of SRH care services

Engaging the Community

Central to CIDRZ healthcare programme and research activity is engaging the community and key stakeholders through the traditional social infrastructure.

After all required Government, Ministry and local and international Ethical approvals have been received, our health and research programmes must sensitise the relevant health facility staff, local government ward counsellors, and other key stakeholders through face-to-face or small group meetings.

However, sensitising the general community is done Zambian style. First, is the rhythmic pounding of the African drums to attract attention interspersed with energetic traditional dancing and singing. This may be followed by a humorous skit or song to demonstrate the message, and end with a health talk or small group sessions to allow for questions and answers. Formal events with dignitaries may follow the same style, but may also include brass bands, flag-off marches, speeches, ribbon-cutting, and much pomp and ceremony.

When engaging the community it is very important to respect the Zambian social infrastructure and ensure that the local Traditional Chief or Chieftainess, the Indunas (Advisors), Village Headmen, Traditional Marriage Counselors, and Traditional Health Practitioners are also sensitised on the purpose of the programme/research or health message.

Right: Her Highness Chieftainess Nkomeshya at the National Rotavirus Vaccine launch

After a sensitisation event for traditional rulers in Eastern Province the Voluntary Medical Male Circumcision (VMMC) programme saw an increased acceptance of circumcision in the entire province, with some Chiefs becoming MC Champions and undergoing the procedure themselves! Sensitising the Faith-based community and Neighbourhood Health Committee members is also very important as their involvement assists in raising awareness, and promoting the health programme and the desired behaviours, because the public better trust the messenger and thus the message.

Research: A Core Component of Our Mission

We conduct high-quality, clinical trials & implementation science that follow Good Clinical Practices (GCP) and the UNAIDS/AVAC Good Participatory Practices (GPP). We have dedicated research regulatory affairs, data management & analysis, quality control & assurance, research pharmacy & lab departments. Every study receives all necessary local & international ethical and regulatory approval prior to initiation, and undergoes annual ethical review. All research staff has current Human Subjects Protection certification.

Because of our strong focus on programme implementation, integration & evaluation, many of our studies seek to directly improve the provision and uptake of healthcare services, using culturally-relevant, resource appropriate strategies. We collaborate with District & Provincial Health Offices and working together raise healthcare provision to new standards.

Knowledge generated during healthcare service delivery inform research questions, and results of research studies directly inform programmes. CIDRZ has conducted numerous influential studies, and this work has been enhanced by our relationship and engagement with local and international policymakers.

We strive to bridge the gap between research and policy, allowing CIDRZ to inform clinical practice and promote evidence-based strategies locally, regionally, and globally.

CIDRZ research activities range from small diagnostic and pharmacokinetic trials, to behavioural studies, to individual & multi-site clinical trials, to multi-district or multi-country evaluations.

CIDRZ is committed to answering key research questions relevant to Zambia. As of September 2014, CIDRZ has 40 research studies in planning, enrollment or follow-up.

- Our U.S. National Institutes of Health-funded **Clinical Trials Unit** takes part in international multi-site clinical trials as part of the International Maternal, Pediatric, Adolescent AIDS (IMPAACT) Network, and the HIV Prevention Trials Network (HPTN).
- We also take part in the U.S. National Institute of Allergy and Infectious Disease - funded International Epidemiologic Databases to Evaluate AIDS (IeDEA) research consortium which addresses unique and evolving research questions in HIV/AIDS that are unanswerable by single cohorts. By pooling large data sets data can be generated which address high priority research questions in a more timely and cost efficient manner. We take part in the pooled regional analysis for ART, and have sub-awards for hepatitis and malaria research.
- We are involved in the U.S. National Institute of Child Health and Human Development-funded Global Network for Maternal and Child Health and have completed over 10 field studies.
- We also manage 6 observational databases.

More About Our Research

Key *NEW* Research Project

Better Information for Health in Zambia (BetterInfo)

This Bill & Melinda Gates Foundation supported grant award aims to systematically gain a better understanding of why some patients enrolled in anti-retroviral treatment (ART) care stay in care, while others are 'lost' from care.

It is estimated that 25 - 40% of patients enrolled in ART care may be lost-to-follow-up.

The 'BetterInfo' study will trace lost patients, learn of their outcomes, and more importantly, why. It will provide more accurate estimates of patient outcomes at both the clinic and provincial levels which will help the Government of the Republic of Zambia to make informed decisions about HIV care service programmes and facilities to better meet the needs of ART patients so that they stay in life-saving care. Study staff will use best practices when tracing 'lost' patients to protect their privacy and confidentiality, and patients that have stopped receiving care will be encouraged to resume.

BetterInfo will be conducted in 30 sites in Lusaka, Western, Southern & Eastern Provinces over 29-months.
The study involves dynamic stakeholder engagement including guidance by a local and international Advisory Committee of scientists and government officials and quarterly meetings with Neighbourhood Health Committees at the sites. BetterInfo is lead by CIDRZ Principal Investigators, Dr Charles Holmes and Dr Izukanji Sikazwe, and Dr Elvin Geng of the University of California, San Francisco.

In the Research Pipeline for 2015

⇒ New collaboration with **HIV Vaccine Trials Network (HVTN)** to conduct a **Phase 1 HIV vaccine trial** to evaluate the safety and immunogenicity of a candidate HIV Clade C vaccine in healthy, HIV-uninfected adult participants

⇒ New collaboration with **AERAS TB Vaccine Network** to conduct TB - 018, a Phase 2b trial of a Protective Immunity TB Vaccine

⇒ New collaboration with **TB Alliance - Global Alliance for TB Drug Development** to conduct the Phase 3 STAND trial to evaluate the efficacy, safety and tolerability of a treatment shortening regimen for TB

Select 2014 CIDRZ Publications

Since inception CIDRZ has published over 260 peer-reviewed manuscripts

Rainwater-Lovett K, Nkamba H, Mubiana-Mbewe M, Bolton Moore C, Margolick J, Moss W. **Antiretroviral therapy restores age-dependent loss of resting memory B cells in young HIV-infected Zambian children.** J Acquir Immune Defic Syndr. 2013 Dec 8. PubMed PMID: 24326598.

De Vuyst H, Alemany L, Lacey C, Chibwesha CJ, Sahasrabuddhe V, Banura C, Denny L, Parham GP. **The burden of human papillomavirus infections and related diseases in sub-Saharan Africa.** Vaccine. 2013 Dec 29;31 Suppl 5:F32-46. PubMed PMID: 24331746.

Denny LA, Sankaranarayanan R, De Vuyst H, Kim JJ, Adefuye PO, Alemany L, Adewole IF, Awolude OA, Parham G, de Sanjosé S, Bosch FX. **Recommendations for cervical cancer prevention in sub-Saharan Africa.** Vaccine. 2013 Dec 29;31 Suppl 5:F73-4. doi: 10.1016/j.vaccine.2012.11.077. PubMed PMID: 24331750.

Holmes CB, Sikazwe I, Raelly RL, Freeman BL, Wambulawae I, Silwizya G, Topp SM, Chilengi R, Henostroza G, Kapambwe S, Simbeye D, Sibajene S, Chi H, Godfrey K, Chi B, Moore CB. **Managing multiple funding streams and agendas to achieve local and global health and research objectives: lessons from the field.** J Acquir Immune Defic Syndr. 2014 Jan 1;65 Suppl 1:S32-5. PubMed PMID: 24321983.

Holmes, Charles; Pillay, Yogan; Mwango, Albert; Perriens, Jos; Ball, Andrew; Barreneche, Oscar; Wignall, Steven; Hirnschall, Gottfried; Doherty, Meg C. **Health systems implications of the 2013 WHO consolidated antiretroviral guidelines and strategies for successful implementation.** AIDS: March 2014 Volume 28 p S231-S239 doi: 10.1097/QAD.0000000000000250 PMID: 24849483.

Topp SM, Chipukuma JM, Hanefeld J. **Understanding the dynamic interactions driving Zambian health centre performance: a case-based health systems analysis.** Health Policy Plan. 2014 May 14. pii: czu029 PMID: 24829316.

Harris JB, Siyambango M, Levitan EB, Maggard KR, Hatwiinda S, Foster EM, Chamot E, Kaunda K, Chileshe C, Krüüner A, Henostroza G, Reid SE. **Derivation of a tuberculosis screening rule for sub-Saharan African prisons.** Int J Tuberc Lung Dis. 2014 Jul;18(7):774-80. doi:10.5588/ijtld. PMID: 24902551.

Saleem S, McClure EM, Goudar SS, Patel A, Esamai F, Garces A, Chomba E, Althabe F, Moore J, Kodkany B, Pasha O, Manasyan A, Belizan J, Derman RJ, Hibberd PL, Liechty EA, Krebs NF, Hambidge MK, Buekens P, Carlo WA, Wright LL, Koso-Thomas M, Jobe AH, Goldenberg RL, and the Global Network Maternal Newborn Health Registry Study Investigators. **A Global Network Cohort Study of Maternal Mortality and Risk of Adverse Birth Outcomes in Communities in Low-resource Settings.** Bull World Health Organ. 2014 Aug 1;92(8):605-12. doi: http://dx.doi.org/10.2471/BLT.13.127464.

Rainwater-Lovett K, Hc N, Mubiana-Mbewe M, Moore CB, Jb M, Wj M. **Changes in Cellular Immune Activation and Memory T Cell Subsets in HIV-Infected Zambian Children Receiving HAART.** J Acquir Immune Defic Syndr. 2014 Sep 15. PMID: 25226208.

Mweemba A, Zanolini A, Mulenga L, Emge D, Chi BH, Wandeler G, Vinikoor MJ. **Chronic hepatitis B virus co-infection is associated with renal impairment among Zambian HIV-infected adults.** Clin Infect Dis. 2014 Sep 16. pii: ciu734 PMID: 25228705 PMCID: PMC4311179.

Training: A Core Component of Our Mission

Above: Community Compact programme Psychosocial counselling graduates in rural Kalabo, Western Province

Training is central to almost every healthcare programme & research study we conduct. Some examples are increasing the knowledge and skills of community - based counsellors to provide door-to-door VCT and Couples Counselling at the grassroots level in our PEPFAR/CDC- funded Community Compact programme; updating frontline health workers on how to correctly manage childhood diarrhoea as part of the rotavirus vaccine scale-up programme; training research staff on how to correctly administer informed consent to research volunteers following Good Clinical Practice (GCP) guidelines; and mentoring District nurse-midwives, laboratory technicians and pharmacy personnel in our PEPFAR/CDC- funded HILO programme.

In addition to project specific training, CIDRZ staff also received training on Finance, ICT and ERP systems as well as extracurricular health messages linked to celebrations of World Health Days & commemorative days. This year there were events featuring the importance of blood donation followed by a blood drive, cervical cancer prevention and screening, handwashing with soap, and a TB Knowledge Fair.

Clockwise: Dr Joseph Mulenga, Medical Director of the Zambia National Blood Transfusion Service; ICT training; TB Knowledge Fair

⇒ CIDRZ hosts a Weekly Research Meeting where Lusaka-based healthcare and research members hear local & international experts present on their areas of expertise. Key presentations in 2014 were delivered by:

- Dr Paul Kelly, London School of Hygiene and Tropical Medicine
- Dr Edward Hook, University of Alabama at Birmingham
- Dr Omar Siddiqi, Harvard Medical School
- Dr Samuel Zuercher, Infectious Disease Institute of the University of Bern
- Dr Elvin Geng, University of California, San Francisco

⇒ CIDRZ researchers also come together at bi-weekly Analysis Meetings and Journal Clubs.

Public Health & Research Training Opportunities

CIDRZ HIVCorps Public Health Fellowships

This fellowship provides a valuable field training opportunity for Zambian and expatriate students and early-career public health professionals through one-year long attachments in programme implementation & management, clinical trials research, clinical care quality improvement systems, data management & analysis, implementation science, or public health communications.

Global Health Corps Fellowship Programme

CIDRZ is a site for this international programme for promising early career public health professionals. The emphasis on 'paired' local and international trainees enhances the bi-directional exchange of knowledge and encourages future collaboration.

Fogarty Global Health Fellowship

Through a competitive process, pre- and post-doctoral trainees are provided 12 months of dedicated Fogarty/U.S. National Institutes of Health-support to gain international research experience. Mentored by senior investigators in Zambia, trainees work in the areas of HIV, TB, maternal-child health, primary healthcare, childhood immunisation, and reproductive health screening, among others.

Doris Duke International Clinical Research Fellowship

Expatriate medical students explore international clinical research careers through exposure to one-year long attachments. Under CIDRZ mentors, fellows gain experience in various steps of clinical and epidemiologic research, including study concept development, project implementation, and results dissemination.

Cervical Cancer Research Capacity Initiative

In collaboration with U.S. and Zambian institutions, CIDRZ has developed a multidisciplinary cancer research training programme with U.S. National Cancer Institute funding to build research capacity within the Lusaka-based University Teaching Hospital and Cancer Diseases Hospital through individualised mentorship and grant support for seed projects in various fields of epidemiology, nutrition, pathology, gynaecologic oncology, radiation oncology, and virology.

Short-term CIDRZ Internship Attachments

We accept applications from Zambian under- or post-graduate students seeking one to six month long placements on a case-by-case basis including a range of technical (e.g., laboratory, study implementation, pharmacy) and administrative (e.g., accounting, human resource, ICT) disciplines.

Training and Dissemination Events

Left:
Physician, HIV prevention activist and journalist, Dr Mannasseh Phiri with Deputy CEO Dr Izukanji Sikazwe

8th National Anti-Retroviral Technical Update Meeting

Harmonised, Integrated and Simplified Quality HIV Care

Every year CIDRZ HIV/AIDS Clinicians, Pharmacists and Programme Managers take part in the National ART Technical Update either through collaboration with MOH and MCDMCH colleagues to organise the event, to make presentations, and/or to attend. This year's update included eight CIDRZ presentations as well as a Civil Society Plenary chaired by CEO Dr Charles Holmes and Dr Jonas Mwale of CDC– Zambia (left).

Right: Hon. Deputy Minister of Health, Dr Chitalu Chilufya, officially opening the Pharmacy Research Conference

Pharmacy Research Conference

Promoting Pharmacists' Involvement in Quality Research to Improve Health

With the support of ABBVIE Pharmaceuticals, the CIDRZ Pharmaceutical Services Department staff (left) convened a conference for local public and private sector pharmacists and technicians to provide updates on ART and prevention of drug resistance as well as to train on the role of pharmacy-related research. This training conference is intended to become an annual event.

TB Programme Dissemination

Presentations were made by CIDRZ TB Project Managers and Coordinators (right) to multiple Ministries, Zambian regulators, partners, NGOs, TB stakeholders, and the media. The event was officially opened by the Hon. Deputy Minister of Health and closing remarks were delivered by the National TB/Leprosy Control Programme Manager, Dr Nathan Kapata (left).

Key Organisational Updates

Successful Implementation of Sage X3 ERP

A big accomplishment in 2014 was the successful implementation of the Sage X3 Enterprise Resource Planning (ERP) business system; CIDRZ is the first NGO in Zambia to do so! In the past, CIDRZ ran AccPac for accounting, PURIDIOM for web-based procurement processing, and LIMS for lab tests, but these programmes could not exchange data amongst themselves, thus slowing decision-making, reporting and increasing risk of error. Implementation of ERP has increased transparency and accountability as users can now view the workflow process to see how their task is progressing. Now, performing financial transactions is streamlined with automated workflows and controls built in. Implementation of ERP included initial and refresher staff training as well as the production of one-page training guides and tools.

⇒ In 2015 we look forward to introducing a Human Resource Self-Service Portal where staff will file time sheets, submit performance assessments and access leave forms and payslips online.

CIDRZ Celebrates National Labour Day

May 1st is important for the Zambian workforce, so it was with pleasure that in Zambia's Independence Jubilee year CIDRZ took part in this annual event under the theme 'Zambia at 50: Creating Decent Work and Promoting Socio-Economic Justice for National Development'.

CIDRZ was the only health NGO represented at the event. Thirty staff volunteered to walk behind the CIDRZ banner in the National march-past and Presidential Salute event. The following day staff gathered at the CIDRZ Head Office in Lusaka for a ceremony and lunch to honour the 39 CIDRZ Labour Day employee awardees who received certificates, a gift voucher and a photo with the Board of Directors Chairman. The categories of CIDRZ staff awards were: Most Outstanding, Most Innovative, Most Cost-Efficient, and Most Improved and Committed Employees.

Fundraising Campaign

Left: CEO Dr Charles Holmes

In late 2014, CIDRZ launched the first-ever fundraising campaign with the target of raising USD 2.5 million.

In this initiative we chose to partner with Accordia Global Health Foundation, an organisation dedicated to building Africa's permanent capacity for health leadership and innovation through the establishment and support of sustainable African Health Institutions such as CIDRZ. Secure donations may be made through the Accordia website and being a 501 (C) (3) organisation, individual donors may receive a U.S. Internal Revenue Service deduction, if desired. (http://www.accordiafoundation.org/).

Right: Accordia Foundation President Dr Robert L. Mallet speaking at the CIDRZ fundraising event

Although CIDRZ has a very successful record of winning and executing competitive grant awards, as a newly independent organisation we also require non-grant or 'unrestricted' revenue. A reserve of this nature will provide CIDRZ with the financial flexibility we need to be able to act quickly on innovative ideas and strategic opportunities, to continue to develop our laboratory and other infrastructure so that we may expand our programmes to serve more Zambians, to provide professional development training for our staff, and to continue our work and training to build the next generation of Zambian public health leaders.

To date the campaign has centred on social media call-to-action activities and small hosted events where CEO Charles Holmes, and other dedicated supporters such as Mary Fisher speak and show our film CIDRZ: Bringing Hope and Health in Zambia (https://www.youtube.com/watch?v=6q-tYLbM6Ws) which features employee, health advocate and woman living with HIV, Susan Chirwa sharing her CIDRZ story.

Left:
Mary Fisher, AIDS advocate, artist, author and longtime CIDRZ supporter

Our aim is for CIDRZ to be a long-term resource to the country of Zambia, one that will create knowledge, build the capacity of future health leaders and save and improve more lives.

Financials

01 October 2013 - 30 September 2014

An independent local organisation, CIDRZ supports Zambia's national health priorities. Our ultimate aim is to strengthen primary health care systems to improve health for ALL Zambians.

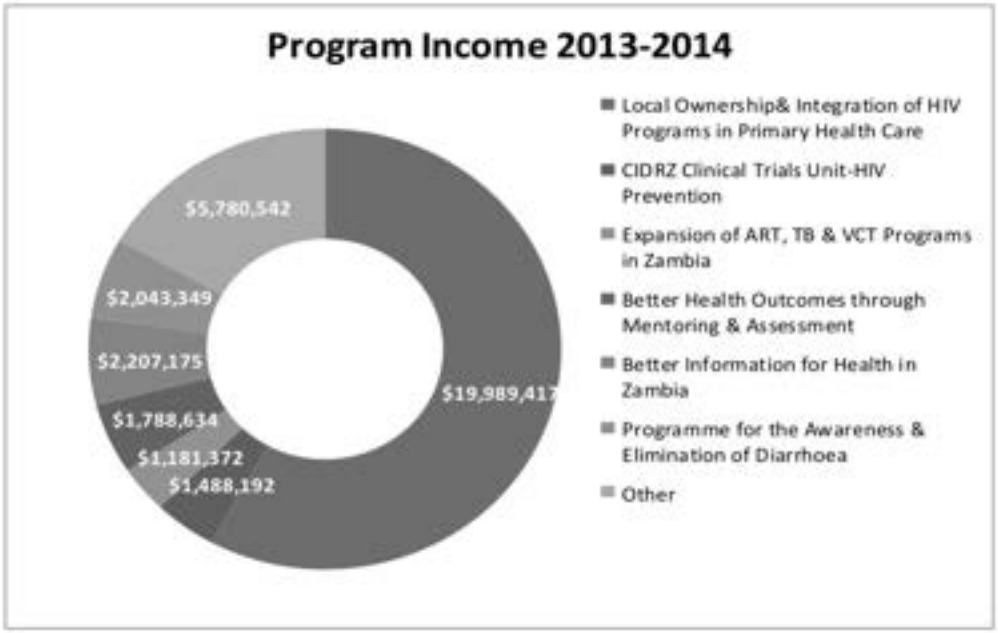
During FY 2014 CIDRZ focused on recruiting skilled and experienced Board members, and building robust internal management structures and governance systems/controls to anchor organisational functioning. Success was achieved and CIDRZ now has:

⇒ **A reconstituted Board with subcommittees of Audit and Finance, Investment, and Scientific and Programmatic Performance**
⇒ **A strong Internal Audit Department led by a Certified Internal Auditor and Fraud Examiner**
⇒ **Implemented a Financial and Operations Enterprise Resource Planning (ERP) system to streamline organisational processes**

In September 2013, CIDRZ signed Ministry of Justice approved Memorandums of Understanding with the Ministry of Health and Ministry of Community Development Mother and Child Health as well as reached an agreement with the Zambian Revenue Authority to ring-fence historical tax liabilities and become fully tax compliant regarding Pay-As-You-Earn source deductions for all employees. Other notable accomplishments were the closing of both the 2013 and 2014 books with unqualified audits by top auditing firms.

CIDRZ manages over USD 34 million worth of grant awards ranging from U.S. Federal to Private Foundations.

Notable accomplishments this year was winning 10 new grant awards totaling over USD 6,325,000 with 4 awards from new funders: M·A·C AIDS Fund, Elma, the National Cancer Institute, and the HIV Vaccines Trials Network.



Thank You to Our Donors and Partners

Without the collaboration, confidence and generous support of our donors and partners, CIDRZ would not be able to contribute to improving health in Zambia. We thank you!

AIDS Clinical Trials Group
Abataka Zambia
ABBVIE Pharmaceuticals
Accordia Global Health Foundation
Aeras
Ark
Bill & Melinda Gates Foundation
Bush Institute
Canadian International Development Agency
Cancer Diseases Hospital (Zambia)
Centers for Disease Control and Prevention
Cervical Cancer Research Capacity Initiative
Churches Health Association of Zambia
Columbia University ICAP
Comic Relief
Delft
DFID
Doris Duke Charitable Foundation
Doris Duke International Clinical Research Fellowship
ELMA Vaccine and Immunizations Foundation
European Union
Fogarty Global Health Fellowship
GlaxoSmithKline
Global Advocacy for HIV Prevention - AVAC
Global Health Corps
Groundwork Initiative for Global Health at MIT Sloan
HIV Prevention Trials Network
HIV Vaccine Trials Network
International Epidemiologic Databases to Evaluate AIDS
International, Maternal, Pediatric Adolescent AIDS Clinical Trials
International Initiative for Impact Evaluation 3ie
Japan International Cooperation Agency JICA
Johns Hopkins University
London School of Hygiene and Tropical Medicine
M·A·C AIDS Fund
Mary Fisher
Max M & Marjorie S Fisher Foundation
Ministry of Chiefs and Traditional Affairs
Ministry of Community Development Mother and Child Health
Ministry of Education
Ministry of Health
Ministry of Home Affairs
Ministry of Housing and Local Government
National Cancer Institute
National Institute of Allergy and Infectious Disease
National Institute of Child Health and Human Development
National Institutes of Health
Pink Ribbon Red Ribbon
Susan G. Komen
TB Alliance - Global Alliance for TB Drug Development
UKAID
United National Children's Fund
United States Agency for International Development - USAID
U.S. President's Emergency Plan for AIDS Relief
University of Alabama at Birmingham
University of North Carolina at Chapel Hill
University Teaching Hospital (Zambia)
Vanderbilt University
WaterAid Zambia
World Health Organization
Zambian AIDS Related Tuberculosis Project
Zambian Prisons Services
Zambian Center for Applied Health Research and Development

Abbreviations and Acronyms

AIDS - Acquired Immunodeficiency Syndrome

AMAI - Accelerating Maternal care Access Initiative

ART - Anti-Retroviral Treatment

BHOMA - Better Health Outcomes through Mentoring and Assessment

CDC - Centers for Disease Control and Prevention

CLTS - Community-Led Total Sanitation

EGPAF - Elizabeth Glaser Pediatric AIDS Foundation

EmONC - Emergency Obstetric and Neo-natal Care

EPI - Expanded Programme on Immunisations

ERP - Enterprise Resource Planning

GCP - Good Clinical Practices

GPP - Good Participatory Practices

GRZ - Government of the Republic of Zambia

HILO - HIV Integration into Local Ownership

HIV - Human Immunodeficiency Virus

HSP - Human Subjects Protections (Ethics)

ICT - Information, Communication and Technology

IMCI - Improved Management of Childhood Illness

LAM - Lipoarabinoman

LEEP - Loop Electrosurgical Excision Procedure

MC - Male Circumcision

MCDMCH - Ministry of Community Development Mother and Child Health

MLGH - Ministry of Local Government and Housing

MOH - Ministry of Health

MOHA - Ministry of Home Affairs

NGO - Non Governmental Organisation

NIH - National Institutes of Health

ODF - Open Defecation Free

ORS - Oral Rehydration Salts

PITC - Provider-Initiated Testing and Counselling

SLTS - School-Led Total Sanitation

SMAG - Safe Motherhood Action Group

SMGL - Saving Mothers Giving Life

SRH - Sexual Reproductive Health

TB - Tuberculosis

TOT- Training/Trainer of Trainers

PEPFAR - U.S. President's Emergency Plan for AIDS Relief

PMTCT - Prevention of Mother to Child Transmission (of HIV)

UNZA - University of Zambia

UTH - University Teaching Hospital

VCT - Voluntary Counseling and Testing

VIA - Visual Inspection with Acetic Acid

VMMC - Voluntary Medical Male Circumcision

WASH - Water, Sanitation and Hygiene

WHO - World Health Organization

ZAMRA - Zambia Medicines Regulatory Authority

ZaPHSS - Zambia Prisons Health Systems Strengthening

Centre for Infectious Disease Research in Zambia (CIDRZ)

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From:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
To:	Glass, Roger (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=glassr <glassr@mail.nih.gov>
Subject:	Fw: Greetings: Visit of Albanian Minister of Health to NIH
Date:	2016/02/24 07:23:53
Priority:	Normal
Type:	Note

FYI - Albania info.
Peter Kilmarx, MD, FACP, FIDSA
Fogarty International Center, NIH

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Monday, February 22, 2016 3:59 PM
To: Herrfurth, George (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Thanks very much George for great legwork

I also found:

https://en.wikipedia.org/wiki/Albania#Science_and_technology

Science and technology

Main article: Science and technology in Albania

From 1993 human resources in sciences and technology have drastically decreased. Various surveys show that during 1991–2005, approximately 50% of the professors and research scientists of the universities and science institutions in the country have emigrated.[136] However, in 2009 the government approved the "National Strategy for Science, Technology and Innovation in Albania"[137] covering the period 2009–2015. It aims to triple public spending on research and development (R&D) to 0.6% of GDP and augment the share of gross domestic expenditure on R&D from foreign sources, including via the European Union's Framework Programmes for Research, to the point where it covers 40% of research spending, among others.

And link to the Strategy, which mentions public health but no details:
http://portal.unesco.org/en/files/47499/12677115709STI_english.pdf/STI%2Benglish.pdf

Also of note, 520 articles in:
http://www.ncbi.nlm.nih.gov/pubmed?term=Albania%5BAffiliation%5D

PK

From: Herrfurth, George (NIH/FIC) [E]
Sent: Monday, February 22, 2016 2:43 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]

Subject: FW: Greetings: Visit of Albanian Minister of Health to NIH
Importance: High

Hi Peter: Attached are the bios for the visitors from Albania.

We don't know too much about biomedical or behavioral research in Albania given the paucity of data for the country. Health care in Albania declined steeply after the collapse of socialism in the country, but a process of modernization has reportedly been taking place since 2000. In the 2000s, there were 51 hospitals in the country, including a military hospital and specialist facilities. Albania has successfully eradicated diseases such as malaria.

Life expectancy is estimated at 77.59 years, ranking 51st worldwide, and outperforming a number of European Union countries, such as Hungary and the Czech Republic. Demographic and Health Surveys completed a survey in April 2009, detailing various health statistics in Albania, including male circumcision, abortion and more.

The Faculty of Medicine of the University of Tirana is the main medical school in the country. There are also nursing schools in other cities.

The general improvement of health conditions in the country is reflected in the lower mortality rate, down to an estimated 6.49 deaths per 1,000 in 2000, as compared with 17.8 per 1,000 in 1938. In 2000, average life expectancy was estimated at 74 years, compared to 38 years at the end of World War II. Albania's infant mortality rate, estimated at 20 per 1,000 live births in 2000, has also declined over the years since the high rate of 151 per 1,000 live births in 1960. There were 69,802 births in 1999 and the fertility rate in 1999 was 2.5 while the maternal mortality rate was 65 per 100,000 live births in 1993. In addition, in 1997, Albania had high immunization rates for children up to one year old: tuberculosis at 94 percent; diphtheria, pertussis, and tetanus, 99 percent; measles, 95 percent; and polio, 99.5%. In 1996, the incidence of tuberculosis was 23 in 100,000 people. In 1995 there were two reported cases of AIDS and seven cases in 1996. In 2000 the number of people living with HIV/AIDS was estimated at less than 100 cases. The leading causes of death are cardiovascular disease, trauma, cancer, and respiratory disease.

Alternative medicine is also practiced among the population in the form of herbal remedies as the country is reportedly a net exporter of aromatic and medicinal herbs.

Hope this helps. However, it still does not address what, if any, significant biomedical research is ongoing in the country of nearly 2.9 million

George

From: Mamica Toska [mailto:[redacted by agreement]
Sent: Monday, February 22, 2016 11:11 AM
To: Glass, Roger (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]; Floreta Faber
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH
Importance: High

Dear Dr. Glass,

Please find attached the bios of the Albanian delegation's members that will visit NIH.

Best regards,
Mamica

Mamica Toska
Minister Plenipotentiary
Embassy of the Republic of Albania
2100 S Street, NW
Washington DC 20008
Tel. (202) 223 4942
Fax. (202) 628 7342
Mob. Redacted by agreement
Email. Redacted by agreement

From: Floreta Faber
Sent: Monday, February 22, 2016 10:13 AM
To: Glass, Roger (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]; Mamica Toska
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Dear Dr. Glass:

It was nice to hear from you and thank you for giving your time in putting this meeting and tour together.

Please let me confirm Wednesday, February 24 at 9:00.

The delegation is composed as following, all Albanian citizens:

Ilir Beqaj Redacted by agreement
Klodiana Spahiu, Redacted by agreement
Floreta Faber,
Edmond Faber

We will bring you shortly the Bios of the members of the delegation.

I would highly appreciate to also have the bio of who we are meeting at NIH, hopefully in a very short note the meeting can also meet with Director Collins. I am also hoping that Ms. Diane can also be with us during the visit.

Looking forward to it.

Sincerely,

Floreta

Floreta FABER
Ambassador
Embassy of the Republic of Albania

2100 S Street, NW
Washington DC 20008
Tel. (202) 223 4942
Fax. (202) 628 7342
Mob. Redacted by agreement
Email. Redacted by agreement

From: Stover, Kathleen (NIH/FIC) [E] [stoverka@mail.nih.gov] on behalf of Glass, Roger (NIH/FIC) [E] [glassr@mail.nih.gov]
Sent: Monday, February 22, 2016 9:33 AM
To: Floreta Faber
Cc: Glass, Roger (NIH/FIC) [E]; Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]
Subject: FW: Greetings: Visit of Albanian Minister of Health to NIH

Dear Ambassador Faber,

We are delighted that you and Minister Beqaj will be able to visit NIH this week. Unfortunately, Dr. Collins' heavy schedule does not allow for a meeting with the Minister this week and I have instead been given the honor of hosting the meeting to discuss issues of mutual interest. We propose that the Albanian delegation meet us at 9:00 on Wednesday, February 24, in the Fogarty International Center's facilities followed by a tour of the NIH Clinical Center at 10:00AM, time permitting.

If acceptable, then in order to adequately clear the Albanian delegation through NIH Security for the visit we will need the full name (first, middle and last), dates of birth, and citizenship of each individual and we will also need that information for the vehicle that you will be using to convey the delegation to NIH, including the make, model and color of the vehicle as well as the Driver's full name, date of birth and citizenship. We would greatly appreciate the above information by 12 noon tomorrow.

Thank you and please do not hesitate to contact me if you wish to discuss.

Best regards,

Roger

Roger I. Glass, M.D., Ph.D.
Associate Director for International Research
&Director, Fogarty International Center
National Institutes of Health

From: Floreta Faber [mailto Redacted by agreement
Sent: Sunday, February 21, 2016 10:09 AM
To: Roger Glass < Redacted by agreement
Cc: Glass, Roger (NIH/FIC) [E]
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Dear Dr. Glass:

I am so happy to have heard from you. Minister of Health, H.E. Ilir Beqaj will be in Washington DC available for meetings until Wednesday, February 24th.

I hope you find appropriate one of the following time slots:
February 22, at 4.30 pm
February 23, at 9.00 am
February 23, at 3.30 pm
February 24, at 11.30 am

The delegation accompaining the Minister in visiting NIH will be:

Dr. Klodiana Spahiu, MP, Vice Chair of the Health Commision of the Albanian Parliament

Floreta Fabe, Ambassador of Albania

Dr. Edmond Faber, ex Director for Trauma Center in Albania, now living in DC.

Thank you very much in advance.

Looking forward to hear from you.

Sincerely,

Floreta

Floreta FABER
Ambassador
Embassy of the Republic of Albania
Mob. Redacted by agreement

Sent from my Samsung device

-------- Original message --------
From: Roger Glass <Redacted by agreement
Date: 2/20/2016 12:02 (GMT-05:00)
To: Floreta Faber <Redacted by agreement
Cc: glassr@mail.nih.gov
Subject: Greetings: Visit of Albanian Minister of Health to NIH

Dear Ambassador Faber,

Greetings . Diane Baker spoke to us about your visit and we have received the official notice from your Office about the arrival of your Minister of Health H.E. Ilia Beqja to Washington. My office would be happy to set up a visit to NIH and the clinical center and we can request a meeting with the Director, Dr. Collins, if he is available. I serve as his Associate Director for Global Health so we can also brief you and the Minister about NIH.

Mr. George Herrfurth in my office (Herrfurg@mail.nih.gov) will be helping me and has already contacted the Embassy to find the prospective dates. This note is to reassure you that we will help facilitate the visit whenever the Minister arrives. Please let us know if the Minister has any areas of special interest.

Best personal regards and please let me or Mr. Herrfurth know if you have questions or need extra help.

Roger

Roger Glass, M.D., Ph.D
Director, Fogarty International Center and
Associate Director for Global Health
National Institutes of Health

Tel: 301-496-1415

Sent from my iPad

Informacioni i trasmetuar në përmbajtje të këtij mesazhi është i destinuar vetëm për individin ose për institucionin të cilit i është nisur, mund të përmbajë materiale konfidenciale dhe / ose të privilegjuara vetëm për marrësin. Çdo rishikim, trasmetim, shpërndarje apo kryerje e ndonjë veprimi tjetër të ngjashëm me këto, nga personat apo nga subjekte të tjera të ndryshme nga marrësi i synuar,është i ndaluar. Nëse merni gabimisht këtë mesazh, ju lutem kontaktoni urgjentisht dërguesin e tij dhe fshini çdo material të trasmetuar në kompjuterin tuaj. Ne nuk pranojmë asnjë detyrim lidhur me dëmtimin apo humbjen e shkaktuar nga programe të dëmshme apo nga viruse , përveç rastit të neglizhencës së plotë, apo sjelljes së gabuar dhe të qëllimshme.

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
Recipient:	Glass, Roger (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=glassr <glassr@mail.nih.gov>
Sent Date:	2016/02/24 07:23:52
Delivered Date:	2016/02/24 07:23:53

From:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
To:	Glass, Roger (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=glassr <glassr@mail.nih.gov>
Subject:	Fw: Greetings: Visit of Albanian Minister of Health to NIH
Date:	2016/02/24 07:22:41
Priority:	Normal
Type:	Note

Hi Roger,
George says you will be with Albanians. Please let me know if you want me to join you.
Thanks,
PK
Peter Kilmarx, MD, FACP, FIDSA
Fogarty International Center, NIH

From: Herrfurth, George (NIH/FIC) [E]
Sent: Tuesday, February 23, 2016 6:26 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: Re: Greetings: Visit of Albanian Minister of Health to NIH

RG will lead so you might want to check with him. There is no agenda as the Albanians never clued RG in on exactly what they want to address.
Sent from my BlackBerry 10 smartphone.

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Tuesday, February 23, 2016 5:55 PM
To: Herrfurth, George (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Officer, Jackie (NIH/FIC) [E]
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Hi George,
Do we have an agenda for tomorrow? Where are we meeting? 9 am?

Do you have an NIH 101 PowerPoint? Otherwise I can use mine.

Thanks,
PK

From: Herrfurth, George (NIH/FIC) [E]
Sent: Monday, February 22, 2016 2:43 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]
Subject: FW: Greetings: Visit of Albanian Minister of Health to NIH
Importance: High

Hi Peter: Attached are the bios for the visitors from Albania.

We don't know too much about biomedical or behavioral research in Albania given the paucity of data for the country. Health care in Albania declined steeply after the collapse of socialism in the country, but a process of modernization has reportedly been taking place since 2000. In the 2000s, there were 51 hospitals in the country, including a military hospital and specialist facilities. Albania has successfully eradicated diseases such as malaria.

Life expectancy is estimated at 77.59 years, ranking 51st worldwide, and outperforming a number of European Union countries, such as Hungary and the Czech Republic. Demographic and Health Surveys completed a survey in April 2009, detailing various health statistics in Albania, including male circumcision, abortion and more.

The Faculty of Medicine of the University of Tirana is the main medical school in the country. There are also nursing schools in other cities.

The general improvement of health conditions in the country is reflected in the lower mortality rate, down to an estimated 6.49 deaths per 1,000 in 2000, as compared with 17.8 per 1,000 in 1938. In 2000, average life expectancy was estimated at 74 years, compared to 38 years at the end of World War II. Albania's infant mortality rate, estimated at 20 per 1,000 live births in 2000, has also declined over the years since the high rate of 151 per 1,000 live births in 1960. There were 69,802 births in 1999 and the fertility rate in 1999 was 2.5 while the maternal mortality rate was 65 per 100,000 live births in 1993. In addition, in 1997, Albania had high immunization rates for children up to one year old: tuberculosis at 94 percent; diphtheria, pertussis, and tetanus, 99 percent; measles, 95 percent; and polio, 99.5%. In 1996, the incidence of tuberculosis was 23 in 100,000 people. In 1995 there were two reported cases of AIDS and seven cases in 1996. In 2000 the number of people living with HIV/AIDS was estimated at less than 100 cases. The leading causes of death are cardiovascular disease, trauma, cancer, and respiratory disease.

Alternative medicine is also practiced among the population in the form of herbal remedies as the country is reportedly a net exporter of aromatic and medicinal herbs.

Hope this helps. However, it still does not address what, if any, significant biomedical research is ongoing in the country of nearly 2.9 million

George

From: Mamica Toska [mailto:Redacted by agreement
Sent: Monday, February 22, 2016 11:11 AM
To: Glass, Roger (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]; Floreta Faber
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH
Importance: High

Dear Dr. Glass,

Please find attached the bios of the Albanian delegation's members that will visit NIH.

Best regards,
Mamica

Mamica Toska
Minister Plenipotentiary
Embassy of the Republic of Albania
2100 S Street, NW
Washington DC 20008
Tel. (202) 223 4942
Fax. (202) 628 7342
Mob. Redacted by agreement
Email. (b)(6)

From: Floreta Faber
Sent: Monday, February 22, 2016 10:13 AM
To: Glass, Roger (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]; Mamica Toska
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Dear Dr. Glass:

It was nice to hear from you and thank you for giving your time in putting this meeting and tour together.

Please let me confirm Wednesday, February 24 at 9:00.

The delegation is composed as following, all Albanian citizens:

Ilir Beqaj, DoB Redacted by agreement
Klodiana Spahiu, Redacted by agreement
Floreta Faber,
Edmond Faber

We will bring you shortly the Bios of the members of the delegation.

I would highly appreciate to also have the bio of who we are meeting at NIH, hopefully in a very short note the meeting can also meet with Director Collins. I am also hoping that Ms. Diane can also be with us during the visit.

Looking forward to it.

Sincerely,

Floreta

Floreta FABER
Ambassador
Embassy of the Republic of Albania
2100 S Street, NW
Washington DC 20008
Tel. (202) 223 4942
Fax. (202) 628 7342

Mob Redacted by agreement
Email. Redacted by agreement

From: Stover, Kathleen (NIH/FIC) [E] [stoverka@mail.nih.gov] on behalf of Glass, Roger (NIH/FIC) [E] [glassr@mail.nih.gov]
Sent: Monday, February 22, 2016 9:33 AM
To: Floreta Faber
Cc: Glass, Roger (NIH/FIC) [E]; Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]
Subject: FW: Greetings: Visit of Albanian Minister of Health to NIH

Dear Ambassador Faber,

We are delighted that you and Minister Beqaj will be able to visit NIH this week. Unfortunately, Dr. Collins' heavy schedule does not allow for a meeting with the Minister this week and I have instead been given the honor of hosting the meeting to discuss issues of mutual interest. We propose that the Albanian delegation meet us at 9:00 on Wednesday, February 24, in the Fogarty International Center's facilities followed by a tour of the NIH Clinical Center at 10:00AM, time permitting.

If acceptable, then in order to adequately clear the Albanian delegation through NIH Security for the visit we will need the full name (first, middle and last), dates of birth, and citizenship of each individual and we will also need that information for the vehicle that you will be using to convey the delegation to NIH, including the make, model and color of the vehicle as well as the Driver's full name, date of birth and citizenship. We would greatly appreciate the above information by 12 noon tomorrow.

Thank you and please do not hesitate to contact me if you wish to discuss.

Best regards,

Roger

Roger I. Glass, M.D., Ph.D.
Associate Director for International Research
&Director, Fogarty International Center
National Institutes of Health

From: Floreta Faber [mailto Redacted by agreement
Sent: Sunday, February 21, 2016 10:09 AM
To: Roger Glass < Redacted by agreement
Cc: Glass, Roger (NIH/FIC) [E]
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Dear Dr. Glass:

I am so happy to have heard from you. Minister of Health, H.E. Ilir Beqaj will be in Washington DC available for meetings until Wednesday, February 24th.

I hope you find appropriate one of the following time slots:

February 22, at 4.30 pm
February 23, at 9.00 am
February 23, at 3.30 pm
February 24, at 11.30 am

The delegation accompaining the Minister in visiting NIH will be:

Dr. Klodiana Spahiu, MP, Vice Chair of the Health Commision of the Albanian Parliament

Floreta Fabe, Ambassador of Albania

Dr. Edmond Faber, ex Director for Trauma Center in Albania, now living in DC.

Thank you very much in advance.

Looking forward to hear from you.

Sincerely,

Floreta

Floreta FABER
Ambassador
Embassy of the Republic of Albania
Mob Redacted by agreement

Sent from my Samsung device

-------- Original message --------
From: Roger Glass <(b)(6)
Date: 2/20/2016 12:02 (GMT-05:00)
To: Floreta Faber <Redacted by agreement
Cc: glassr@mail.nih.gov
Subject: Greetings: Visit of Albanian Minister of Health to NIH

Dear Ambassador Faber,

Greetings . Diane Baker spoke to us about your visit and we have received the official notice from your Office about the arrival of your Minister of Health H.E. Ilia Beqja to Washington. My office would be happy to set up a visit to NIH and the clinical center and we can request a meeting with the Director, Dr. Collins, if he is available. I serve as his Associate Director for Global Health so we can also brief you and the Minister about NIH.

Mr. George Herrfurth in my office (Herrfurg@mail.nih.gov) will be helping me and has already contacted the Embassy to find the prospective dates. This note is to reassure you that we will help facilitate the visit whenever the Minister arrives. Please let us know if the Minister has any areas of special interest.

Best personal regards and please let me or Mr. Herrfurth know if you have questions or need extra help.

Roger

Roger Glass, M.D., Ph.D
Director, Fogarty International Center and
Associate Director for Global Health
National Institutes of Health

Tel: 301-496-1415

Sent from my iPad

Informacioni i trasmetuar në përmbajtje të këtij mesazhi është i destinuar vetëm për individin ose për institucionin të cilit i është nisur, mund të përmbajë materiale konfidenciale dhe / ose të privilegjuara vetëm për marrësin. Çdo rishikim, trasmetim, shpërndarje apo kryerje e ndonjë veprimi tjetër të ngjashëm me këto, nga personat apo nga subjekte të tjera të ndryshme nga marrësi i synuar,është i ndaluar. Nëse merni gabimisht këtë mesazh, ju lutem kontaktoni urgjentisht dërguesin e tij dhe fshini çdo material të trasmetuar në kompjuterin tuaj. Ne nuk pranojmë asnjë detyrim lidhur me dëmtimin apo humbjen e shkaktuar nga programe të dëmshme apo nga viruse , përveç rastit të neglizhencës së plotë, apo sjelljes së gabuar dhe të qëllimshme.

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
Recipient:	Glass, Roger (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=glassr <glassr@mail.nih.gov>
Sent Date:	2016/02/24 07:22:41

From:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
To:	Herrfurth, George (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=herrfurg <herrfurg@mail.nih.gov>
Subject:	Re: Greetings: Visit of Albanian Minister of Health to NIH
Date:	2016/02/24 07:07:53
Priority:	Normal
Type:	Note

Thanks George.
Peter Kilmarx, MD, FACP, FIDSA
Fogarty International Center, NIH

From: Herrfurth, George (NIH/FIC) [E]
Sent: Wednesday, February 24, 2016 5:41 AM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: Re: Greetings: Visit of Albanian Minister of Health to NIH

It will be in the FIC Conference room. Thanks
Sent from my BlackBerry 10 smartphone.

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Tuesday, February 23, 2016 6:32 PM
To: Herrfurth, George (NIH/FIC) [E]
Subject: Re: Greetings: Visit of Albanian Minister of Health to NIH

Oh, thanks. I don't think Roger and I both need to be there. I may bow out. 9 am in Bldg 31?
Peter Kilmarx, MD, FACP, FIDSA
Fogarty International Center, NIH

From: Herrfurth, George (NIH/FIC) [E]
Sent: Tuesday, February 23, 2016 6:26 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: Re: Greetings: Visit of Albanian Minister of Health to NIH

RG will lead so you might want to check with him. There is no agenda as the Albanians never clued RG in on exactly what they want to address.
Sent from my BlackBerry 10 smartphone.

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Sent: Tuesday, February 23, 2016 5:55 PM
To: Herrfurth, George (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Officer, Jackie (NIH/FIC) [E]
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Hi George,
Do we have an agenda for tomorrow? Where are we meeting? 9 am?

Do you have an NIH 101 PowerPoint? Otherwise I can use mine.

Thanks,
PK

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Sent: Monday, February 22, 2016 2:43 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]
Subject: FW: Greetings: Visit of Albanian Minister of Health to NIH
Importance: High

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Alternative medicine is also practiced among the population in the form of herbal remedies as the country is reportedly a net exporter of aromatic and medicinal herbs.

Hope this helps. However, it still does not address what, if any, significant biomedical research is ongoing in the country of nearly 2.9 million

George

From: Mamica Toska [mailto:Redacted by agreement
Sent: Monday, February 22, 2016 11:11 AM
To: Glass, Roger (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]; Floreta Faber
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH
Importance: High

Dear Dr. Glass,

Please find attached the bios of the Albanian delegation's members that will visit NIH.

Best regards,
Mamica

Mamica Toska
Minister Plenipotentiary
Embassy of the Republic of Albania
2100 S Street, NW
Washington DC 20008
Tel. (202) 223 4942
Fax. (202) 628 7342
Mob. Redacted by agreement
Email. Redacted by agreement

From: Floreta Faber
Sent: Monday, February 22, 2016 10:13 AM
To: Glass, Roger (NIH/FIC) [E]
Cc: Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]; Mamica Toska
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Dear Dr. Glass:

It was nice to hear from you and thank you for giving your time in putting this meeting and tour together.

Please let me confirm Wednesday, February 24 at 9:00.

The delegation is composed as following, all Albanian citizens:

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Klodiana Spahiu, Redacted by agreement
Floreta Faber,
Edmond Faber

We will bring you shortly the Bios of the members of the delegation.

I would highly appreciate to also have the bio of who we are meeting at NIH, hopefully in a very short note the meeting can also meet with Director Collins. I am also hoping that Ms. Diane can also be with us during the visit.

Looking forward to it.

Sincerely,

Floreta

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Washington DC 20008
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Fax. (202) 628 7342
Mob. Redacted by agreement
Email: Redacted by agreement

From: Stover, Kathleen (NIH/FIC) [E] [stoverka@mail.nih.gov] on behalf of Glass, Roger (NIH/FIC) [E] [glassr@mail.nih.gov]
Sent: Monday, February 22, 2016 9:33 AM
To: Floreta Faber
Cc: Glass, Roger (NIH/FIC) [E]; Bridbord, Ken (NIH/FIC) [E]; Herrfurth, George (NIH/FIC) [E]
Subject: FW: Greetings: Visit of Albanian Minister of Health to NIH

Dear Ambassador Faber,

We are delighted that you and Minister Beqaj will be able to visit NIH this week. Unfortunately, Dr. Collins' heavy schedule does not allow for a meeting with the Minister this week and I have instead been given the honor of hosting the meeting to discuss issues of mutual interest. We propose that the Albanian delegation meet us at 9:00 on Wednesday, February 24, in the Fogarty International Center's facilities followed by a tour of the NIH Clinical Center at 10:00AM, time permitting.

If acceptable, then in order to adequately clear the Albanian delegation through NIH Security for the visit we will need the full name (first, middle and last), dates of birth, and citizenship of each individual and we will also need that information for the vehicle that you will be using to convey the delegation to NIH, including the make, model and color of the vehicle as well as the Driver's full name, date of birth and citizenship. We would greatly appreciate the above information by 12 noon tomorrow.

Thank you and please do not hesitate to contact me if you wish to discuss.

Best regards,

Roger

Roger I. Glass, M.D., Ph.D.
Associate Director for International Research
&Director, Fogarty International Center
National Institutes of Health

From: Floreta Faber [mailto:Redacted by agreement
Sent: Sunday, February 21, 2016 10:09 AM
To: Roger Glass <Redacted by agreement
Cc: Glass, Roger (NIH/FIC) [E]
Subject: RE: Greetings: Visit of Albanian Minister of Health to NIH

Dear Dr. Glass:

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February 24, at 11.30 am

The delegation accompaining the Minister in visiting NIH will be:

Dr. Klodiana Spahiu, MP, Vice Chair of the Health Commision of the Albanian Parliament

Floreta Fabe, Ambassador of Albania

Dr. Edmond Faber, ex Director for Trauma Center in Albania, now living in DC.

Thank you very much in advance.

Looking forward to hear from you.

Sincerely,

Floreta

Floreta FABER
Ambassador
Embassy of the Republic of Albania
Mob: Redacted by agreement

Sent from my Samsung device

-------- Original message --------
From: Roger Glass <Redacted by agreement
Date: 2/20/2016 12:02 (GMT-05:00)
To: Floreta Faber <Redacted by agreement

Cc: glassr@mail.nih.gov
Subject: Greetings: Visit of Albanian Minister of Health to NIH

Dear Ambassador Faber,

Greetings . Diane Baker spoke to us about your visit and we have received the official notice from your Office about the arrival of your Minister of Health H.E. Ilia Beqja to Washington. My office would be happy to set up a visit to NIH and the clinical center and we can request a meeting with the Director, Dr. Collins, if he is available. I serve as his Associate Director for Global Health so we can also brief you and the Minister about NIH.

Mr. George Herrfurth in my office (Herrfurg@mail.nih.gov) will be helping me and has already contacted the Embassy to find the prospective dates. This note is to reassure you that we will help facilitate the visit whenever the Minister arrives. Please let us know if the Minister has any areas of special interest.

Best personal regards and please let me or Mr. Herrfurth know if you have questions or need extra help.

Roger

Roger Glass, M.D., Ph.D
Director, Fogarty International Center and
Associate Director for Global Health
National Institutes of Health

Tel: 301-496-1415

Sent from my iPad

Informacioni i trasmetuar në përmbajtje të këtij mesazhi është i destinuar vetëm për individin ose për institucionin të cilit i është nisur, mund të përmbajë materiale konfidenciale dhe / ose të privilegjuara vetëm për marrësin. Çdo rishikim, trasmetim, shpërndarje apo kryerje e ndonjë veprimi tjetër të ngjashëm me këto, nga personat apo nga subjekte të tjera të ndryshme nga marrësi i synuar,është i ndaluar. Nëse merni gabimisht këtë mesazh, ju lutem kontaktoni urgjentisht dërguesin e tij dhe fshini çdo material të trasmetuar në kompjuterin tuaj. Ne nuk pranojmë asnjë detyrim lidhur me dëmtimin apo humbjen e shkaktuar nga programe të dëmshme apo nga viruse , përveç rastit të neglizhencës së plotë, apo sjelljes së gabuar dhe të qëllimshme.

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
Recipient:	Herrfurth, George (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=herrfurg <herrfurg@mail.nih.gov>
Sent Date:	2016/02/24 07:07:53

From:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
To:	Viboud, Cecile (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/CN=FIC/CN=VIBOUDC <viboudc@mail.nih.gov>
CC:	McKenzie, Ellis (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=mckenzel <mckenzel@mail.nih.gov>; Stephen Kissler <sk792@cam.ac.uk>
Subject:	RE: Upcoming December visitors and seminars
Date:	2015/12/11 15:59:38
Priority:	Normal
Type:	Note

Re-reading below - I meant it was syphilis, not HIV!

PK

From: Viboud, Cecile (NIH/FIC) [E]
Sent: Friday, December 11, 2015 2:26 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Cc: McKenzie, Ellis (NIH/FIC) [E]; Stephen Kissler
Subject: RE: Upcoming December visitors and seminars

Thanks Peter, for these two papers, and I have cc-ed Stephen so that he can investigate these as well.

Interestingly, our data also come from SDI, although the company has been bought over by the giant IMS Health since, which is part of our problem. It would be great to pull resources across sister agencies to purchase these costly medical claims datasets –at this point, I feel we (in the RAPIDD/DIEPS group) have exhausted the few contacts we still have within IMS Health and have hit a wall…

Kind regards
Cecile

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Friday, December 11, 2015 1:02 PM
To: Viboud, Cecile (NIH/FIC) [E]
Cc: McKenzie, Ellis (NIH/FIC) [E]
Subject: RE: Upcoming December visitors and seminars

Hi Cecile,
I enjoyed meeting Stephen.

Here's the Route 95 paper I mentioned. It was HIV, not syphilis:
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1508624/
Am J Public Health. 1999 March; 89(3): 369–373. What's driving an epidemic? The spread of syphilis along an interstate highway in rural North Carolina. R L Cook, R A Royce, J C Thomas, and B H Hanusa.

Also, we used SDI data for a paper on male circumcision at CDC: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4578797/ I could put you in touch with folks there (Bob Chen) about joint data procurement.

Bon weekend,
PK

From: Viboud, Cecile (NIH/FIC) [E]
Sent: Monday, December 07, 2015 9:54 AM
To: Alonso, Wladimir (NIH/FIC) [C]; Ambikapathi, Ramya (NIH/FIC) [C]; Carreon, Danny (NIH/FIC) [C]; Doan, Viyada (NIH/FIC) [C]; Durrani, Sahrish (NIH/FIC) [C]; FIC EPS Stone House; Gaffey, Robert (NIH/FIC) [C]; Host, Christel (NIH/FIC) [C]; Kilmarx, Peter (NIH/FIC) [E]; Knobler, Stacey (NIH/FIC) [C]; Lang, Dennis (FNIH) [T]; McGrath, Monica (NIH/FIC) [C]; Nelson, Martha (NIH/FIC) [V]; Rasmussen, Zeba (NIH/FIC) [C]; Richard, Stephanie (NIH/FIC) [C]; Rosenthal, Josh P. (NIH/FIC) [E]; Seidman, Jessica (NIH/FIC) [C]; Skoczdopole, Kate (NIH/FIC) [C]; Szu, Shousun (NIH/FIC) [V]; Thomas, Elizabeth (NIH/FIC) [V]; Viboud, Cecile (NIH/FIC) [E]; Kilmarx, Peter (NIH/FIC) [E]
Subject: Upcoming December visitors and seminars

Dear all

We have a busy schedule of visitors and seminars in the next few days, as follows:

- As announced by Martha: **Tue Dec 8 (tomorrow)**, 2.00-3.00pm. Nidia Trovao, University of Leuven, Belgium. *The genetic traceability of viral pathogens: from isolation by distance to proximity by host mobility.*

- **Fri Dec 11**, 11.00am-12.00pm. Stephen Kissler, University of Cambridge, UK. *Spatiotemporal patterns and age structure of the 2009 influenza pandemic in the US.*

- **Mon Dec 14**, 2.00-3.00 pm: Simon Pollett, University of California at San Francisco and University of Sydney, Australia. *Applying molecular and digital epidemiological tools in the Americas: case studies, challenges and future directions*

All seminars will be held in 16A.

Nidia, Stephen, and Simon will stay with us for a few days, so even if you miss their talk, please drop by the 3rd floor and say hello!

Kind regards
Cecile

Sender:	Kilmarx, Peter (NIH/FIC) [E] /O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA <peter.kilmarx@nih.gov>
Recipient:	Viboud, Cecile (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/CN=FIC/CN=VIBOUDC <viboudc@mail.nih.gov>; McKenzie, Ellis (NIH/FIC) [E] /O=NIH/OU=NIHEXCHANGE/cn=FIC/cn=mckenzel <mckenzel@mail.nih.gov>; Stephen Kissler <sk792@cam.ac.uk>
Sent Date:	2015/12/11 15:59:38

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	Samandari, Taraz (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:tts0@CDC.GOV>; LeBaron, Charles (CDC/OID/NCHHSTP) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=CEL3 <cel3@cdc.gov>; Dominguez, Ken (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:kld0@CDC.GOV>; Mermin, Jonathan (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:jhm7@CDC.GOV>
Subject:	RE: Published critique of Earp's attack on the draft CDC circumcision policy
Date:	2015/10/15 10:12:09
Priority:	Normal
Type:	Note

That's too bad. I'll look forward to seeing the CDC recommendations finalized.

PK

From: Samandari, Taraz (CDC/OID/NCHHSTP)
Sent: Thursday, October 15, 2015 7:39 AM
To: Kilmarx, Peter (NIH/FIC) [E]; LeBaron, Charles (CDC/OID/NCHHSTP); Dominguez, Ken (CDC/OID/NCHHSTP); Mermin, Jonathan (CDC/OID/NCHHSTP)
Subject: RE: Published critique of Earp's attack on the draft CDC circumcision policy

Thanks for sharing, PK.

I heard yesterday that the Canadian healthcare system has decided to no longer reimburse infant male circumcision. My feeling about that is that Canada's followed European trends due to the lack of leadership on the issue in the US.

Taraz

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Wednesday, October 14, 2015 8:10 PM
To: LeBaron, Charles (CDC/OID/NCHHSTP) <cel3@cdc.gov>; Dominguez, Ken (CDC/OID/NCHHSTP) <kld0@cdc.gov>; Samandari, Taraz (CDC/OID/NCHHSTP) <tts0@cdc.gov>; Mermin, Jonathan (CDC/OID/NCHHSTP) <jhm7@cdc.gov>
Subject: Fw: Published critique of Earp's attack on the draft CDC circumcision policy

Nice supportive article. Good luck bringing this over the finish line.

Best to all.

Peter Kilmarx, MD, FACP, FISDA
Deputy Director, Fogarty International Center, NIH

From: Brian Morris <brian.morris@sydney.edu.au>
Sent: Wednesday, October 14, 2015 7:33 PM

To: Brian Morris
Subject: Published critique of Earp's attack on the draft CDC circumcision policy

Dear colleagues

You would be familiar with the ridiculous attacks mounted by intactivists and other anti-circs on good evidence-based male circumcision policies produced by the CDC and AAP in recent times.

These have been consistently repudiated by clinical, academic and other experts.

The URL below will take you to my critique of the published criticisms of the CDC draft recommendation by the well-known MC opponent, Brian Earp.

http://journal.frontiersin.org/article/10.3389/fped.2015.00088/full?utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Pediatrics&id=165120

Open access, so free download.

Best wishes

Brian

Brian J. Morris, DSc PhD FAHA
Professor Emeritus
School of Medical Sciences and Bosch Institute
Anderson Stuart Building (F13)
Sydney Medical School
The University of Sydney
Sydney, NSW 2006, Australia

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	Samandari, Taraz (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:tts0@CDC.GOV>; LeBaron, Charles (CDC/OID/NCHHSTP) /O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=CEL3 <cel3@cdc.gov>; Dominguez, Ken (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:kld0@CDC.GOV>; Mermin, Jonathan (CDC/OID/NCHHSTP) </O=NIH/OU=NIHHUB/cn=CDC Proxy List/cn=SMTP:jhm7@CDC.GOV>
Sent Date:	2015/10/15 10:12:09

From:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
To:	'Natalie Culbertson' <nculbertson@jhu.edu>
Subject:	RE: Invitation to review a manuscript for GHSP
Date:	2015/07/13 17:45:45
Priority:	Normal
Type:	Note

Received, thanks.

PK

From: Natalie Culbertson [mailto:nculbertson@jhu.edu]
Sent: Monday, July 13, 2015 5:42 PM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: RE: Invitation to review a manuscript for GHSP

Dear Dr. Kilmarx,

Thanks very much for agreeing to review the manuscript and congratulations on your new position. I have just sent you an email through our system with links and instructions. Often our emails are intercepted as spam so please let me know if you did not receive it.

Please don't hesitate to contact me if you have any questions.

Best,
Natalie Culbertson

Natalie Culbertson
Managing Editor, *Global Health: Science and Practice* Journal
Knowledge for Health (K4Health)

cid:image001.png@01D03ADA.63BFCC60

cid:image002.png@01D03ADA.63BFCC60

Johns Hopkins Bloomberg School of Public Health
111 Market Place, Suite 310
Baltimore, Maryland 21202
Phone: 410-659-6134
Email: nculbertson@jhu.edu

Web: www.ghspjournal.org | ccp.jhu.edu | www.k4health.org

From: Kilmarx, Peter (NIH/FIC) [E] [mailto:peter.kilmarx@nih.gov]
Sent: Monday, July 13, 2015 5:10 PM
To: Natalie Culbertson
Subject: RE: Invitation to review a manuscript for GHSP

Hi Natalie,
I'd be happy to review. Please send the MS and instructions.

Thanks,
Peter H. Kilmarx, MD, FACP, FIDSA
CAPT, U.S. Public Health Service
Deputy Director, Fogarty International Center
U.S. National Institutes of Health
Cell [Redacted by government] Email peter.kilmarx@nih.gov

NIH - Fogarty International Center - Advancing Science for Global Health

---

From: Natalie Culbertson [mailto:nculbertson@jhu.edu]
Sent: Monday, July 13, 2015 11:00 AM
To: Kilmarx, Peter (NIH/FIC) [E]
Subject: Invitation to review a manuscript for GHSP

Dear Dr. Kilmarx,

I'm writing because I recently sent you an invitation to review an original manuscript for ***Global Health: Science and Practice***. You didn't accept or decline the invitation and so it was withdrawn. However, I realize now that you are no longer with CDC Zimbabwe and are with NIH. I am writing in the hopes that you might be willing to review this manuscript.

I have included the title and abstract below for your reference. We would need your review in 2-3 weeks.

Thanks and I look forward to hearing from you.

Natalie Culbertson
Managing Editor
Global Health: Science and Practice

****

Sexual Satisfaction, Performance and Partner Response following Voluntary Medical Male Circumcision in Zambia: A Cluster Randomized Controlled Trial

Voluntary medical male circumcision (VMMC) represents an important strategy to prevent HIV infection in men, particularly in countries or regions with high HIV incidence and low rates of male circumcision, e.g., Eastern and Southern Africa. This study examined the post-VMMC responses of Zambian men who initially were unwilling to consider circumcision as an HIV prevention option, and their female partners. Men (n = 800) undergoing HIV Testing and Counselling (HTC) were enrolled and given the option of inviting their female partners (n = 668). Clinics were randomized to offer a sexual risk reduction/VMMC promotion intervention (experimental) or a time- equivalent control condition. Results indicated that despite their initial unwillingness to consider circumcision, men who underwent VMMC experienced increased levels of sexual satisfaction and acceptability. Nearly all men and their partners indicated they would recommend VMMC to a friend. Approximately half of the men reported increased erections, orgasms and increased time to achieve orgasms or no change from pre-VMMC, while one-third of participants indicated fewer erections, orgasms and decreased time to achieve orgasms post-VMMC. Nearly half of the participants said their sexual pleasure increased while 22% reported less sexual pleasure post-VMMC. Cleanliness and appearance were considered improved by the majority of both men and women. Men who engaged in sexual intercourse prior to full healing incurred the most adverse events and generally reported lower levels of post-VMMC sexual satisfaction. Future studies should consider innovative interventions to assist men in their efforts to abstain from engaging in sexual activities prior to complete healing. Future studies should also include female partners when attempting to increase VMMC acceptability among "hard to reach" men.

****

Natalie Culbertson
Managing Editor, *Global Health: Science and Practice* Journal
Knowledge for Health (K4Health)

cid:image001.png@01D03ADA.63BFCC60

cid:image002.png@01D03ADA.63BFCC60

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Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KILMARXPH4BA>
Recipient:	'Natalie Culbertson' <nculbertson@jhu.edu>
Sent Date:	2015/07/13 17:45:44
Delivered Date:	2015/07/13 17:45:45

From:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
To:	Gordon, Latoya (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43d702b63f14d0fad8e8eb2c32777ce-gordonlr <latoya.gordon@nih.gov>
Subject:	RE: 6284539: Manuscript Review
Date:	2018/10/21 05:26:00
Priority:	Normal
Type:	Note

Hi Latoya,
Please print attached for me.

Thanks,
PK

-----Original Message-----
From: Advances in Urology <heba.abdelsabour@hindawi.com>
Sent: Sunday, October 21, 2018 5:24 AM
To: Kilmarx, Peter (NIH/FIC) [E] <peter.kilmarx@nih.gov>
Subject: 6284539: Manuscript Review

Dear Dr. Kilmarx,

Thank you for agreeing to review the Review Article titled "Arguments Opposing Male Circumcision Are Undermined by Strong Scientific Evidence From a Systematic Review" by Brian Morris, Stephen Moreton and John N. Krieger.

You can view the full PDF file of the manuscript and post your review report using the following URL:

http://mts.hindawi.com/reviewer/8924231586213940/

Best regards,

--
****
Heba Abdelsabour
Editorial Office
Hindawi
http://www.hindawi.com
****

Sender:	Kilmarx, Peter (NIH/FIC) [E] </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E4ECF449BD7044BA9FD585C8DA4D47B4-KILMARXPH>
Recipient:	Gordon, Latoya (NIH/FIC) [C] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43d702b63f14d0fad8e8eb2c32777ce-gordonlr <latoya.gordon@nih.gov>
Sent Date:	2018/10/21 05:26:25
Delivered Date:	2018/10/21 05:26:00

Aug 9, 2018

Advances in Urology
Word count:
Abstract: 299
Main text: 11,558
References: 396

Arguments Opposing Male Circumcision Are Undermined by Strong Scientific Evidence From a Systematic Review

Brian J. Morris,[1] Stephen Moreton,[2] John N. Krieger[3]

[1]School of Medical Sciences and Bosch Institute, University of Sydney, Sydney, New South Wales, 2006, Australia

[2]33 Marina Avenue, Warrington, England, WA5 1HY, UK

[3]Department of Urology, University of Washington School of Medicine, Seattle, Washington, 98195, USA

Correspondence should be addressed to Brian J. Morris; brian.morris@sydney.edu.au

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Abstract

Multiple claims are used by opponents in arguing against male circumcision (MC), especially in minors. We evaluated such claims by a PRISMA-compliant systematic review of the scientific evidence from searches of PubMed, Google Scholar, EMBASE and Cochrane databases. Database searches retrieved 283 publications for inclusion. Examination of bibliographies of these yielded 69 further publications. Evaluation of arguments and evidence claiming that MC is either unnecessary or harmful, when compared with scientific data rated by quality found: (1) frequency of adverse events from early infant MC by medical providers using local anesthesia is low (approximately 0.5%). (2) Virtually all adverse events are minor and easily treated with complete resolution. (3) The evidence shows no long-term psychological harm. (4) There are no adverse effects on sexual function or pleasure. (5) MC provides a lifetime of protection against urinary tract infections, oncogenic types of human papillomavirus, genital herpes, human immunodeficiency virus, various other sexually transmitted infections (STIs), candidiasis, inferior hygiene, penile inflammatory conditions, very strong protection against penile cancer and modest protection against prostate cancer. (6) In female sexual partners, MC reduces the risk of cervical cancer and various STIs. To maximize benefits and minimize risks, the evidence supported early infant MC rather than delay of the procedure until males are old enough to decide for themselves. Risk-benefit analyses have reported that benefits exceed risks by 100–200 to 1. A balanced evaluation of ethical issues supported the rights of children to be provided with low-risk, high-benefit interventions such MC in order to protect their health. Expert evaluations of case-law have supported the legality of MC of minors. Other data have demonstrated that early infant MC is cost-saving to health systems. In conclusion, arguments opposing MC are supported mostly by low quality evidence and opinion and are contradicted by strong scientific evidence.

Key words: Male circumcision; infancy; adulthood; evidence, arguments; public health; urinary tract infection; sexually transmitted infection; complications; sexual function; sexual pleasure; ethics; policy

"The human understanding when it has once adopted an opinion (either as being the received opinion or as being agreeable to itself) draws all things else to support and agree with it. And though there be a greater number and weight of instances to be found on the other side, yet these it either neglects and despises, or else by some distinction sets aside and rejects, in order that by this great and pernicious predetermination the authority of its former conclusions may remain inviolate."
Sir Francis Bacon, *The New Organon*, 1620.

1. Introduction

Compelling data, such as randomized controlled trials (RCT), systematic reviews and meta-analyses, showing net benefits of male circumcision (MC) to males and their female sexual partners led the American Academy of Pediatrics (AAP) in 2012 [1, 2] and the US Centers for Disease Control and Prevention (CDC) in 2014 [3, 4] to release affirmative guidelines in support of non-therapeutic early infant MC (EIMC) and non-therapeutic MC of older males. These statements supersede older policies in the US, as well as non-evidence-based negative policies in other countries [5-8] (**Table 1**).

Various individuals, certain small professional organizations and lay lobby groups (**Table 1**) actively discourage non-therapeutic circumcision of boys. Members use social media and other tactics to bully and threaten parents, physicians, academics and others regarding MC [9-13]. Contradicting the AAP and CDC policy recommendations, opponents have lobbied to have MC of minors banned in the US [14] and Scandinavian countries, although to date such efforts have not been successful [15-18]. Arguments opposing non-therapeutic MC, especially in minors, appear to start with the premise that MC has no benefits, only harms, or that any benefits only apply later in life when the male can make his own decision to get circumcised [19-22]. In this "post-truth" era, vocal minority groups consider that their opinions count more than those of medical and scientific experts [23]. These attitudes fit with a pattern of radical individualism, devaluation of scientific evidence, and promotion of autonomy, in which life-saving childhood vaccines, for example, may be refused by parents, as is their legal right, which must be respected.

To help provide clarity to this vexing issue, especially given the adverse consequences to global public health and individual well-being of getting MC policy wrong, the aim of the present systematic review was to evaluate the arguments made against non-therapeutic MC (summarized in **Table 2**), as well as the claims by opponents of functions of the foreskin that are lost to circumcision (listed in **Table 3**). In particular, we examine the extent to which arguments used to oppose non-therapeutic MC are supported by current scientific evidence. In our article, benefits (and harms) of non-therapeutic MC (hereinafter referred to simply as "MC" and "EIMC") are judged according to the difference in

prevalence of an adverse medical condition in those who have received MC compared with those who have not.

2. Literature Searches

2.1. Methods. We conducted sequential literature searches of PubMed, Google Scholar, EMBASE, and the Cochrane Systematic Review database for articles dating from 1 Jan 2005 until 28 Feb 2018; with an update to 8 June 2018. PubMed searches used the keyword "circumcision" in combination with one of 35 other relevant keywords shown in **Table 4**. An extraction file was created for each set and examined by the authors. Google Scholar, EMBASE and Cochrane database searches to find additional references used "circumcision" as keyword. Bibliographies of articles were examined to retrieve further key references. In accord with the hierarchy of scientific evidence, articles were graded for quality using the Scottish Intercollegiate Guidelines Network (SIGN) grading system [24] (**Figure 1**). Those rated 2+ and above by conventional criteria were given emphasis. In instances in which a MC-related topic had been the subject of recent high quality systematic reviews or meta-analyses (level 1++ or 1+ evidence), these were cited for efficiency instead of all the individual studies on that topic. Internet searches were conducted for other relevant information, including MC policies. The study complied with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [25].

2.2. Search Results: PubMed searches yielded 12,344 "hits" (**Table 4**). Any pertaining to "circumcision" of women were excluded. The most relevant 269 of these were selected for inclusion. A Google Scholar search yielded 14 additional articles from the maximum return of 1,000 "hits" for this search engine. Searches of the EMBASE database and Cochrane Central Register of RCTs yielded, respectively, 5220 and 37 "hits", but did not generate additional citable articles. Examination of bibliographies of the articles chosen yielded 63 further articles and 6 book chapters. Thus, total number of publications included was 352. We also included 44 relevant items from the Internet. **Figure 2** summarizes the search strategy in accord with the PRISMA statement [25].

3. Urinary Tract Infection

The most recent meta-analysis reported UTI incidence as 10-times lower in circumcised vs. uncircumcised infant males [26]. Prevalence was 0.1% vs. 1%, respectively. Infant UTI has been regarded by some as rare [20, 27], although pediatric urologists consider it to be a common problem [28]. Number needed to treat is 25–100 [29]. In the case of influenza vaccination, one outpatient visit can be prevented through vaccination of less than 50 children, leading the authors to conclude that

"influenza vaccination can reduce influenza-attributable medical visits in children significantly, even in years with modest vaccine efficacy" [30]. UTI in infancy can result in significant morbidity[31] and is the most common cause of sepsis in male neonates[32]. Within the first 2 years incidence of pyelonephritis, kidney disease, hypertension and vesicoureteral reflux per 100 person-years in 2,334 neonatally circumcised vs. 573 uncircumcised US infant males was 0 vs. 0.67, 0.063 vs. 0.13, 0.031 vs. 0.27 and 0.13 vs. 0.27, respectively [29]. Rate for all diagnoses combined was 0.65 vs. 3.5 (p <0.0001) [29]. Progression to renal damage occurred in 19% of children with UTI aged < 2 years [33].

Studies questioning the value of EIMC for UTI prevention [34, 35] were found to contain flaws [26, 36, 37]. Diagnosis of UTI is more challenging in infant males than in older children or adults. Patients are more likely to present with nonspecific, systemic symptoms, and history must be obtained from the parents. Obtaining a good urine specimen can prove challenging in this age group. Of infant males with UTI, 27.6% were hospitalized in a US study, so adding to costs [38]. The authors stated that most of these UTIs could have been avoided by EIMC [38].

A neonate with possible UTI presents with a systemic illness and symptoms that include distress and fever, requiring diagnosis. This may entail blood collection and lumbar puncture [15]. It has been argued that infants with UTI can be easily treated with oral antibiotics [20, 27]. However, this applies to older boys and men. It is difficult to get a neonate to take medications reliably and some drugs are not absorbed well because of their diet, so if UTI is diagnosed, they need to be hospitalized to enable intravenous antibiotic administration [15, 39]. Emergence of resistance to most or all antibiotics, including methicillin, will make treatment of UTI more challenging [40-45]. Maternal antibiotic use during pregnancy also increases the risk of resistant pathogens responsible for early infant UTI [46]. Antibiotics disrupt the microbiome, now increasingly linked to various adverse medical conditions.

Swabs taken from under the foreskin of boys aged 7 days to 11 years identified 50 bacterial isolates, most being multi-drug-resistant strains [47]. The continual rise in antibiotic-resistant uropathogens could further add to hospital admissions and poor clinical outcomes. Uncircumcised males of all ages are more likely to harbor subpreputial uropathogenic bacteria. Foreskin swabs taken prior to MC at age 2 months to 9 years (mean 5.7 years) contained 72 microorganisms, including 54 gram-positive bacteria (57% Enterococcus species) and 17 gram-negative bacteria (41% *Escherichia coli*) and Candida species [48]. Swabs from healthy uncircumcised males (mean age 26.5 years) contained a higher proportion of potentially uropathogenic gram negative rods (17%) than in circumcised males (4%) [49]. Gram positive cocci, which are less likely to cause UTI, were seen in 62% of uncircumcised and 80% of circumcised males, while streptococci, strict anaerobes and genital mycoplasmas were only present in the

uncircumcised males [49]. A RCT found that MC significantly reduced both the prevalence and load of genital anaerobic bacteria [50].

A meta-analysis further illustrated how common UTI is over the lifetime [26]. Prevalence was 32.1% in uncircumcised males and 8.8% in circumcised males [26]. Number needed to treat was 4.29 [26]. The foreskin contributed to 72.6% of lifetime UTI risk in an uncircumcised male UTI patient. UTI risk in uncircumcised males was 1.26% in the first year of life and cumulatively 2.68% from age 1–16 years [26]. Level of protection afforded by circumcision declined with age [26].

In summary, EIMC reduces the substantial risk of UTI in infancy and beyond.

4. Physical Harm

4.1. Terminology. MC has been termed, "*male genital mutilation*" [14], a term adopted from *"female genital mutilation"*, which has no medical benefits and is often harmful. Mutilation means damage or disfigurement. Below we examine whether this applies to MC. MC has also been referred to as *"amputation"*, a term used in the medical literature when referring to removal of a limb, digit or the entire penis. A belief in physical harm underlies arguments that MC presents, "*intractable moral, child abuse, human rights, and ethical problems*" [51], the veracity of which will be addressed in the section on ethical issues.

4.2. Immediate Complications of MC and Their Frequency. A 2014 study by CDC researchers of 1.4 million circumcisions in the US, based on inpatient data as well as data from more than 870 000 unique outpatient medical providers found frequency of adverse events associated with EIMC was 0.4% [52]. The AAP's 2012 policy statement [1] reported figures of 0.19%[53] and 0.22%[32] from two large US studies, and 0.34% from a large Israeli study [54]. The most common complications were: hemorrhage (0.08–0.18%), infection (0.06%) and injury to the penis (0.01–0.04%) [52].

4.3. Deaths From EIMC. Data from a MC opponent reporting that 117 or over 100 newborn males die from MC in the US each year originated from his assumption that the well-known higher infant mortality in males was entirely due to MC complications [55]. This sex difference is, however, also seen in non-circumcising countries (tabulated in ref.[56]). Moreover, in non-circumcising Norway, this gender difference (30%) is greater than in the US (19%) and in Israel (5%)[56].

While it is difficult to ascertain actual deaths attributable to EIMC, no death was found among neonatal records of 100,157 boys circumcised in US Army hospitals from 1980–1985 [32]. In contrast, amongst 35,929 infant males who were not circumcised, 88 (0.24%) developed a UTI, leading to

meningitis in 3, renal failure in 2, and death in 2 [32]. Thus, death rate was much higher in the 26.4% boys who were not circumcised. That article stated in the Discussion that no EIMC-related deaths occurred amongst 300,000 boys born in US Army hospitals between 1970 and 1986, nor amongst 650,000 infants who had EIMC in Texas from 1971–1987 [32]. It further stated, "*We can find evidence for no more than two to three deaths per year that can be attributed to the procedure among the more than 1,200,000 boys that are circumcised* [in the US annually]." Other studies found no deaths [57]. One death from an *"at home"* procedure was found in records of the New York City Health Department in 1953 [58]. There were no deaths after 500,000 EIMCs in the US in 1982 [59]. In the mid-1940s in England, deaths during MC of boys aged 0–4 years were mostly from the types of general anesthetics used at the time [60]. Data from the US National Inpatient Sample found that during 2000 to 2010 noted one death was recorded per 49,166 circumcisions during the first 30 days of life [61]. The authors stressed that, "*this figure should not be interpreted as causal but correlational.*" Deaths were more likely in boys with significant co-morbidities such as cardiac disease (OR = 697.8). Since the authors had access to data on deaths in uncircumcised boys, the authors failure to present such data is a major limitation that undermines the findings.

In Canada, where approximately half of males are circumcised, only 3 deaths were attributed to EIMC [62] and 3 to vaccination over the period 1992–2004 [63]. The report also documented 38 cases of anaphylaxis, 37 cases of convulsions, and 4 brain infections attributable to vaccination. Like EIMC, benefits of childhood vaccination greatly outweigh the risks. In comparison to deaths from EIMC, in Canada there were 43 deaths from penile cancer [64], 3,708 annual deaths from prostate cancer and 443 from cervical cancer [64]. The evidence, discussed below, shows EIMC reduces risk of each.

The data show that mortality from MC performed by a qualified medical practitioner is rare. Risk is higher for MC performed by non-medically qualified circumcisers. MC-associated deaths, mostly in adolescent males, have been reported after traditional "bush" MCs. Nevertheless, rare, undiagnosed hemophilia has resulted in hemorrhage so severe as to cause death during medical MC.

4.4. Breastfeeding Outcomes. A longitudinal study in New Zealand found that, over the course of 4 months, there was no difference in initiation of, duration of, or stopping of breastfeeding in circumcised vs. uncircumcised males [65]. Similar findings were obtained for infants from discharge to 2 weeks in a large retrospective San Diego study [66]. Outcomes associated with breastfeeding, such as being less prone to gastrointestinal problems and asthma, were also unaffected [65]. Whether or not anesthesia was used for the EIMC procedures was not stated, although would have been less likely for this cohort of boys born in the 1970s. The New Zealand authors concluded, "*These results strongly suggest that*

claims about the adverse effects of neonatal circumcision on breastfeeding and child health are not sound, and have arisen as a result of unjustified extrapolation from the evidence on neonatal responses to circumcision" [65].

4.5. Meatal Stenosis (MS). MS has been said to be a common complication of circumcision [67]. Often quoted by opponents is a prevalence of 20% reported in a small study of neonatally-circumcised boys at age 5–10 years attending a pediatric clinic in Iran for other problems, the incidental MS diagnosed being asymptomatic [68]. MS data from a large Danish study [69] were further evaluated by critics, revealing a MS prevalence of 0.099% in Muslim (circumcised) males and 0.12% in non-Muslim (uncircumcised) males, making the condition uncommon [70]. A US study that reported a figure of 7% [71] was criticized by a former chair of the AAP's infant MC policy committee [72]. In the Danish study, prevalence of other urethral stricture disease was 0.55% in Muslim and 0.82% in non-Muslim males [69, 70]. In elderly men prevalence of MS was 1.9-times higher in the uncircumcised [69]. Each condition was higher in younger ethic Danish men circumcised for medical problems compared with uncircumcised Danish men [69]. Rather than being a long-term complication of MC [73], onset was found recently to occur in the first 2 months after neonatal MC[74], but diagnosis is much later [75].

A recent systematic review and meta-analysis of all published data involving 31 strata from 27 studies reported in total 350 MS cases among 1,498,536 males [76]. The overall summary risk estimate for MS was 0.66% [76]. The authors pointed out that in uncircumcised males MS gradually increases in prevalence with age, mostly as a result of penile inflammation caused by lichen sclerosis, which is much more common in uncircumcised males [69, 70, 76]. It is likely that MS in uncircumcised males is under-reported [76]. While more studies are warranted, the current data do not support MS being a major adverse effect of MC.

4.6. Glans Keratinization. An argument that over time the glans of a circumcised penis becomes thickened, hardened and cornified is contradicted by histological studies comparing glans skin of circumcised and uncircumcised men [77, 78]. A difference in rete ridges was, however, found in a small study [78], but the finding could have been confounded by age.

5. Psychological Harm

5.1. "False Beliefs". In a recent survey of 902 US men by MC opponents, a satisfaction score of 3.5–3.9 out of 5 amongst 732 circumcised men was found, compared to lower scores among 170 uncircumcised men [79]. Rather than accepting the findings at face value, the authors then asserted that circumcised

men held, "*false beliefs concerning circumcision and the foreskin*", and that, "*These findings provide tentative support for the hypothesis that the lack-of-harm reported by many circumcised men .... may be related to holding inaccurate beliefs concerning unaltered genitalia and the consequences of childhood genital modification*" [79].

5.2. Neurological Damage. It has been argued that pain associated with EIMC causes permanent, harmful, neurological changes in the brain [80]. As support, a small study by Taddio *et al.* found neonatally circumcised infants exhibited a stronger pain response to vaccination at 4 or 6 months than did uncircumcised infants [81]. This finding was, however, confined to infants circumcised without anesthetic. Infants circumcised with topical local anesthesia (EMLA cream) had significantly lower pain scores at later vaccination than those circumcised without anesthetic [81]. Taddio *et al.* recommended there be a, *"study of the vaccination pain response of infants who had received more effective circumcision pain management".* Pain can be avoided when local anesthetic creams are applied *an hour* prior to the MC procedure [82].

An *"after-hours"* MRI brain scan of a single infant before and after circumcision without anesthesia was reported to reveal changes in parts of the brain associated with reasoning, perception and emotion [83]. Ethical approval, logistics and compliance with procedural guidelines were not stated. The mother was strongly opposed to MC, leading critics to question her approval for this experiment and an assertion that the on-line report by an opponent was a fabrication [84].

5.3. Cognitive Ability Later in Life. A New Zealand longitudinal study comparing boys circumcised in 1977 or left uncircumcised found no adverse effect on cognitive ability (IQ at age 8–9 years and scholastic ability at age 13) [65]. Similarly, a Swedish study found no adverse psychological effect of MC [85]. A longitudinal study in the UK, beginning in 1946, of more than 5,000 individuals followed from birth to age 27 found no difference in developmental and behavioral indices between circumcised and uncircumcised males [86]. A study of boys aged 9–11 in San Francisco found that circumcised boys had higher satisfaction scores, although general body image was no different [87]. Taken together, these consistent findings in different populations support an absence of an effect of MC on cognitive ability.

5.4. Autism Spectrum Disorder (ASD). Analysis of a Danish national medical records databank led to a finding that infant *"circumcision pain"* causes ASD and hyperkinetic disorder [88]. Critics exposed numerous flaws in the study[89]. Firstly, the number of cases was small and statistical significance was marginal. The association with ASD diagnosis was stronger for boys under the age of 4 years, whereas it

should have been greater with the benefit of the higher number in the entire cohort of circumcised (mostly Muslim) boys aged up to 10 years [89]. No attempt was made to examine whether pain in *uncircumcised* boys – such as caused by UTI, that is 10-times more frequent in uncircumcised vs. circumcised male infants, might be associated with ASD [89].

The study authors did not consider alternative explanations. General anesthesia, sometimes advocated for infant MC [90], is neurotoxic and associated with later cognitive impairment [91], and has been disavowed in favour of local anesthesia [92]. Medications for post-EIMC analgesia – specifically, the use of acetaminophen (paracetamol), found in 1994 to be effective for management of post-EIMC pain [93], led the AAP to recommend it [94]. In support of acetaminophen use, rather than EIMC, being responsible for the association, a US study by Bauer *et al*. found no association of EIMC with ASD prior to 1995 [95]. Unlike in older individuals, acetaminophen metabolism in immature brains generates neurotoxic by-products. Bauer criticized the Danish ASD study for falsely suggesting that her group's findings applied to EIMC [96]. These observations may also explain why the older boys in the Danish study (i.e., boys born before the introduction of the guidelines in 1999) showed only a weak association of MC with autism, whereas the younger ones (born after 1999) showed a stronger association. Another Danish study, by Sneppen and Thorup, found an extraordinarily high prevalence of ASD of 7.2% in *uncircumcised* boys [97]. They suggested that the figure of 1.5% reported by Frisch and Simonsen for uncircumcised Danish boys [88] indicated confounding in the latter study. Diagnosis of ASD has been rising steady over the years but has now plateaued in males at 3.6% in the US [98, 99] and 3.7% in South Korea [100], whilst rate of MC has been steadily declining in each country. Other authorities have also criticized the Danish autism study [101, 102].

5.5. Alexithymia. Alexithymia is an idiopathic personality trait characterized by difficulty identifying and describing an individual's own, or other peoples' emotions. Like many personality traits, a complex interaction of genetics and environment is generally postulated to be responsible. It has been argued that early trauma, such as pain from EIMC (presumably when performed contrary to recommendations to use local anesthesia) affects the brain, leading to alexithymia [103]. Research support for the hypothesis was provided in a study involving subjects recruited by advertisements on an anti-MC website [103]. Psychiatric problems appeared to be more common in men unhappy at having been circumcised [104]. Body dysmorphic disorder has been linked to alexithymia [105]. Consistent with bias in the small self-selected sample, the overall rate of alexithymia was over 3-times higher than seen in the general population [106]. There was, moreover, no association between age of MC and alexithymia. The authors

later conceded that, *"Circumcision pain itself did not seem to effect* [sic] *acquiring alexithymia"*, that their sample may be biased, and that the findings were both *"preliminary"* and needed replication [107].

There is strong empirical support for alexithymia being a stable personality trait rather than just a consequence of psychological distress [108]. A large survey evaluating a comprehensive array of emotional problems in pre-school [109] and in 6–16 year-old [110] children from 24 different societies found differences in severity of these between countries, irrespective of MC prevalence in each. While some, but not all [111], studies have shown that men exhibit higher alexithymia scores than women, the difference is seen in countries with divergent MC rates [106].

5.6. Psychological Trauma. An unpublished study in 2000 claimed MC was associated with post-traumatic stress disorder [112]. This was contradicted by the survey above [103]. We found no studies to support other MC trauma-related claims [113].

5.7. Conclusion. As summarized in **Table 5**, high quality studies show little or no adverse effect of MC on physical or psychological outcomes.

6. Sexual Function and Pleasure

6.1. Sexual Function. All systematic reviews of relevant research studies rated by quality found no harmful effect [114-117]. One systematic review included data from 19,542 uncircumcised and 20,931 circumcised men [114]. The key finding was that MC had no adverse effect on sexual function, including erectile function, premature ejaculation, ejaculatory latency, orgasm difficulties, and pain during penetration. Evaluations by researchers in China [115, 116] and Denmark [117], where MC is uncommon, found the same. The findings were, moreover, supported by a meta-analysis of each sexual dysfunction [115]. A UK study of 6,293 men and 8,869 women added further support [118]. The recent systematic review from China found pain during intercourse was 64% more common in uncircumcised males [116]. It also found that erectile dysfunction was significantly less common in circumcised men. A case-control study in Kenya found that circumcised men reported less pain during sexual intercourse than uncircumcised control men during 2 years of follow-up [119]. Other aspects of sexual function did not differ between circumcised and uncircumcised men. Included in each review were 2 RCTs [120, 121], which are regarded as high quality evidence [24]. Each RCT found no adverse effect on any aspect of sexual function by the 2-year post-MC follow-up point. Coital injuries were significantly lower in circumcised men [122-124].

Sexual dysfunction is common in men. The evidence that MC may be responsible included outlier studies that were generally small and of low quality, as well as anecdotes and speculation.

6.2. Sexual Pleasure. Several studies concluded that MC diminishes sexual pleasure for men and their female sexual partners[125-131]. Evaluation of these identified multiple flaws [114, 132-138]. Other studies [139-142], including RCTs [120-122, 143], found MC had no adverse effect. In fact, the RCTs found a net increase in sexual pleasure in men and their female partners. The reasons given by women for favoring MC were also esthetics, vaginal penetration, hygiene and reduced infection risk [143].

A list of "*16 functions of the foreskin*" [144] has been compiled by opponents (**Table 3**). Here we evaluate some of these proposed functions and related claims. The others are mostly speculative, there being no evidence to assess their veracity.

It has been argued that the foreskin contains "*10,000*" or "*20,000*" nerve endings essential for sexual pleasure. The "*10,000*" figure (specifically fine-touch nerve endings; Meissner's corpuscles) stemmed from a calculation by Prof. Ken McGrath, which he subsequently retracted as being, "*an order of magnitude too high*" [145].

Fingertips have the highest concentration of Meissner's corpuscles of any human glabrous skin, and the foreskin the lowest [146]. Meissner's corpuscles in the foreskin are most abundant up to age 10–14 years, then decline substantially [147], which was stated to contradict the sexual pleasure claim [137]. Cox *et al.* provided data explaining that other types of nerve endings specific to the glans, but absent from the foreskin, are responsible for sexual pleasure [137].

The figure of *"20,000"* nerve endings appeared in a 1997 magazine article [148] by Paul Fleiss [149]. It cited as support a 1932 paper [150] that did not state there are 20,000 nerve endings in the foreskin. Instead, the *"20,000"* figure stemmed from a count of 212 nerve endings in 1 cm^2 of an undisclosed part of a single foreskin from an individual of unknown age [150]. Amongst these were 2 fine-touch receptors, but no genital corpuscles that have been invoked as the nerve endings responsible for erogenous sensations [137]. To arrive at *"20,000"*, 212 would need to be multiplied by 94.3. The 94.3 cm^2 value for both inner and outer surfaces combined, is near the top of the range of 7–99.8 cm^2 (av. 38.5 cm^2) reported more recently for total foreskin surface area [151].

It has also been argued that the foreskin has a surface area of "*15 square inches*" [22]. This value is at the upper (~0.1%) limit of the range found for the combined inner and outer foreskin area of 965 Ugandan men (aged 15–49 year) of 7–99.8 cm^2 (mean 38.5 cm^2) [151], i.e., 1.1–15.5 square inches. The only other study, involving 8 cadavers (of unstated age, race, etc), reported a combined outer and inner foreskin area of 18.1–67.5 cm^2 (2.8–10.5 square inches, mean 7.2

square inches [46.7 cm^2]) [152]. Those measurements showed that foreskin size is highly variable, very much more so than penis length [153]. Darwin noted, "*An organ, when rendered useless, may well be variable, for its variations cannot be checked by natural selection*" [154].

We could find no evidence to support the existence of pheromones in the foreskin [155].

It has been postulated that, "*In heterosexual intercourse, the non-abrasive gliding of the* [uncircumcised] *penis in and out of itself within the vagina facilitates smooth and pleasurable intercourse for both partners*", meaning easier penetration, nerve stimulation and prevention of loss of vaginal lubricant [156]. No gliding would, however, occur for men with short foreskins. We could find no studies investigating this proposed phenomenon in men or their sexual partners. The purported lubrication provided by "*gliding*" should reduce pain during intercourse (dyspareunia). However, the better-quality studies reported either no difference or less pain in circumcised men [114-117, 119-122, 157] and their female sexual partners [143] (**Table 6**). Contrary claims appeared to be based on speculation, anecdotes or low quality studies [158].

Further information addressing the "16 functions" is available [159].

6.3. Data From High Quality Studies. Two high quality studies, a RCT in Kenya [121] and a cohort study in the Caribbean [122], found that sexually experienced adults reported improved sexual pleasure and function after circumcision. A meticulously conducted systematic review of all studies found that, overall, MC had no adverse effect on penile sensitivity, sexual arousal, sexual sensation or pleasure [114]. Criticisms of that study [131] were shown to lack merit [136]. The findings were consistent with a systematic review of histological correlates of sexual sensation showing that the sensory receptors responsible for sexual pleasure (genital corpuscles) reside in the glans, not the foreskin, meaning loss of the foreskin by MC should not diminish sexual pleasure [137]. By exposing the glans, as often occurs in an uncircumcised man during erection, MC was proposed to increase sexual pleasure [137]. The foreskin, just as other skin on the body, contains sensory receptors that respond to touch, temperature and pain. Since the density of Meissner's corpuscles in the prepuce diminishes at puberty when male sexual activity is increasing, these touch receptors are unlikely to be involved in sexual sensation [137]. Moreover, free nerve endings (that also respond to touch) showed no correlation with sexual response. Sensitivity of the glans to touch decreased with sexual arousal, so further diminishing a role for touch receptors in sexual sensation [160]. Sensitivity of the penis to vibration, which is able to elicit arousal and ejaculation, is not related to MC status [137].

6.4. "Foreskin Restoration". This undertaking involves stretching the skin on the shaft of the circumcised penis using weights. Various psychological disorders [161, 162] were found to be more prevalent in circumcised men preoccupied with their absent foreskin [104]. Such men were more likely to undertake *"foreskin restoration,"* which was found to occasionally require subsequent "re-circumcision" [163-165] or medical attention for resulting genital mutilation [163, 166].

6.5. Conclusion: As summarized in **Table 7**, high quality research shows that MC has no adverse effect on sexual function, sensitivity or pleasure. This finding contradicts arguments based on low-quality evidence.

7. HIV Infection

7.1. Heterosexual Men. Evidence showing that MC provides protection against heterosexually acquired HIV infection in men has been disputed [31, 167-184]. Early evidence of protection was confirmed by three RCTs in sub-Saharan Africa [185-187], a review [188] and a Cochrane committee meta-analysis that showed high consistency of the trial results [189], leading to endorsement of MC by the World Health Organization (WHO) and UNAIDS as an additional important intervention to help reduce HIV prevalence in epidemic settings [190, 191]. Roll-out of VMMC programs has resulted in 15 million MC procedures in high-priority countries [192], so helping reduce infections and save lives [192]. Criticisms of the RCT findings by MC opponents [168-171, 180-184] were shown by scientists and public health authorities to contain fundamental flaws [56, 193-209]. The suggestion that, once circumcised, men would forego condom use was contradicted by a recent meta-analysis that found no difference in use of condoms for up to 2 years post-MC [210].

Recent meta-analyses have shown protective effects of MC in circumcised men of 70% (95% CI 0.24–0.38; $p<0.00001$) [211] and 72% (95% CI 1.7–7.1) [212].

Compelling biological reasons have been used to explain the vulnerability of the foreskin to HIV infection [77, 213-217]. Infectivity is exacerbated in inflammatory states and ulceration from sexually transmitted infections (STIs) [218-222], coital injuries more common in uncircumcised men [122-124] and foreskin size [151]. Langerin, produced by the mucosal epithelium of the foreskin, is protective at low viral loads [223], but becomes overwhelmed at high HIV loads [223, 224].

Those who had denied the evidence, but have now accepted that MC is effective in HIV prevention in sub-Saharan Africa, continue to dispute its effectiveness in developed countries, despite US data to the contrary in heterosexual men [225, 226], supported by the US CDC [3, 4, 227]. In European

countries (low MC rate) heterosexually-acquired HIV was 6 times higher in men and 10 times higher in women compared with Israel (high MC rate) [228].

7.2. HIV infection in women. Based on data from two studies [229, 230], it was argued that MC increases women's HIV infection risk. In the Rwanda study, women with higher HIV-positivity were from higher socioeconomic groups [229] in which MC is more common, as is promiscuity. Cross-infection from unhygienic traditional MC may also have contributed [231]. The Uganda study found that the marginally higher (p=0.04) HIV infection in women was limited to women whose male partner disobeyed medical advice and resumed sexual intercourse prior to the 6 weeks post-MC wound-healing period [230]. Inadequate recruitment, and thus power, resulted in the trial being stopped at interim analysis[230]. Enrolment of the necessary 10,000 serodiscordant couples was deemed "*logistically unfeasible*" [232].

Meta-analyses have found 20% [232] and 32% [211] non-significantly lower HIV risk in women with circumcised male partners. Much lower HIV prevalence was seen in South African women who only had circumcised male partners [233, 234].

7.3. HIV Infection in Men Who Have Sex With Men (MSM). A Cochrane meta-analysis concluded that, "*Current evidence suggests that male circumcision may be protective among MSM who practice insertive anal sex, but the role of male circumcision overall in the prevention of HIV* […] *among MSM remains to be determined*" [235]. The meta-analysis found a 73% decrease in HIV infection risk in studies of MSM reporting an *insertive* role during anal intercourse, but no significant difference in studies of men reporting a receptive role [235]. The protective effect of MC was 89% in a study of insertive MSM in Sydney, Australia [236].

7.4. Intercountry Comparisons. Arguments that HIV rate is higher in the US than Europe despite higher MC rate in the US, have failed to acknowledge that the major route of HIV infection in the US is receptive anal intercourse amongst MSM, for which MC affords no protection [56].

8. Other Sexually Transmitted Infections

8.1. Overview. An extensive article disputed the ability of MC to protect against other STIs [237]. Detailed evaluation of that article revealed serious flaws in statistical analyses, as well as obfuscation and misrepresentation of data [238]. That author's previous MC and (non-HIV) STI analyses [237, 239-241] have also been shown to contain serious analytical and evidential flaws [238, 242, 243].

The following summarizes the high-quality evidence addressing the role of MC in protecting against various specific STIs.

8.2. Oncogenic Human Papillomavirus (HPV) Genotypes. A recent meta-analysis of 30 studies found MC was strongly associated with reduced odds of genital HPV prevalence (OR 0.68; 95% CI 0.56–0.82) [244]. That meta-analysis treated all study types equally. Risk reduction was 53–65% in 2 earlier meta-analyses and 40% in 6 RCTs (see recent risk-benefit analyses [245, 246]). A large multinational study found penile HPV in 19.6% of uncircumcised vs. 5.5% of circumcised men [247]. After adjustment for age at first intercourse, lifetime number of sexual partners, and other potential confounders, circumcised men were 63% less likely to be infected with HPV [247]. A large UK survey found high-risk HPV types were 86% less prevalent in circumcised men [248]. A RCT published in 2012 found that the incidence of flat penile lesions (mostly caused by high-risk HPV types) was 98% lower among circumcised men [249]. Thus, these high-quality studies and analyses confirm the protective effect of MC.

MC also protects against low-risk (non-oncogenic) HPV types responsible for genital warts [250]. These HPV types infect the shaft and genital area generally, whereas high-risk types mostly infect the foreskin and underlying glans [250]. A RCT found that circumcised men had a shorter duration of HPV infection of the glans/coronal sulcus [251], but duration of infection did not vary by circumcision status in the penile shaft, scrotum, or all genital sites combined. Thus, clearance is greatest in precisely the area of the penis exposed by MC. A US study found that MC was associated with a statistically significant increased likelihood of clearance of any HPV infection (HR 2.7; 95% CI, 1.3–5.7) and of clearance of oncogenic HPV infection (HR 3.2; 95% CI, 1.4 –7.4]), but not with an increased clearance of non-oncogenic HPV infection [252]. The meta-analysis cited above conceded that, *"sampling sites also played an important role in the final results,"* and that, *"selection bias in our meta -analysis"* (i.e., not taking into account penile sites used for sampling) affected the conclusions [244]. Use of a single combined sample for the penis and scrotum was the likely explanation for a negative result in one study [253]. Foreskin HPV infection is significantly higher in men with phimosis [254].

In summary, MC reduces penile infection by, and increases clearance of, high-risk HPV genotypes.

8.3. Genital Herpes Simplex Virus-2 (HSV-2): Data from 3 RCTs in sub-Saharan Africa found significant decreases of 45%, 30%, and 28% in HSV-2 infection in men after MC [255-258]. A 2006 meta-analysis, that predated publication of the RCTs, found HSV-2 was 15% (OR 0.74–0.98) lower in circumcised men, after adjustment for confounding factors [259].

8.4. Protection of Men Against Other STIs. As documented in a critical review [238], RCTs and other studies have found MC affords protection against *Trichomonas vaginalis* (50%) [260], *Mycoplasma genitalium* (40%) [261], *Treponema pallidum* (syphilis) (33–50%) [259, 262, 263], chancroid (50%) [259] and genital ulcer disease (50%) [264, 265]. Genital ulcers in uncircumcised men contain a higher prevalence of anaerobic bacteria. RCT data showed that MC reduces total bacterial load and microbiota biodiversity [50]. A RCT found no syphilis infections in the 24 months after MC compared with 9.6% in men who remained uncircumcised (p=0.09) [218]. Although RCT data by Tobian *et al.* failed to find a reduction in syphilis, this might have reflected lack of statistical power due to the small number of syphilis infections identified on follow-up testing [266]. Tobian, in an editorial covering another large study that found 42% lower syphilis in circumcised men [262], acknowledged that MC *does* reduce syphilis risk [267]. Arguments disputing the use of MC for syphilis risk reduction [268] have been criticized [205]. Data show that MC does not, however, protect men against sexually transmitted urethritis [243].

8.5. Protection Against STIs in Women. Findings on the impact of MC on STIs in women are mixed. At the very least, it should be obvious that any measure that reduces risk to the male partner of being infected should reduce STI prevalence in women. Below we summarize available data.

In women, high-risk HPV infection may cause cervical dysplasia that can progress to cervical cancer. High-risk HPV also contributes to other genital cancers and to oropharyngeal cancers. Over her lifetime, a woman may have sexual partners of either MC status, potentially confounding associations between male partner MC status and a woman's HPV risk. This issue was addressed in a large multinational study, in which confounding was minimized by restricting the analysis to 1,420 men whose female partner reported having had only a single sexual partner [247]. The men were rated for their "sexual-behavior risk index". Men who were high-risk had had ≥6 sexual partners and first intercourse prior to 17 years of age. Men who were low-risk had had ≤ 5 sexual partners and first sexual intercourse at >17 years of age. The remaining men were classified as having an intermediate risk. Monogamous women whose male partner had either a high or an intermediate sexual-behavior risk index were much less likely to have had a cervical cancer diagnosis if the male partner was circumcised (OR 0.18 [95% CI 0.04–0.89] and 0.50 [95% CI 0.27–0.94], respectively). An RCT found prevalence and incidence of high-risk HPV after 2 years to be, respectively, 28% and 23% lower among women with circumcised male partners than women with uncircumcised partners [269].

An argument that effective HPV vaccines render MC for protection irrelevant fails to appreciate that current HPV vaccines are prophylactic not therapeutic, are primarily administered to girls in early

high school, and are directed at only the two most common of the >14 mucosotropic HPV genotypes. In theory, the advent of a nonavalent HPV vaccine could, only if 100% effective, increase protection from the current 70% to as much as 93%. A recent systematic review of real-world experience with HPV vaccination [270] revealed its suboptimal effectiveness (see Figure 3C of that publication). In Australia, one of the earliest countries to vaccinate girls (in 2007), there was an 86% (not 100%) decrease in the 4 *vaccine genotypes* (HPVs 6, 11, 16 and 18) [270].

As with other public health interventions, a package of multiple preventive measures is likely to have a greater impact than vaccination alone. HPV vaccination against a subset of HPV types in early adolescence can help mitigate cervical cancer risk, but uptake is not widespread in all settings and durability of effectiveness remains to be seen. The emerging switch from pap smears to primary screening for HPV in high-income countries, by a PCR-based test [271], will improve risk detection, but is not practicable in resource-constrained settings.

Genital herpes infection risk in a Pittsburgh study was twice as high in women who had ever had intercourse with an uncircumcised man (OR 2.2; 95% CI 1.4–3.6; n=1,207). Similarly, a RCT found 2-fold higher HSV-2 infection over 12 months in 783 wives of uncircumcised men [272]. Secondary data from another RCT found HSV-2 was the primary pathogen in 96% of the 67% of genital ulcers in the female partners in whom an etiological agent had been identified [273]. Most participants had been infected with HSV-2 prior to commencement of the trial and HSV-2 detected in these women represented mostly reactivation of pre-existing infection.

Chlamydia trachomatis seropositivity in a large, multinational study was 5.6-fold higher in women with an uncircumcised male partner [274]. The finding also applied to women who had only had one sexual partner. Prevalence of *C. pneumoniae*, which is not transmitted sexually, did not differ. The authors suggested that infected cervicovaginal secretions may be trapped under the foreskin for longer in uncircumcised men, increasing risk of penile urethral infection and transmission to the vagina during sexual intercourse [274]. A prospective study involving populations from Uganda, Zimbabwe and Thailand, however, found no difference in chlamydial, gonococcal or trichomonal infections in women as a function of MC status [275].

For other STIs, a RCT found that genital ulcer disease risk was 22% lower in women with circumcised male partners, bacterial vaginosis was 40% lower, severe bacterial vaginosis was 61% lower, and *Trichomonas vaginalis* was 48% lower, but there was no difference in dysuria or vaginal discharge [272]. A large prospective cohort study of 2,946 HIV-negative couples found syphilis was 75% lower in the female partners of circumcised men [262]. A prospective study in Kenya by the same

authors found that those with circumcised male partners had a 58% lower risk of incident *Trachomatis vaginalis* compared to women with uncircumcised partners [276].

A recent systematic review of MC and STIs in women identified 9 RCTs and 48 observational studies of populations globally [277]. Overall, MC reduced acquisition of STIs and cervical cancer in women, being strongest for HSV-2, chlamydia and syphilis. The authors found medium consistency evidence for protection against any HPV type and low-risk HPV types, intermediate consistency for any STI, candidiasis, dysuria, genital warts, gonorrhoea, high-risk HPV viral load and *Mycoplasma genitalium*, with discrepant values for bacterial vaginosis, HIV, high-risk HPV, non-specific genital ulcers, trichomonas and vaginal discharge that rendered the latter low-consistency. More information was presented in an editorial [278]. Clearly, reduced population prevalence of STIs in men will translate into lower risk of STI exposure in women.

8.6. STI Vaccination. Development of prophylactic vaccines against HIV and STIs other than HPV remains a desirable, but to date elusive goal. Thus, although STI diagnosis and treatment continues to improve, prevention has to remain a priority for many reasons, not the least of which is cost.

8.7. Protection Against Other STIs in MSM. A study in 2012 found that MC provided 57% protection against the major oncogenic HPV type, HPV16, in Australian MSM who practiced predominantly insertive anal intercourse [279]. Not surprisingly, no protection was observed for men who predominantly assumed the receptive role during anal intercourse. A 2011 Cochrane meta-analysis examined syphilis, HSV-1 or HSV-2 in MSM and found no overall significant association with MC status [235]. The Australian group found that MC protected against *incident* syphilis (HR 0.35; 95% CI 0.15–0.85), particularly in the one-third of MSM who engaged predominantly in insertive anal intercourse (HR 0.10; 95% CI 0.01–0.81)[280]. An explanation for association with incident but not prevalent syphilis in that study was that MSM who initiated sexual activity during the late 1980s and 1990s when syphilis prevalence was low would have been at very low risk of acquiring syphilis irrespective of their MC status, but only since 2001 has syphilis re-emerged in Australian MSM [280].

8.8. Conclusion. As summarized in **Table 8**, high quality data show that MC protects against risk of HIV and various other STIs.

9. Condoms for Protection Against STIs

It has been argued that condoms afford complete protection against HIV and other STIs, so obviating the need for MC [67, 180, 181]. Current data show, however, that condoms provide protection against HIV infection that ranges from 80% [281] to 71–77% [282]. This protection only applies if condoms are used consistently and correctly [281, 283]. A Cochrane systematic review and meta-analysis of RCTs of condom use (2 in the US, one in England and 4 in Africa) found, *"little clinical evidence of effectiveness"* and no, *"favorable results"* for HIV prevention [284]. That study did, however, find that condoms were 42% effective in prevention of syphilis infection [284].

Unlike condoms, MC is a one-off procedure that does not require future compliance each time a man has sexual intercourse. In this respect MC can be compared with vaccination. However, the only vaccines currently in widespread use (in early high school females and increasingly in males) for STI prevention are those that protect against certain HPV genotypes. MC and condom use each provide a reasonable degree of protection against STIs. When both are in place protection is higher [56].

10. Delay of MC Until Males Become Sexually Active

It has been argued that MC be delayed to allow the male to decide if he wishes to reduce his risk by choosing to get circumcised when he is old enough to be sexually active [285, 286]. Substantial problems with this argument have been enunciated [287] (**Table 9**). First, MC has other benefits besides STI prevention and these benefits start early in life (see UTIs section above and inflammatory skin conditions and physical problems sections below). The benefit-to-risk ratio from EIMC is high and has increased over the years as more evidence has accumulated [245, 246, 287-291] (**Table 10**). Second, EIMC is simpler, quicker, less expensive, with lower risk of complications [52], healing is faster and the scar can be almost invisible [287]. Third, there are substantial barriers to later circumcision [287]. These barriers include: the decision process, peer pressure, affordability, slower healing, pain during nocturnal erections, the need to abstain from sexual activity for ~6 weeks, and a visible scar afterwards. The sexual abstinence period is often cited by men as a significant barrier, so favoring EIMC as the preferred time [292].

An argument that infant MC should be banned, discouraged or at least delayed until the boy is old enough to decide for himself [19-21, 293, 294] was refuted by authorities in ethics, who have presented sound reasons why such reasoning is flawed [295-301]. It was argued that being circumcised boosts autonomy more than constraining it [302]. The AAP recommended that prior to or early in a pregnancy the medical practitioner should provide parents with unbiased education about risks and benefits of EIMC so they have adequate opportunity to choose what is in their child's best interests should they have a boy [1]. Furthermore, MC later in life is not only associated with a 10–20-fold higher risk of

adverse events [52], but, as explained above, having MC performed later poses significant barriers to adolescent boys and men that usually mean MC will not happen except for a medical reason [287].

11. Penile Inflammatory Conditions and Treatment

There has been a trend away from MC and toward use of steroid creams for treatment of phimosis and penile inflammation [303]. This approach is not ideal [304, 305]. Commitment is needed for regular application, there is a risk of side effects from long-term use of steroids, and effectiveness of 2 (range 1–23) months' treatment was only 35% during 4 (range 1.5–60) months' follow-up in a recent meta-analysis on the very serious foreskin-related inflammatory condition, lichen sclerosus [305]. In contrast, MC is close to 100% effective [306].

Phimosis, balanitis and candidiasis can occur alone, or can co-occur. A meta-analysis found 68% lower balanitis rates in circumcised males [307]. Penile candidiasis was reported in 7.7% of uncircumcised men vs. 4.9% of circumcised men in a large Australian survey [308]. In boys aged 8 months to 18 years (mean 6.4 years) the prevalence of fungal infection was 44% in uncircumcised boys vs. 18% in circumcised boys [309]. The fungal species were, in order of decreasing prevalence: *Malassezia globosa*, *M. furfur*, *M. slooffiae*, *C. albicans*, *C. tropicalis* and *C. parapsilosis*. Each was present in uncircumcised infants, but none in circumcised infants. A gradual accumulation with age occurred, increasing by age 18 years to 62.5% in uncircumcised boys vs. 37.5% in circumcised boys. Recently, a strong direct link has been found between *C. albicans* antibodies and schizophrenia in men, independent of potential confounders [310].

12. Penile Cancer

The strong protection afforded by MC, especially EIMC, against penile cancer has been disputed by opponents [27, 311, 312]. The arguments used have been criticized as flawed [313-315]. A claim that a penile cancer diagnosis of 1 in 100,000 men indicates that the disease is very rare. This figure is, however, an approximation of the *annual incidence*. The more relevant figure is *lifetime risk*, which is approximately 1 in 1,000 for an uncircumcised man [316]. This would make penile cancer uncommon, but not rare. Its prevalence in *circumcised* men, of 1 in 50,000 to 1 in 12,000,000 [317, 318], might be considered rare. A California study found that uncircumcised men had a 22-fold higher risk [319]. The reason why uncircumcised men are at elevated risk stems from foreskin-related conditions, most prominently phimosis, which was shown in a meta-analysis to increase the risk 12-fold [307]. EIMC eliminates lifetime risk of phimosis. Meta-analyses found that balanitis increases penile cancer risk 3.8-fold and smegma (a whitish film that accumulates under the foreskin of men and that is comprised of

dead and decomposing exfoliated skin cells, bacteria and other microorganisms) increases penile cancer risk 3.0-fold [307].

Penile inflammatory conditions are much more common in uncircumcised men [304]. A meta-analysis found 47% of penile cancers are positive for high-risk HPV genotypes [320]. Since HPV genotypes prevented by current HPV vaccines constitute approximately 70% of population prevalence of all high-risk HPV genotypes, one might predict that HPV vaccination would offer the potential to reduce penile cancer by up to 47 x 0.7 = 33%. This level of risk reduction is similar to that conferred by MC. An early concern was that, over time, non-vaccine HPV genotypes might replace vaccine genotypes [321]. There is now evidence for this. Eight years after introduction of the HPV vaccination program for girls in Australia, prevalence of HPV 16 and 18 decreased in heterosexual men from 13% to 3% (P <0.0001) [322]. But there was no decrease in HPV genotypes overall, and, *"prevalence of non-vaccine-targeted genotypes"* increased from 16% to 22% ($p < 0.0001$) [322]. A combination of public health measures is normally advocated for disease prevention.

13. Prostate Cancer

Prostate cancer affects ≥10% of men over the lifetime. A 2015 meta-analysis found that, after reducing heterogeneity by removing outlier studies, prostate cancer risk was significantly lower in circumcised men, especially in the post-PSA testing era (p=0.01) [323]. In Blacks, large US [324] and Canadian [325] studies showed risk reductions of up to 36% (95% CI 8–61) and 60% (95% CI 0.19–0.86), respectively. MC prevalence worldwide is inversely correlated with prostate cancer incidence [326]. Countries with high MC prevalence have lower prostate cancer-related mortality, corrected for potential confounding factors [327]. The risk reduction associated with MC is on a par with other commonly recognized factors associated with decreased prostate cancer risk [328, 329].

14. Ethical and Legal Issues

Legal, human rights and other arguments have been invoked in opposing EIMC [27, 67, 294, 330-335]. Evaluation of those arguments have revealed flaws [315, 336-347]. Arguments criticizing the AAP's policy statement on ethical and legal grounds [1, 2, 27, 286, 294, 330, 348, 349] were followed by evaluations undermining the arguments used [336, 337, 340, 347, 350-352]. Articles critical of the CDC's draft recommendations on similar grounds [3, 4, 67, 303, 331] have also been shown to contain serious flaws [338, 339, 341].

Scholarly assessments concluded that MC of minors is ethical [295, 297, 298, 300, 301, 344, 353]. Given the wide-ranging protection against multiple medical conditions and infections in infancy and

childhood, including STIs in adolescents who become sexually active, it was argued that it would be unethical to leave boys uncircumcised [297, 344]. It was argued that Article 24(3) of the United Nations (UN) on the Rights of the Child might be interpreted as mandating EIMC, since not circumcising boys has been deemed as prejudicial to their health [297].

The statement "*First do no harm*" (often incorrectly attributed to the Hippocratic Oath) has been used to argue against MC. That statement is derived from the four pillars of medical ethics. The argument presupposes that MC is harmful, meaning that it is based on a false premise. It ignores the principal of beneficence – acting in the patient's best interest. The statement in the Hippocratic Oath, "*I will prevent disease whenever I can, for prevention is preferable to cure*" [354, 355] is pertinent. Recent evaluation of the legal and ethical issues was provided by professors of law, bioethics, urology and medical sciences in the *International Journal of Children's Rights* [339] and the *Journal of Law, Medicine and Ethics* [315]. Rivin *et al.* determined that given the strong evidence for diverse benefits and very low risk, in the light of current international conventions it would be unethical not to recommend EIMC [339].

Evaluation of US and international statutes as well as US case-law, including of cases used by a lawyer to support his arguments against MC [67], revealed no precedent for outlawing parent-approved MC of minors [315, 341]. A report by the Tasmanian Law Reform Commission [333] was shown by legal, public health and medical experts to be seriously flawed [344]. If it was, "*unlawful for physicians to circumcise*" [67], then EIMC would not be one of the most common medical procedures in the US [339]. It was noted, moreover, in a detailed treatise by a US lawyer opposed to MC that, "*Most circumcision lawsuits go nowhere*" [356].

An evaluation pointed out that those who condemn parent-approved MC of boys are not as quick to condemn other procedures in children, such as ear-piercing, cosmetic orthodontia, surgery for correction of harelip and tongue-tie, removal of supernumerary digits, and treatment of dwarfism by growth hormone injections [297]. Removal of birthmarks and moles can be included. It was suggested that these interventions should be regarded by parents and physicians as being beneficial to the child, and that it seemed odd that infant MC is regarded by some as controversial [297].

15. Logic

15.1. False Equivalence. It has been pointed out that, unlike EIMC, it is not the practice to routinely cut off ear lobes and breast buds to prevent future cancers or to remove the appendix to prevent appendicitis [22]. The fallacy of false equivalence was invoked in disputing the argument [357, 358]. It was pointed out that the breast is a body part with an important function. In contrast to MC, none of the other

proposed prophylactic interventions would come close to the outcome of risk-benefit (Table 10) or cost-benefit analyses obtained for EIMC.

Another example we found was associating MC with female genital cutting/mutilation, the more extreme forms of which cause severe harm. The closest female equivalent of MC, clitoral hoodectomy, was introduced in the 1950s for women with an excessive or phimotic clitoral foreskin [359, 360]. In a sexual dysfunction clinic in Boston, severity of clitoral phimosis was associated with increased likelihood of anorgasmia [361]. We could find no evidence for its practice today. No scientific reason was found to equate the strong arguments favoring MC because of its multiple medical benefits with female genital mutilation or other procedures without proven medical benefits.

15.2. Genetic Fallacy. Historical anecdotes, such as a belief by some in Victorian times that MC could be used to cure masturbation, have been used by opponents to dismiss MC [362]. It has been suggested that irritation from balanitis, smegma and infections could cause an uncircumcised boy to touch his penis, leading to stimulation and masturbation, behaviors frowned on in Victorian times [363, 364]. A major 1913 textbook that expressed disdain for masturbation, made no mention of MC as a "cure" [365].

MC is an ancient practice [366, 367]. Evidence of MC in Europe during the Upper Paleolithic era (38,000–11,000 BCE) was found in portable art and rock art at that time [366]. It was suggested that the practice of MC may have accompanied the radiation of *Homo sapiens* out of Africa [367] ~220,000 years ago [368]. It has further been suggested that privation and other forces explain why MC subsequently ceased in some cultures [367]. In Victorian times, health benefits, such as protection against syphilis [369], balanitis, inferior hygiene and phimosis [370], have been used to explain why MC became popular in Anglophone countries [367]. MC is common in diverse cultures globally [371]. The modern continuation or re-emergence of ancient practices such as MC and hand-washing likely stem from underlying disease prevention measures. Over time these may have been subsumed into religious custom [367]. The reasons humans might have had for MC hundreds or thousands of years ago can nevertheless be separated from the reasons for medical MC in contemporary society, the latter being based on sound scientific evidence described above, this being independent of these earlier reasons.

16. Cost Effectiveness

In the US, a downturn in MC prevalence has been attributed to weak pediatric policy statements prior to 2012, increased immigration from countries in which MC is less common, a reduction in access and affordability, and lobbying by organizations opposed to MC [291]. Similar trends occurred in Australia from the 1970s and the UK from the mid-20th century. In the US, this has included cessation of

Medicaid coverage for elective MC in 18 States. US studies show that, in the long-term, costs will be substantially higher because of the need for later, more expensive, medically indicated MC [226, 372-375], which carries a 10–20 fold higher risk of an adverse event [52], and for treatment of a wide array of conditions that EIMC protects against [226, 343, 372-377]. One study, of UTI and STIs in the US, estimated that if MC declined from current levels to a level of 10%, costs would escalate to in excess of US$4.4 billion over 10 annual birth cohorts, the increase in expenditure being $313 per foregone MC [372]. Just for HIV in the US, the, "*associated indirect costs may be more than 4 times the total direct medical expenses*" [378]. It was suggested out that if other conditions prevented by MC, as well as the indirect costs, were to be considered, the true cost would be considerably higher [372]. For prostate cancer in the US, in the absence of MC it was estimated that there would be 24–40% more cases and US$0.8–1.1 billion extra in costs for treatment and terminal care per year [328]. The CDC found MC in the US was cost-saving for HIV prevention in black and Hispanic males in whom HIV prevalence is highest [226].

Medicaid does not cover elective MC in several US states, thus making it unaffordable for poor families. The ensuing decrease in infant MC has been estimated to result in >100 additional HIV cases and $30M in net medical costs for treatment per year [373]. The cost to circumcise males in this birth cohort was US$4,856,000, i.e., 6% of the cost of treating just HIV. Modelling studies have, moreover, found cost savings initially generated by non-coverage of elective infant MC by Medicaid in Louisiana [374] and Florida [375] were mitigated by increases in rate and expense of medically indicated MC. The Louisiana study only considered the costs of later MC for boys aged 0–5 years. Lifetime costs would therefore represent a far greater financial burden on healthcare systems. The Florida study found Medicaid defunding led to a 6-fold rise in publicly-funded MCs at a cost of US$112M [375], leading Florida to restore Medicaid coverage for non-medical MC [379].

Medical MC is enormously cost-saving in high-HIV settings [380], and continues to be rolled out in 14 high-priority sub-Saharan African countries with the approval of the WHO, the US CDC, UNAIDS, PEPFAR, the Bill & Melinda Gates Foundation, and local government and medical bodies dealing with the epidemic. Since EIMC is more cost-effective, procedurally simpler, has a lower risk of adverse events, is quicker, more convenient, acceptable, and confers immediate benefits, albeit with a considerable lag before its HIV protection benefits begin, the CDC has recommended EIMC in 12 of these countries [381].

17. US and Non-US Policies

MC policies by the AAP 2012 [1, 2] and, in draft form, by the CDC [3, 4] arrived at affirmative recommendations. Although the Canadian Pediatric Society (CPS) produced a position statement in 2015, it only recommended MC for males in high-risk situations [8]. Its recommendations stemmed from a faulty risk-benefit analysis that was subsequently performed correctly by critics [245]. The CPS responded to the criticisms[62], but their response was also seriously flawed [382].

Current policies in other countries are negative and out-of-date. The 2010 Royal Australasian College of Physicians (RACP) policy [6] led to a detailed critique by Fellows of the RACP and other medical bodies showing it was not evidence-based [383]. A defence by the chair of RACP committee [177] was repudiated [384]. Arguments by another commentator [385] were also criticized [386]. Guidance by the British Medical Association has been negative [5]. The only actual MC policy in Europe is by the Royal Dutch Medical Association [7]. It was formulated by Gert van Dijk, a philosopher having no relevant scientific or medical background, and appears ideology-based, rather than science-based. Significantly, none of the policies opposing MC of boys denies MC's importance in high-HIV settings, or make extravagant claims about foreskin function.

In summary, our detailed evaluation of the high-quality evidence shows that policies opposing MC are out-dated and are not based on scholarly reviews of the medical scientific literature. At this point, we conclude that only policies by US medical bodies [1-4] and the Circumcision Academy of Australia [290], each involving a detailed evaluation of the scientific evidence, should be relied on.

18. Consequences

Based on our evaluation of the scientific evidence, a downturn in MC, as intended by MC opponents, would have a detrimental impact on public health and individual wellbeing. This will in turn drive up costs for treatment of foreskin-related conditions and more expensive MC in older males.

Men circumcised as adults are able to compare their experience before and after MC, but men circumcised as infants have no experience to draw upon. Arguments used opposing MC can result in psychological problems[387] and their sequelae [388] in vulnerable men. The risk of distress, depression and the broader psychological impact of arguments opposing MC in vulnerable men, and parents, merit further investigation.

In light of the above, one might appreciate the importance of MC education based on strong scientific evidence. Pseudoscience concerning HIV and AIDS led the then South African President, Thabo Mbeki, to disavow antiviral drugs, leading to loss of 330,000 lives and 35,000 babies being born with HIV [389].

19. Limitations

A limitation of this study is that many arguments opposing MC are absent from the scientific literature, but are popular on anti-MC websites and social media. Searching only publication databases will miss these. We address this limitation to some extent by examining the *"16 functions of the foreskin"* meme (Table 3), which is particularly popular, as an Internet search will show. Some others are mentioned where they are relevant to published claims. But others will, inevitably, be overlooked as our review gives priority to published claims, these being the ones more likely to be influential to health care professionals. Not being in the peer-reviewed scientific literature necessarily reduces the credibility of certain claims in the first place and, it is to be hoped, health-care professionals at least should be wary of claims that are not supported by scientific evidence published in reputable journals.

Another limitation is that the degree of benefit over the long-term may be higher than evident from age-restricted or short-term studies. For example, early studies of UTIs in infancy found MC conferred a 10-fold risk reduction, but only 1% of uncircumcised males were diagnosed with a UTI in the first year of life, whereas inclusion of data for older children and men found the lower risk reduction later meant overall lifetime risk reduction was 4-fold, but the proportion of uncircumcised males experiencing a UTI over their lifetime was 32% compared with 8.8% for circumcised males [26]. Long-term follow-up of the three MC and VMMC RCTs have shown a continuation of level of effectiveness of approximately 60% in two of these [390, 391], but an increase in effectiveness in another RCT to 73% [392]. Thus, with larger and wider studies we expect the data will continue to consolidate and even increase the strength of the protective effect conferred by MC.

The specific focus of our evaluation is another potential limitation. The purpose of our systematic review was to assess the scientific and medical data, including data on sexual function. We did not address psychosocial, religious or emotional arguments that might be posed. Nor did we address local or regional factors, MC practice in developed countries vs. developing countries, or Muslims vs. others.

20. Conclusions

The present systematic review has contrasted evidence used to argue against MC with evidence from RCTs, systematic reviews and meta-analyses, in particular, that has demonstrated the multiple medical and health benefits and low risk of MC to males [246, 291, 393] and their female sexual partners [277, 278]. The key publications forming the framework of the present systematic review are provided in **Table 11**, as required by PRISMA guidelines. We find that based on the evidence rated by quality, MC, especially when performed in early infancy, is favored.

One should be aware of confirmation bias and asymmetric Bayesianism [394] when it comes to any discussion of a contentious topic such as MC. A recent study revealed, moreover, that *ad hominen* attacks on scientists themselves, rather than the empirical basis of the science, are an effective strategy by those who reject scientific evidence on a topic [395].

Following the 2012 AAP infant MC policy, a commentary in *AAP News* [396] suggested that the statement by the AAP Task Force that, *"It is important that clinicians routinely inform parents of the health benefits and risks of male newborn circumcision in an unbiased and accurate manner,"* may require pediatricians, at least those in the US, to modify their discussions about newborn health interventions with parents, since, "*physicians sometimes can be held accountable for harm that results from not telling patients about an available medical treatment or procedure*" [396].

The AAP suggested that after evaluation of the evidence by parents those individuals should be free to either consent to having their son circumcised or decline circumcision for a son [396]. Women can have considerable power in regard to the decision. They can influence the choice of EIMC or later MC for their sons [287], brothers, other male family members and friends. They can, moreover, choose to have a circumcised sexual partner or encourage an uncircumcised partner to undergo the procedure.

The present systematic review should help prioritize the best scientific evidence when it comes to MC, especially EIMC, as an important public health issue worldwide. It should also provide a useful resource for those confronted with contrary information.

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Conflicts of Interest

The first author is a member of the Circumcision Academy of Australia, a not-for-profit, government registered, medical association that provides evidence-based information on male circumcision to medical practitioners, parents and others, as well as contact details of doctors who perform the procedure. The other authors declare that they have no conflicts of interest regarding the publication of this article. All authors have no religious or other affiliations that might influence the topic of circumcision.

References

[1] American Academy of Pediatrics Task Force on Circumcision, "Male circumcision," *Pediatrics*, vol. 130, no. 3, pp. e756-e785, 2012.

[2] American Academy of Pediatrics Task Force on Circumcision, "Circumcision policy statement," *Pediatrics*, vol. 130, no. 3, pp. 585-586, 2012.

[3] Centers for Disease Control and Prevention [Docket No. CDC–2014–0012-0001], "Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and Other Health Outcomes," Federal Register, vol. 79, No. 231, 71433. [accessed 2018 Jan 30]. Available from URL: https://www.federalregister.gov/documents/2014/12/02/2014-27814/recommendations-for-providers-counseling-male-patients-and-parents-regarding-male-circumcision-and," 2014.

[4] Centers for Disease Control and Prevention [Docket No. CDC-2014-0012-0002], "Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and Other Health Outcomes," [accessed 2018 Jan 30]. Available from URL: http://www.regulations.gov/ - !documentDetail;D=CDC-2014-0012-0002," vol., no., pp., 2014.

[5] British Medical Association, "The law and ethics of male circumcision. Guidance for doctors," [accessed 2018 Mar 15]. Available at URL: http://jme.bmj.com/content/30/3/259.full," 2006.

[6] Royal Australasian College of Physicians, Paediatrics & Child Health Division, "Circumcision of infant males, " [accessed 2017 Dec 18]. Available from URL: http://www.racp.edu.au/index.cfm?objectid=65118B16-F145-8B74-236C86100E4E3E8E, 2010.

[7] Royal, Royal Dutch Medical Association (KNMG), "Non-therapeutic circumcision of male minors, " Utrecht: Royal Dutch Medical Association (KNMG), [accessed 2018 Jan 20]. Available from URL: http://knmg.artsennet.nl/Publicaties/KNMGpublicatie/Nontherapeutic-circumcision-of-male-minors-2010.htm, 2010.

[8] S. T. Sorokan, J. C. Finlay and A. L. Jeffries, "Newborn male circumcision. Position Statement. Canadian Paediatric Society," *Paediatrics and Child Health*, vol. 20, no., pp. 311-315, 2015.

[9] S. Moreton, "Cyber Bullying," *CircFacts.org* [accessed 2018 Feb 7]. Available from URL: http://circfacts.org/cyber-bullying/, 2017.

[10] Circumcision Choice. [accessed 2018 Feb 7]. Available from URL: https://docs.wixstatic.com/ugd/b794cb_26336ebcba35422983c62f4bbfb665ef.pdf, 2017.

[11] A. Gross, "Its time for anti-circumcision extremists to stop the bullying," *The Jewish News of Northern California* [accessed 2018 Feb 7]. Available from URL: https://www.jweekly.com/2015/04/17/its-time-for-anti-circumcision-extremists-to-stop-the-bullying/, 2015.

[12] M. J. Stern, "How circumcision broke the Internet," *Slate* [accessed 2018 Feb 9]. Available from URL: http://www.slate.com/articles/health_and_science/medical_examiner/2013/09/intactivists_online_a_fringe_group_turned_the_internet_against_circumcision.html, 2013.

[13] Notyourstocut.com, "The biggest risk factor and the quickest path to change," [accessed 2018 Feb 9]. Available from URL: http://notyourstocut.com/2014/12/06/the-biggest-risk-factor-and-the-quickest-path-to-change/, 2014.

[14] mgmbill.org, "Federal Prohibition of Genital Mutilation Act," [accessed 2018 Feb 10]. Available from URL: http://www.mgmbill.org/, 2014.

[15] B. J. Morris and A. A. Tobian, "Legal threat to infant male circumcision," *JAMA Pediatrics*, vol. 167, no. 10, pp. 890-891, 2013.

[16] California Assembly Bill 768, 'Male circumcision," [accessed 2018 Feb 10]. Available from URL: http://legiscan.com/CA/text/AB768/id/348729, 2011.

[17] DW news-service, "Circumcision remains legal in Germany, " [accessed 2018 Feb 7]. Available from URL: http://www.dw.de/circumcision-remains-legal-in-germany/a-16399336, 2012.
[18] N. Stafford, "German ethics council backs religious circumcision if specific conditions met," *BMJ*, vol. 345, no., pp. e5789, 2012.
[19] R. J. L. Darby, "The child's right to an open future: is the principle applicable to non-therapeutic circumcision?," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 463-468, 2013.
[20] J. S. Svoboda, "Circumcision of male infants as a human rights violation," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 469-474, 2013.
[21] R. S. Van Howe, "Infant circumcision: the last stand for the dead dogma of parental (sovereignal) rights," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 475-481, 2013.
[22] P. Testa and W. E. Block, "Libertarianism and circumcision," *International Journal of Health Policy and Management*, vol. 3, no. 1, pp. 33-40, 2014.
[23] N. Enfield, "Giving advice in a post-truth world," [accessed 2018 Aug 8]. Available from URL: https://www.acuitymag.com/opinion/giving-advice-in-a-post-truth-world, 2018.
[24] R. Harbour and J. Miller, "A new system for grading recommendations in evidence based guidelines," *BMJ*, vol. 323, no. 7308, pp. 334-336, 2001.
[25] D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman and P. Group, "Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement," *PLoS Medicine*, vol. 6, no. 7, pp. e1000097, 2009.
[26] B. J. Morris and T. E. Wiswell, "Circumcision and lifetime risk of urinary tract infection: a systematic review and meta-analysis," *Journal of Urology*, vol. 189, no. 6, pp. 2118-2124, 2013.
[27] J. S. Svoboda, P. W. Adler and R. S. Van Howe, "Circumcision Is unethical and unlawful," *Journal of Law Medicine and Ethics*, vol. 44, no. 2, pp. 263-282, 2016.
[28] C. H. Chon, F. C. Lai and L. M. Shortliffe, "Pediatric urinary tract infections," *Pediatric Clinics of North America*, vol. 48, no. 6, pp. 1441-1459, 2001.
[29] M. L. Eisenberg, D. Galusha, W. A. Kennedy and M. R. Cullen, "The relationship between neonatal circumcision, urinary tract infection, and health," *The World Journal of Men's Health*, Epub ahead of print Mar 22, 2018.
[30] E. N. Lewis, M. R. Griffin, P. G. Szilagyi, Y. Zhu, K. M. Edwards and K. A. Poehling, "Childhood influenza: number needed to vaccinate to prevent 1 hospitalization or outpatient visit," *Pediatrics*, vol. 120, no. 3, pp. 467-472, 2007.
[31] M. A. Koyle, A. Barqawi, J. Wild, M. Passamaneck and P. D. Furness, 3rd, "Pediatric urinary tract infections: the role of fluoroquinolones," *Pediatric Infectious Diseases Journal*, vol. 22, no. 12, pp. 1133-1137, 2003.
[32] T. E. Wiswell and D. W. Geschke, "Risks from circumcision during the first month of life compared with those for uncircumcised boys," *Pediatrics*, vol. 83, no. 6, pp. 1011-1015, 1989.
[33] S. Swerkersson, U. Jodal, R. Sixt, E. Stokland and S. Hansson, "Urinary tract infection in small children: the evolution of renal damage over time," *Pediatric Nephrology*, vol. 32, no. 10, pp. 1907-1913, 2017.
[34] D. Singh-Grewal, J. Macdessi and J. Craig, "Circumcision for the prevention of urinary tract infection in boys: a systematic review of randomised trials and observational studies," *Archives of Disease in Childhood*, vol. 90, no. 8, pp. 853-858, 2005.
[35] R. S. Van Howe, "Effect of confounding in the association between circumcision status and urinary tract infection," *Journal of Infection*, vol. 51, no. 1, pp. 59-68, 2005.
[36] E. J. Schoen, "Circumcision for preventing urinary tract infections in boys: North American view," *Archives of Dieases of Childhood*, vol. 90, no. 8, pp. 772-773, 2005.
[37] N. Simforoosh, A. Tabibi, S. A. R. Khalili, M. H. Soltani, A. Afjehi, F. Aalami, et al., "Neonatal circumcision reduces the incidence of asymptomatic urinary tract infection: A large prospective study with long-term follow up using Plastibell," *Journal of Pediatric Urology*, vol. 8, no. 3, pp. 320-323, 2012.

[38] E. J. Schoen, C. J. Colby and G. T. Ray, "Newborn circumcision decreases incidence and costs of urinary tract infections during the first year of life," *Pediatrics*, vol. 105, no. 4 Pt 1, pp. 789-793, 2000.

[39] S. S. Long, "Can lumbar puncture be deferred in febrile neonates with suspected UTI?," *Journal of Pediatrics*, vol. 184, no., pp. 3, 2017.

[40] A. Pallett and K. Hand, "Complicated urinary tract infections: practical solutions for the treatment of multiresistant Gram-negative bacteria," *The Journal of Antimicrobial Chemotherapy*, vol. 65, Suppl 3, pp. iii25-33, 2010.

[41] O. Fasugba, A. Gardner, B. G. Mitchell and G. Mnatzaganian, "Ciprofloxacin resistance in community- and hospital-acquired Escherichia coli urinary tract infections: a systematic review and meta-analysis of observational studies," *BMC Infectious Diseases*, vol. 15, no. 1, pp. 545, 2015.

[42] A. Bryce, A. D. Hay, I. F. Lane, H. V. Thornton, M. Wootton and C. Costelloe, "Global prevalence of antibiotic resistance in paediatric urinary tract infections caused by Escherichia coli and association with routine use of antibiotics in primary care: systematic review and meta-analysis," *BMJ*, vol. 352, pp. i939, 2016.

[43] D. F. M. Looke, T. Thomas Gottlieb, C. A. Jones and D. L. Paterson, "Gram-negative resistance: can we combat the coming of a new "Red Plague"?," *Medical Journal of Australia*, vol. 198, no. 5, pp. 243-244, 2013.

[44] J. Wang, L. He, J. Sha, H. Zhu, L. Huang, X. Zhu, et al., "Etiology and antimicrobial resistance patterns in pediatric urinary tract infection," *Pediatrics International*, vol. 60, no. 5, pp. 418-422, 2018.

[45] S. Mayor, "Test urine before prescribing antibiotics for most UTIs, says NICE," *BMJ*, vol. 361, pp. k2076, 2018.

[46] M. Arshad and P. C. Seed, "Urinary tract infections in the infant," *Clinics in Perinatology*, vol. 42, no. 1, pp. 17-28, vii, 2015.

[47] L. J. Anyanwu, E. Kashibu, C. P. Edwin and A. M. Mohammad, "Microbiology of smegma in boys in Kano, Nigeria," *The Journal of Surgical Research*, vol. 173, no. 1, pp. 21-25, 2012.

[48] H. N. Ladenhauf, M. A. Ardelean, C. Schimke, F. Yankovic and G. Schimpl, "Reduced bacterial colonisation of the glans penis after male circumcision in children--a prospective study," *Journal of Pediatric Urology*, vol. 9, no. 6 Pt B, pp. 1137-1144, 2013.

[49] F. Serour, Z. Samra, Z. Kushel, A. Gorenstein and M. Dan, "Comparative periurethral bacteriology of uncircumcised and circumcised males," *Genitourinary Medicine*, vol. 73, no. 4, pp. 288-290, 1997.

[50] C. M. Liu, B. A. Hungate, A. A. Tobian, D. Serwadda, J. Ravel, R. Lester, et al., "Male circumcision significantly reduces prevalence and load of genital anaerobic bacteria," *MBio*, vol. 4, no. 2, article e00076 (9pages), 2013.

[51] G. J. Boyle and G. Hill, "Circumcision-generated emotions bias medical literature," *BJU International*, vol. 109, no. 4, pp. E11, 2012.

[52] C. El Bcheraoui, X. Zhang, C. S. Cooper, C. E. Rose, P. H. Kilmarx and R. T. Chen, "Rates of adverse events associated with male circumcision in US medical settings, 2001 to 2010.," *JAMA Pediatrics*, vol. 168, no. 7, pp. 625-634, 2014.

[53] D. A. Christakis, E. Harvey, D. M. Zerr, C. Feudtner, J. A. Wright and F. A. Connell, "A trade-off analysis of routine newborn circumcision," *Pediatrics*, vol. 105, no. 1 Pt 3, pp. 246-249, 2000.

[54] J. Ben Chaim, P. M. Livne, J. Binyamini, B. Hardak, D. Ben-Meir and Y. Mor, "Complications of circumcision in Israel: a one year multicenter survey," *Israeli Medical Association Journal*, vol. 7, no. 6, pp. 368-370, 2005.

[55] D. Bollinger, "Lost boys: An estimate of U.S. circumcision-related infant deaths," *Thymos: Journal of Boyhood Studies*, vol. 4, no., pp. 78-90, 2010.

[56] B. J. Morris, R. C. Bailey, J. D. Klausner, A. Leibowitz, R. G. Wamai, J. H. Waskett, et al., "Review: a critical evaluation of arguments opposing male circumcision for HIV prevention in developed countries," *AIDS Care*, vol. 24, no. 12, pp. 1565-1575, 2012.

[57] W. F. Gee and J. S. Ansell, "Neonatal circumcision: a ten-year overview: with comparison of the Gomco clamp and the Plastibell device," *Pediatrics*, vol. 58, no. 6, pp. 824-827, 1976.

[58] H. Speert, "Circumcision of the newborn; an appraisal of its present status," *Obstetrics and Gynecology*, vol. 2, no. 2, pp. 164-172, 1953.

[59] L. R. King, "Neonatal circumcision in the United States in 1982," *Journal of Urology*, vol. 128, no. 5, pp. 1135-1136, 1982.

[60] D. Gairdner, "The fate of the foreskin, a study of circumcision," *British Medical Journal*, vol. 2, no. 4642, pp. 1433-1437, 1949.

[61] B. D. Earp, V. Allareddy, V. Allareddy and A. T. Rotta, "Factors associated with early deaths following neonatal male circumcision in the United States, 2001 to 2010," *Clinical Pediatrics (Phila)*, E-pub ahead of print Aug 1, 2018.

[62] J. L. Robinson, A. Jefferies and T. Lacaze, "Letter to the Editor - Re: Canadian Pediatrics Society position statement on newborn circumcision: a risk-benefit analysis revisited," *Canadian Journal of Urology*, vol. 24, no. 1, pp. 8684-8687, 2017.

[63] Public Health Agency of Canada, "Canadian National Report on Immunization, 2006, Volume 32S3, Section 5, Vaccine Safety: Surveilance of Adverse Events Following Immunization," [accessed 2018 Mar 2] Available from URL: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/06vol32/32s3/5vacc-eng.php, 2006.

[64] Canadian Cancer Statistics 2016, [accessed 2018 Mar 2] Available from URL: http://www.cancer.ca/~/media/cancer.ca/CW/cancer information/cancer 101/Canadian cancer statistics/Canadian-Cancer-Statistics-2016-EN.pdf?la=en, 2016.

[65] D. M. Fergusson, J. M. Boden and L. J. Horwood, "Neonatal circumcision: effects on breastfeeding and outcomes associated with breastfeeding," *Journal of Paediatrics and Child Health*, vol. 44, no. 1-2, pp. 44-49, 2008.

[66] L. Mondzelewski, S. Gahagan, C. Johnson, H. Madanat and K. Rhee, "Timing of circumcision and breastfeeding initiation among newborn boys," *Hospital Pediatrics*, vol. 6, no. 11, pp. 653-658, 2016.

[67] P. W. Adler, "The draft CDC circumcision recommendations: Medical,ethical, legal, and procedural concerns," *International Journal of Children's Rights*, vol. 24, no. 2, pp. 237-262, 2016.

[68] M. Joudi, M. Fathi and M. Hiradfar, "Incidence of asymptomatic meatal stenosis in children following neonatal circumcision," *Journal of Pediatric Urology*, vol. 7, no. 5, pp. 526-528, 2011.

[69] M. Frisch and J. Simonsen, "Cultural background, non-therapeutic circumcision and the risk of meatal stenosis and other urethral stricture disease: Two nationwide register-based cohort studies in Denmark 1977-2013," *Surgeon*, vol. 16, no. 2, pp. 107-118, 2018.

[70] B. J. Morris and J. N. Krieger, "Re: Cultural background, non-therapeutic circumcision and the risk of meatal stenosis and other urethral stricture disease: Two nationwide register-based cohort studies in Denmark 1977-2013," *Surgeon*, vol. 16, no. 2, pp. 126-129, 2018.

[71] R. S. Van Howe, "Incidence of meatal stenosis following neonatal circumcision in a primary care setting," *Clinical Pediatrics (Phila)*, vol. 45, no. 1, pp. 49-54, 2006.

[72] E. J. Schoen, "Meatal stenosis following neonatal icscircumcision. [Critique of Van Howe. Clin Pediatr (Phila) 2006;45:49-54]." *Clinical Paediatr (Phila)*, vol. 46, no. 1, pp. 86, 2007.

[73] R. S. Van Howe, "Letter: Re: Morris and Krieger: Does circumcision increase meatal stenosis risk?—A systematic review and meta-analysis (Urology 2017;110:16-26)," *Urology*, vol. 118, pp. 244-245, 2018.

[74] A. Salimi, M. Besharati, S. Rashidi Nia, S. Shahmoradi and S. S. Eftekhari, "Application of topical hydrocortisome ointment decreases post-circumcision meatal stenosis in neonates: A cross-sectional study," *International Journal of Pediatrics*, vol. 5, no. 6, pp. 5061-5067, 2017.

[75] B. J. Morris and J. N. Krieger, "Re: Morris and Krieger: Does circumcision increase meatal stenosis risk?—A systematic review and meta-analysis (Urology 2017;110:16-26). Reply by the authors," *Urology*, vol. 118, pp. 245-246, 2018.

[76] B. J. Morris and J. N. Krieger, "Does circumcision increase meatal stenosis risk?—A systematic review and meta-analysis," *Urology*, vol. 110, no. Dec, pp. 16-26, 2017.

[77] R. Szabo and R. V. Short, "How does male circumcision protect against HIV infection?," *BMJ* vol. 320, no. 7249, pp. 1592-1594, 2000.

[78] Z. Halata and B. L. Munger, "The neuroanatomical basis for the protopathic sensibility of the human glans penis," *Brain research*, vol. 371, no. 2, pp. 205-230, 1986.

[79] B. D. Earp, L. M. Sardi and W. A. Jellison, "False beliefs predict increased circumcision satisfaction in a sample of US American men," *Culture, Health & Sexuality*, vol. 20, no. 8, pp. 945-959, 2018.

[80] G. J. Boyle, R. Goldman, J. S. Svoboda and E. Fernandez, "Male circumcision: pain, trauma and psychosexual sequelae," *Journal of Health Psychology*, vol. 7, no. 3, pp. 329-343, 2002.

[81] A. Taddio, J. Katz, A. L. Ilersich and G. Koren, "Effect of neonatal circumcision on pain response during subsequent routine vaccination," *Lancet*, vol. 349, no. 9052, pp. 599-603, 1997.

[82] C. T. Russell and J. Chaseling, "Topical anaesthesia in neonatal circumcision: a study of 208 consecutive cases," *Australian Family Physician*, vol. 25, suppl 1, pp. S30-34, 1996.

[83] P. D. Tinari, "MRI studies: The brain permanently altered from infant circumcision," *Peaceful Parenting* [accessed 2018 Jan 8]. Available at URL: http://www.drmomma.org/2009/10/mri-studies-brain-permanently-altered.html, 2009.

[84] M. L. Schaab, "MRI scans and circumcision brain damage. The lie that just won't die," [accessed 2018 Feb 12]. Available from URL: http://circfacts.org/debunking-corner/ - debk4, 2017.

[85] A. Stenram, G. Malmfors and L. Okmian, "Circumcision for phimosis–indications and results," *Acta Paediatrica Scandinavica*, vol. 75, no. 2, pp. 321-323, 1986.

[86] M. Calnan, J. W. B. Douglas and H. Goldstein, "Tonsillectomy and circumcision: comparison of two cohorts.," *International Journal of Epidemiology*, vol. 7, no. 1, pp. 79-85, 1978.

[87] N. M. Schlossberger, R. A. Turner and C. E. Irwin, Jr., "Early adolescent knowledge and attitudes about circumcision -- Methods and implications for research," *Journal of Adolescent Health*, vol. 13, no. 4, pp. 293-297, 1992.

[88] M. Frisch and J. Simonsen, "Ritual circumcision and risk of autism spectrum disorder in 0- to 9-year-old boys: national cohort study in Denmark," *Journal of the Royal Society of Medicine*, vol. 108, no. 7, pp. 266-279, 2015.

[89] B. J. Morris and T. E. Wiswell, "'Circumcision pain' unlikely to cause autism," *Journal of the Royal Society of Medicine*, vol. 108, no. 8, pp. 297, 2015.

[90] B. Paix, "Correcting Morris et al. with respect to anaesthesia for neonatal circumcision," *Internal Medicine Journal*, vol. 42, no. 11, pp. 1276-1277.

[91] C. Ing, C. DiMaggio, A. Whitehouse, M. K. Hegarty, J. Brady, B. S. von Ungern-Sternberg, et al., "Long-term differences in language and cognitive function after childhood exposure to anesthesia," *Pediatrics*, vol. 130, no. 3, pp. e476-485, 2012.

[92] A. V. Dilley and B. J. Morris, "Reply [Correcting Paix's misunderstandings about anaesthesia for neonatal circumcision.] " *Internal Medicine Journal*, vol. 42, no. 12, pp. 1277-1278, 2012.

[93] C. R. Howard, F. M. Howard and M. L. Weitzman, "Acetaminophen analgesia in neonatal circumcision: the effect on pain," *Pediatrics*, vol. 93, no. 4, pp. 641-646, 1994.

[94] American Academy of Pediatrics. Task Force on Circumcision, "Circumcision policy statement," *Pediatrics*, vol. 103, no. 3, pp. 686-693, 1999.

[95] A. Z. Bauer and D. Kriebel, "Prenatal and perinatal analgesic exposure and autism: an ecological link," *Environ Health*, vol. 12, pp. 41, 2013.

[96] A. Z. Bauer, PubMed Commons, comment, [accessed 2018 Jan 24] Availabel from URL: http://www.ncbi.nlm.nih.gov/pubmed/25573114, 2015.

[97] I. Sneppen and J. Thorup, "Foreskin morbidity in uncircumcised males," *Pediatrics*, vol. 137, no. 5, pp. e20154340, 2016.

[98] B. Zablotsky, L. I. Black and S. J. Blumberg, "Estimated prevalence of children with diagnosed developmental disabilities in the United States, 2014–2016. Centers for Disease Control and Prevention, NCHS Data Brief, No. 291," [accessed 2018 Jan 24]. Available from URL: https://www.cdc.gov/nchs/data/databriefs/db291.pdf, 2017.

[99] G. Xu, L. Strathearn, B. Liu and W. Bao, "Prevalence of autism spectrum disorder among US children and adolescents, 2014-2016.," *JAMA*, vol. 319, no. 1, pp. 81-82, 2018.

[100] Y. S. Kim, B. L. Leventhal, Y. J. Koh, E. Fombonne, E. Laska, E. C. Lim, et al., "Prevalence of autism spectrum disorders in a total population sample," *American Journal of Psychiatry*, vol. 168, no. 9, pp. 904-912, 2011.

[101] A. Neyer, "The problem with articles on autism risks and how to evaluate studies. Or why circumcision is unlikely to increase rates of autism," [accessed 2018 Jan 28]. Available at URL: https://chimericalcapuchin.wordpress.com/2015/01/10/the-problem-with-articles-on-autism-risks-and-how-to-evaluate-studies/, 2015.

[102] K. Sjøgren, "[Researchers find link between autism and circumcision]," *videnskab.dk* [*science.dk*], [in Danish], [accessed 2018 Jan 30]. Available at URL: https://videnskab.dk/krop-sundhed/forskere-finder-sammenhaeng-mellem-autisme-og-omskaering, 2015.

[103] D. Bollinger and R. S. Van Howe, "Alexithymia and circumcision trauma: a preliminary investigation," *International Journal of Men's Health*, vol. 10, no. 2, pp. 184-195, 2011.

[104] P. C. Mohl, R. Adams, D. M. Greer and K. A. Sheley, "Prepuce restoration seekers: psychiatric aspects," *Archives of Sexual Behavior*, vol. 10, no. 4, pp. 383-393, 1981.

[105] A. S. Fenwick and K. A. Sullivan, "Potential link between body dysmorphic disorder symptoms and alexithymia in an eating-disordered treatment-seeking sample," *Psychiatry Research*, vol. 189, no. 2, pp. 299-304, 2011.

[106] B. J. Morris and J. H. Waskett, "Claims that circumcision increases alexithymia and erectile dysfunction are unfounded: : A critique of Bollinger and Van Howe's "Alexithymia and circumcision trauma: A preliminary investigation"," *International Journal of Men's Health*, vol. 11, no. 2, pp. 177-181, 2012.

[107] D. Bollinger and R. Van Howe, "Preliminary results are preliminary, not "unfounded": Reply to Morris and Waskett," *International Journal of Men's Health*, vol. 11, no. 2, pp. 181-184, 2012.

[108] G. J. Taylor, R. M. Bagby and J. D. A. Parker, "*Disorders of Affect Regulation: Alexithymia in Medical and Psychiatric Illness*," Cambridge University Press, Cambridge, UK, 1997.

[109] L. A. Rescorla, T. M. Achenbach, M. Y. Ivanova, V. S. Harder, L. Otten, N. Bilenberg, et al., "International comparisons of behavioral and emotional problems in preschool children: parents' reports from 24 societies," *Journal of Clinical Child & Adolescent Psychology*, vol. 40, no. 3, pp. 456-467, 2011.

[110] L. Rescorla, T. M. Achenbach, M. Y. Ivanova, L. Dumenci, F. Almqvist, N. Bilenberg, et al., "Behavioral and emotional problems reported by parents of children ages 6 to 16 in 31 societies," *Journal of Emotional and Behavioral Disorders*, vol. 15, no. 3, pp. 130-142, 2007.

[111] O. Mason, M. Tyson, C. Jones and S. Potts, "Alexithymia: its prevalence and correlates in a British undergraduate sample," *Psychology and Psychotherapy*, vol. 78, Pt 1, pp. 113-125, 2005.

[112] S. Ramos and G. J. Boyle, "Ritual and medical circumcision among Filipino boys: Evidence of post-traumatic stress disorder," *Humanities & Social Sciences Papers 2000.* [accessed 2018 Feb 20]. Available from URL: http://epublications.bond.edu.au/hss_pubs/114/, 2000.

[113] R. L. Mateo, "Circumcision, serial killing, criminal behavior and American medical violence," *Salem News*, [accessed 2018 Apr 10]. Available from URL: http://www.salem-news.com/articles/august312012/circumcision-violence-rm.php, 2012.

[114] B. J. Morris and J. N. Krieger, "Does male circumcision affect sexual function, sensitivity, or satisfaction?--A systematic review," *Journal of Sexual Medicine*, vol. 10, no. 11, pp. 2644-2657, 2013.

[115] Y. Tian, W. Liu, J. Z. Wang, R. Wazir, X. Yue and K. J. Wang, "Effects of circumcision on male sexual functions: a systematic review and meta-analysis," *Asian Journal of Andrology*, vol. 15, no. 5, pp. 662-666, 2013.

[116] Y. Yang, X. Wang, Y. Bai and P. Han, "Circumcision does not have effect on premature ejaculation: A systematic review and meta-analysis," *Andrologia*, vol. 50, no. 2, pp. e12851, 2018.

[117] D. M. Shabanzadeh, S. Düring and C. Frimont-Moller, "Male circumcision does not result in inferior perceived male sexual function – a systematic review," *Danish Medical Journal*, vol. 63, no. 7, pp. A5245, 2016.

[118] V. Homfray, C. Tanton, K. R. Mitchell, R. F. Miller, N. Field, W. Macdowall, et al., "Examining the association between male circumcision and sexual function: evidence from a British probability survey," *AIDS*, vol. 29, no. 11, pp. 1411-1416, 2015.

[119] M. P. Nordstrom, N. Westercamp, W. Jaoko, T. Okeyo and R. C. Bailey, "Medical male circumcision Is associated with improvements in pain during intercourse and sexual satisfaction in Kenya," *Journal of Sexual Medicine*, vol. 14, no. 4, pp. 601-612, 2017.

[120] G. Kigozi, S. Watya, C. B. Polis, D. Buwembo, V. Kiggundu, M. J. Wawer, et al., "The effect of male circumcision on sexual satisfaction and function, results from a randomized trial of male circumcision for human immunodeficiency virus prevention, Rakai, Uganda," *BJU International*, vol. 101, no. 1, pp. 65-70, 2008.

[121] J. N. Krieger, S. D. Mehta, R. C. Bailey, K. Agot, J. O. Ndinya-Achola, C. Parker, et al., "Adult male circumcision: effects on sexual function and sexual satisfaction in Kisumu, Kenya," *Journal of Sexual Medicine*, vol. 5, no. 11, pp. 2610-2622, 2008.

[122] M. O. Brito, S. Khosla, S. Pananookooln, P. J. Fleming, L. Lerebours, Y. Donastorg, et al., "Sexual pleasure and function, coital trauma, and sex behaviors after voluntary medical male circumcision among men in the Dominican Republic," *Journal of Sexual Medicine*, vol. 14, no. 4, pp. 526-534, 2017.

[123] S. D. Mehta, J. N. Krieger, K. Agot, S. Moses, J. O. Ndinya-Achola, C. Parker, et al., "Circumcision and reduced risk of self-reported penile coital injuries: results from a randomized controlled trial in Kisumu, Kenya," *Journal of Urology*, vol. 184, no. 1, pp. 203-209, 2010.

[124] N. Westercamp, S. D. Mehta, W. Jaoko, T. A. Okeyo and R. C. Bailey, "Penile coital injuries in men decline after circumcision: Results from a prospective study of recently circumcised and uncircumcised men in western Kenya," *PLoS One*, vol. 12, no. 10, pp. e0185917, 2017.

[125] K. O'Hara and J. O'Hara, "The effect of male circumcision on the sexual enjoyment of the female partner," *BJU International*, vol. 83, Suppl 1, pp. 79-84, 1999.

[126] G. J. Boyle and G. A. Bensley, "Adverse sexual and psychological effects of male infant circumcision," *Psychology Reports*, vol. 88, no. 3 Pt 2, pp. 1105-1106, 2001.

[127] D. Kim and M. G. Pang, "The effect of male circumcision on sexuality," *BJU International*, vol. 99, no. 3, pp. 619-622, 2007.

[128] M. L. Sorrells, J. L. Snyder, M. D. Reiss, C. Eden, M. F. Milos, N. Wilcox, et al., "Fine-touch pressure thresholds in the adult penis," *BJU International*, vol. 99, no. 4, pp. 864-869, 2007.

[129] M. Frisch, M. Lindholm and M. Gronbaek, "Male circumcision and sexual function in men and women: a survey-based, cross-sectional study in Denmark," *International Journal of Epidemiology*, vol. 40, no. 5, pp. 1367-1381, 2011.

[130] G. A. Bronselaer, J. M. Schober, H. F. Meyer-Bahlburg, G. T'sjoen, R. Vlietinck and P. B. Hoebeke, "Male circumcision decreases penile sensitivity as measured in a large cohort.," *BJU International*, vol. 111, no. 5, pp. 820-827, 2013.

[131] G. J. Boyle, "Does circumcision adversely affect sexual sensation, function, or satisfaction? Critical comment on Morris and Krieger (2013)," *Advances in Sexual Medicine*, vol. 5, no. 2, pp. 7-12, 2015.

[132] R. Willcourt, "The effect of male circumcision on sexuality. [Comment on: Kim D, Pang MG. The effect of male circumcision on sexuality. BJU Int. 2007;99:619-22]," *BJU International*, vol. 99, no. 5, pp. 1169-1170, 2007.

[133] J. H. Waskett and B. J. Morris, "Fine-touch pressure thresholds in the adult penis. [Critique of Sorrells ML, et al. BJU Int 2007;99:864-869]," *BJU International*, vol. 99, no. 6, pp. 1551-1552, 2007.

[134] B. J. Morris, J. H. Waskett and R. H. Gray, "Does sexual function survey in Denmark offer any support for male circumcision having an adverse effect?," *International Journal of Epidemiology*, vol. 41, no. 1, pp. 310-312, 2012.

[135] B. J. Morris, J. N. Krieger and G. Kigozi, "Male circumcision decreases penile sensitivity as measured in a large cohort. [Critique of Bronselaer et al. BJU Int 2013; 111: 820-827] " *BJU International*, vol. 111, no. 5, pp. E269-E270., 2013.

[136] B. J. Morris and J. N. Krieger, "Male circumcision does not reduce sexual function, sensitivity or satisfaction.," *Advances in Sexual Medicine*, vol. 5, no. 2, pp. 53-60, 2015.

[137] G. Cox, J. N. Krieger and B. J. Morris, "Histological correlates of penile sexual sensation: Does circumcision make a difference?," *Sexual Medicine*, vol. 3, no. 2, pp. 76-85, 2015.

[138] J. A. Bossio, C. F. Pukall and S. S. Steele, "Examining penile sensitivity in neonatally circumcised and intact men using quantitative sensory testing," *Journal of Urology*, vol. 195, no. 6, pp. 1848-1853, 2016.

[139] M. L. Williamson and P. S. Williamson, "Women's preferences for penile circumcision in sexual partners," *Journal of Sex Education and Therapy*, vol. 14, no. 2, pp. 8-12, 2015.

[140] J. R. Cortés-González, J. A. Arratia-Maqueo and L. S. Gómez-Guerra, "[Does circumcision has an effect on female's perception of sexual satisfaction?] [Article in Spanish]," *Revista de Investigatión Clinica*, vol. 60, no. 3, pp. 227-230, 2008.

[141] J. R. Cortés-González, J. A. Arratia-Maqueo, R. Martínez-Montelongo and L. S. Gómez-Guerra, "[Does circumcision affect male's perception of sexual satisfaction?]," [Article in Spanish], *Archivos Espanoles de Urologia*, vol. 62, no. 9, pp. 733-736, 2009.

[142] R. Zulu, D. Jones, N. Chitalu, R. Cook and S. Weiss, "Sexual satisfaction, performance, and partner response following voluntary medical male circumcision in Zambia: The Spear and Shield project," *Global health, science and practice*, vol. 3, no. 4, pp. 606-618, 2015.

[143] G. Kigozi, I. Lukabwe, J. Kagaayi, M. J. Wawer, B. Nantume, G. Kigozi, et al., "Sexual satisfaction of women partners of circumcised men in a randomized trial of male circumcision in Rakai, Uganda," *BJU International*, vol. 104, no. 11, pp. 1698-1701, 2009.

[144] Functions of the Foreskin, [accessed 2018 Jan 29]. Available from URL: http://www.foreskinfunction.org/.

[145] S. Moreton, "'10,000, 20,000, 70,000 nerve endings': a myth that keeps on growing," *Circfacts.org Real Facts About Male Circumcision*, [accessed 2018 Feb 6]. Available from URL: http://circfacts.org/function-sensation/ - sens1, 2016.

[146] G. H. Bhat, M. A. Bhat, K. Kour and B. A. Shah, "Density and structural variations of Meissner's corpuscles at different sites in human glaborous skin," *Journal of the Anatomical Society of India*, vol. 57, no. 1, pp. 30-33, 2008.

[147] H.-y. Jiang, D. Guo, M.-b. Tan, S.-m. Xu and G.-x. Wang, "Observations on Meissner's corpuscle in prepuces of different ages," *Chinese Journal of Urology*, vol. 27, pp. 707-709, 2006.

[148] P. M. Fleiss, "The case against circumcision," *Mothering: the Magazine of Natural Family Living*, Winter issue, pp. 36-45 [accessed 2018 Feb 2028]. Available from URL: http://www.cirp.org/news/Mothering1997//, 1997.

[149] W. M. London, "Medical renegade Paul M. Fleiss, M.D. dead at 80," [accessed 2018 Feb 28]. Available from URL: http://www.skepticink.com/health/2014/08/12/medical-renegade-paul-m-fleiss-m-d-dead-80/, 2014.

[150] H. C. Bazett, B. McGlone, R. G. Williams and H. M. Lufkin, "Depth, distribution and probable identification in the prepuce of sensory end-organs concerned in sensations of temperature and touch; thermometric conductivity," *Archives of Neurology & Psychiatry*, vol. 27, no. 3, pp. 489-517, 1932.

[151] G. Kigozi, M. Wawer, A. Ssettuba, J. Kagaayi, F. Nalugoda, S. Watya, et al., "Foreskin surface area and HIV acquisition in Rakai, Uganda (size matters)," *AIDS*, vol. 23, no. 16, pp. 2209-2213, 2009.

[152] P. M. Werker, A. S. Terng and M. Kon, "The prepuce free flap: dissection feasibility study and clinical application of a super-thin new flap," *Plastic and Reconstructive Surgery*, vol. 102, no. 4, pp. 1075-1082, 1998.

[153] D. Veale, S. Miles, S. Bramley, G. Muir and J. Hodsoll, "Am I normal? A systematic review and construction of nomograms for flaccid and erect penis length and circumference in up to 15,521 men," *BJU International*, vol. 115, no. 6, pp. 978-986, 2015.

[154] C. Darwin, "*The Origin of Species by Means of Natural Selection*," John Murray, London, UK, 1859.

[155] B. A. Cohn, "In search of human skin pheromones," *Archives of Dermatology*, vol. 130, no. 8, pp. 1048-1051, 1994.

[156] NOHARMM, "The foreskin advantage," [accessed 2018 Jan 24]. Available from URL: http://www.noharmm.org/advantage.htm, 2013.

[157] M. Galukande, F. Nakaggwa, E. Busisa, D. Sekavuga Bbaale, T. Nagaddya and A. Coutinho, "Long term post PrePex male circumcision outcomes in an urban population in Uganda: a cohort study," *BMC Research Notes*, vol. 10, no. 1, pp. 522, 2017.

[158] S. Moreton, "Lubrication and lubricant," *Circfacts.org* [accessed 2018 Feb 12]. Available from URL: http://circfacts.org/function-sensation/ - sens9, 2017.

[159] Anonymous, "The 16 Fabulous Functions of the Foreskin – a critical analysis," *circumcisionchoice.com* [accessed 2018 Feb 6]. Available from URL: https://www.circumcisionchoice.com/single-post/2017/04/11/The-16-Functions-of-The-Foreskin-is-a-silly-myth-anticircumcision-activists, 2017.

[160] K. Payne, L. Thaler, T. Kukkonen, S. Carrier and Y. Binik, "Sensation and sexual arousal in circumcised and uncircumcised men," *Journal of Sexual Medicine*, vol. 4, no. 3, pp. 667-674, 2007.

[161] American Psychiatric Association, "Diagnostic & Statistical Manual 5th Revision (DSM-5)," [accessed 2018 Feb 6]. Available from URL: http://www.dsm5.org/Pages/Default.aspx, 2013.

[162] M. P. Kafka, "The DSM diagnostic criteria for paraphilia not otherwise specified," *Archives of Sexual Behavior*, vol. 39, no. 2, pp. 373-376, 2010.

[163] D. Schultheiss, M. C. Truss, C. G. Stief and U. Jonas, "Uncircumcision: a historical review of preputial restoration," *Plastic and Reconstructive Surgery*, vol. 101, no. 7, pp. 1990-1998, 1998.

[164] Circumcision Cener, "Circumcision revision for a gentleman in his late thirties who had done foreskin restoration by stretching," *circumcisioncenter.com* [accessed 2016 Jan 5]. Available from URL: http://www.circumcisioncenter.com/patient14.htm, 2015.

[165] Yahoo Questions: "Should I get re-circumcised after 20 years and restoring improperly?" *yahoo.com* [accessed 2016 Jan 5). Available from URL: https://answers.yahoo.com/question/index?qid=20100401174412AARIqlC (accessed 5 Jan 2016), 2015.

[166] G. Walter and J. Streimer, "Genital self-mutilation: attempted foreskin reconstruction," *British Journal of Psychiatry*, vol. 156, no., pp. 125-127, 1990.
[167] R. S. Van Howe, "Circumcision and HIV infection: review of the literature and meta-analysis," *International Journal of STD & AIDS*, vol. 10, no. 1, pp. 8-16, 1999.
[168] L. W. Green, R. G. McAllister, K. W. Peterson and J. W. Travis, "Male circumcision is *not* the 'vaccine' we have been waiting for!," *Future HIV Therapy*, vol. 2, no. 3, pp. 193–199, 2008.
[169] D. Gisselquist, J. J. Potterat, J. S. St Lawrence, M. Hogan, N. K. Arora, M. Correa, et al., "How to contain generalized HIV epidemics? A plea for better evidence to displace speculation," *International Journal of STD & AIDS*, vol. 20, no. 7, pp. 443-446, 2009.
[170] L. W. Green, J. W. Travis, R. G. McAllister, K. W. Peterson, A. N. Vardanyan and A. Craig, "Male circumcision and HIV prevention. Insufficient evidence and neglected external validity," *American Journal of Preventive Medicine*, vol. 39, no., pp. 479-482, 2010.
[171] G. J. Boyle and G. Hill, "Sub-Saharan African randomized clinical trials into male circumcision and HIV transmission: Methodological, ethical and legal concerns.," *Journal of Law and Medicine*, vol. 19, no., pp. 316-333, 2011.
[172] G. J. Boyle and G. Hill, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 99, 2011.
[173] J. J. Chin, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 100-101, 2011.
[174] N. Conroy, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 99, 2011.
[175] R. L. Darby, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 100, 2011.
[176] R. Darby and R. S. Van Howe, "Not a surgical vaccine: there is no case for boosting infant male circumcision to combat heterosexual transmission of HIV in Australia," *Australian and New Zealand Journal of Public Health*, vol. 35, no. 5, pp. 459-465, 2011.
[177] D. A. Forbes, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 97, 2011.
[178] B. R. Paix, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 100, 2011.
[179] J. W. Travis, S. J. Buckley, P. Mason, K. McGrath, R. S. Van Howe and G. Williams, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. Comment," *Medical Journal of Australia*, vol. 194, no. 2, pp. 97-98, 2011.
[180] R. S. Van Howe and M. R. Storms, "How the circumcision solution in Africa will increase HIV infections," *Journal of Public Health in Africa*, vol. 2, no. 1, article e4, pp. 11-15, 2011.
[181] K. R. de Camargo, Jr., A. L. de Oliveira Mendonca, C. Perrey and A. Giami, "Male circumcision and HIV: a controversy study on facts and values," *Global Public Health*, vol. 8, no. 7, pp. 769-783, 2013.
[182] K. R. de Camargo, Jr., A. L. Mendonca, C. Perrey and A. Giami, "Making the circumcision controversy controversial: going meta and taking aim at the messenger(s): reply to Wamai et al," *Global Public Health*, vol. 10, no. 5-6, pp. 667-671, 2015.
[183] R. S. Van Howe, "Circumcision as a primary HIV preventive: extrapolating from the available data," *Global Public Health*, vol. 10, no. 5-6, pp. 607-625, 2015.

[184] R. S. Van Howe, "Expertise or ideology? A response to Morris et al. 2016, 'Circumcision is a primary preventive against HIV infection: Critique of a contrary meta-regression analysis by Van Howe'," *Global Public Health*, Epub ahead of print Jan 10, 2017.

[185] B. Auvert, D. Taljaard, E. Lagarde, J. Sobngwi-Tambekou, R. Sitta and A. Puren, "Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: The ANRS 1265 Trial.," *PLoS Medicine*, vol. 2, no. e298, pp. 1112-1122, 2005.

[186] R. C. Bailey, S. Moses, C. B. Parker, K. Agot, I. Maclean, J. N. Krieger, et al., "Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial," *Lancet*, vol. 369, no. 9562, pp. 643-656, 2007.

[187] R. H. Gray, G. Kigozi, D. Serwadda, F. Makumbi, S. Watya, F. Nalugoda, et al., "Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial," *Lancet*, vol. 369, no. 9562, pp. 657-666, 2007.

[188] H. A. Weiss, D. Halperin, R. C. Bailey, R. J. Hayes, G. Schmid and C. A. Hankins, "Male circumcision for HIV prevention: from evidence to action?," *AIDS*, vol. 22, no. 5, pp. 567-574, 2008.

[189] N. Siegfried, M. Muller, J. J. Deeks and J. Volmink, "Male circumcision for prevention of heterosexual acquisition of HIV in men," *Cochrane Database of Systemetic Reviews*, Issue 2, article CD003362, 2009.

[190] World Health Organization and Joint United Nations Program on HIV/AIDS, "Male circumcision: Global trends and determinants of prevalence, safety and acceptability," [accessed 2018 Feb 17). Avaiable from URL: http://whqlibdoc.who.int/publications/2007/9789241596169_eng.pdf," World Health Organization, Geneva, 2007."

[191] World Health Organization and UNAIDS, New data on male circumcision and HIV prevention: policy and programme implications," [accessed 2018 Feb 17]. Available from URL: http://who.int/hiv/mediacentre/MCrecommendations_en.pdf, 2007, pp. http://who.int/hiv/mediacentre/MCrecommendations_en.pdf.

[192] A. S. Fauci and R. W. Eisinger, "PEPFAR - 15 years and counting the lives saved," *New England Journal of Medicine*, vol. 378, no. 4, pp. 314-316, 2018.

[193] S. Moses, N. J. D. Nagelkerke and J. F. Blanchard, "Commentary: Analysis of the scientific literature on male circumcision and risk for HIV infection," *International Journal of STD & AIDS*, vol. 10, no. 9, pp. 626-628, 1999.

[194] N. O'Farrell and M. Egger, "Circumcision in men and the prevention of HIV infection: a 'meta-analysis' revisited," *International Journal of STD & AIDS*, vol. 11, no. 3, pp. 137-142, 2000.

[195] R. G. Wamai, H. A. Weiss, C. Hankins, K. Agot, Q. A. Karim, O. Shisana, et al., "Male circumcision is an efficacious, lasting and cost-effective strategy for combating HIV in high-prevalence AIDS epidemics: Time to move beyond debating the science," *Future HIV Therapy*, vol. 2, no. 5, pp. 399-405, 2008.

[196] J. Banerjee, J. D. Klausner, D. T. Halperin, R. Wamai, E. J. Schoen, S. Moses, et al., "Circumcision denialism unfounded and unscientific. [Critique of Green et al., "Male circumcision and HIV prevention: Insufficient evidence and neglected external validity"]," *American Journal of Preventive Medicine*, vol. 40, no. 3, pp. e11-e12, 2011.

[197] B. J. Morris, J. H. Waskett, R. H. Gray, D. T. Halperin, R. Wamai, B. Auvert, et al., "Exposé of misleading claims that male circumcision will increase HIV infections in Africa.," *Journal of Public Health in Africa*, vol. 2, no. e28, pp. 117-122, 2011.

[198] R. Wamai and B. J. Morris, "'How to contain generalized HIV epidemics' article misconstrues the evidence," *International Journal of STD & AIDS*, vol. 22, no. 7, pp. 415-416, 2011.

[199] R. G. Wamai, B. J. Morris, S. A. Bailis, D. Sokal, J. D. Klausner, R. Appleton, et al., "Male circumcision for HIV prevention: current evidence and implementation in sub-Saharan Africa," *Journal of the International AIDS Society*, vol. 14, article 49 (17 pages), 2011.

[200] B. J. Morris, "Boyle and Hill's circumcision 'phallusies'," *BJU International*, vol. 110, no. 3, pp. E153-E154, 2012.
[201] R. G. Wamai, B. J. Morris, J. H. Waskett, E. C. Green, J. Banerjee, R. C. Bailey, et al., "Criticisms of African trials fail to withstand scrutiny: male circumcision *does* prevent HIV infection," *Journal of Law and Medicine*, vol. 20, no. 1, pp. 93-123, 2012.
[202] J. D. Klausner, "Faulty analysis leads to erroneous conclusions," *Journal of Sexual Medicine*, vol. 10, no. 2, pp. 613-614, 2013.
[203] R. G. Wamai, B. J. Morris, R. C. Bailey, J. D. Klausner and M. N. Boedicker, "Male circumcision for protection against HIV infection in sub-Saharan Africa: the evidence in favour justifies the implementation now in progress," *Global Public Health*, vol. 10, no. 5-6, pp. 639-666, 2015.
[204] R. G. Wamai, B. J. Morris, R. C. Bailey, J. D. Klausner and M. N. Boedicker, "Debating male circumcision for HIV prevention: a one-sided argument does not represent a legitimate 'controversy' analysis--reply to de Camargo et al," *Global Public Health*, vol. 10, no. 5-6, pp. 672-678, 2015.
[205] B. J. Morris, R. G. Wamai, J. N. Krieger, J. Banerjee and J. D. Klausner, "Male circumcision to prevent syphilis in 1855 and HIV in 1986 is supported by the accumulated scientific evidence to 2015: Response to Darby," *Global Public Health*, vol. 12, no. 10, pp. 1315-1333, 2017.
[206] B. J. Morris, G. Barboza, R. G. Wamai and J. N. Krieger, "Circumcision is a primary preventive against HIV infection: Critique of a contrary meta-regression analysis by Van Howe," *Global Public Health*, Epub ahead of print Apr 6 2016 (11 pages).
[207] B. J. Morris, G. Barboza, R. G. Wamai and J. N. Krieger, "Expertise and ideology in statistical evaluation of circumcision for protection against HIV infection.," *World Journal of AIDS*, vol. 7, pp. 179-203, 2017.
[208] D. A. Cooper, A. D. Wodak and B. J. Morris, "Matters arising: "The case for boosting infant male circumcision in the face of rising heterosexual transmission of HIV" ... and now the case against. (Author Response)," *Medical Journal of Australia*, vol. 194, pp. 101, 2011.
[209] M. C. Boily, R. F. Baggaley, L. Wang, B. Masse, R. G. White, R. J. Hayes, et al., "Heterosexual risk of HIV-1 infection per sexual act: systematic review and meta-analysis of observational studies," *Lancet Infectious Diseases*, vol. 9, no. 2, pp. 118-129, 2009.
[210] S. N. Kabwama, D. Ssewanyana and G. Berg-Beckhoff, "The association between male circumcision and condom use behavior - a meta-analysis," *Materia socio-medica*, vol. 30, no. 1, pp. 62-66, 2018.
[211] J. H. Lei, L. R. Liu, Q. Wei, S. B. Yan, L. Yang, T. R. Song, et al., "Circumcision status and risk of HIV acquisition during heterosexual intercourse for both males and females: A meta-analysis," *PLoS One*, vol. 10, no. 5, pp. e0125436, 2015.
[212] S. C. Sharma, N. Raison, S. Khan, M. Shabbir, P. Dasgupta and K. Ahmed, "Male circumcision for the prevention of human immunodeficiency virus (HIV) acquisition: a meta-analysis," *BJU International*, vol. 121, no. 4, pp. 515-526, 2018.
[213] S. G. McCoombe and R. V. Short, "Potential HIV-1 target cells in the human penis," *AIDS*, vol. 20, no. 11, pp. 1491-1495, 2006.
[214] T. Hirbod, R. C. Bailey, K. Agot, S. Moses, J. Ndinya-Achola, R. Murugu, et al., "Abundant expression of HIV target cells and C-type lectin receptors in the foreskin tissue of young Kenyan men," *Am J Pathol*, vol. 176, no. 6, pp. 2798-2805, 2010.
[215] Y. Ganor, Z. Zhou, D. Tudor, A. Schmitt, M. C. Vacher-Lavenu, L. Gibault, et al., "Within 1 h, HIV-1 uses viral synapses to enter efficiently the inner, but not outer, foreskin mucosa and engages Langerhans-T cell conjugates," *Mucosal Immunology*, vol. 3, no. 5, pp. 506-522, 2010.
[216] Y. Ganor and M. Bomsel, "HIV-1 transmission in the male genital tract," *American Journal of Reproductive Immunology*, vol. 65, no. 3, pp. 284-291, 2011.

[217] B. J. Morris and R. G. Wamai, "Biological basis for the protective effect conferred by male circumcision against HIV infection," *International Journal of STD & AIDS*, vol. 23, no. 3, pp. 153-159, 2012.

[218] R. H. Gray, D. Serwadda, A. A. Tobian, M. Z. Chen, F. Makumbi, T. Suntoke, et al., "Effects of genital ulcer disease and herpes simplex virus type 2 on the efficacy of male circumcision for HIV prevention: Analyses from the Rakai trials," *PLoS Medicine*, vol. 6, no. 11, article e1000187, (8 pages), 2009.

[219] E. E. Freeman, H. A. Weiss, J. R. Glynn, P. L. Cross, J. A. Whitworth and R. J. Hayes, "Herpes simplex virus 2 infection increases HIV acquisition in men and women: systematic review and meta-analysis of longitudinal studies," *AIDS*, vol. 20, no. 1, pp. 73-83, 2006.

[220] M. C. Boily, K. Desai, B. Masse and A. Gumel, "Incremental role of male circumcision on a generalised HIV epidemic through its protective effect against other sexually transmitted infections: from efficacy to effectiveness to population-level impact," *Sexually Transmitted Infections*, vol. 84, no. Suppl 2, pp. Ii28-Ii34, 2008.

[221] A. A. Tobian and T. C. Quinn, "Herpes simplex virus type 2 and syphilis infections with HIV: an evolving synergy in transmission and prevention," *Current Opinion in HIV and AIDS*, vol. 4, no. 4, pp. 294-299, 2009.

[222] R. C. Bailey and S. D. Mehta, "Circumcision's place in the vicious cycle involving herpes simplex virus type 2 and HIV," *Journal of Infectious Diseases*, vol. 199, no. 7, pp. 923-925, 2009.

[223] L. de Witte, A. Nabatov, M. Pion, D. Fluitsma, M. A. de Jong, T. de Gruijl, et al., "Langerin is a natural barrier to HIV-1 transmission by Langerhans cells," *Nature Medicine*, vol. 13, no. 3, pp. 367-371, 2007.

[224] O. Schwartz, "Langerhans cells lap up HIV-1," *Nature Medicine*, vol. 13, no. 3, pp. 245-246, 2007.

[225] L. Warner, K. G. Ghanem, D. R. Newman, M. Macaluso, P. S. Sullivan and E. J. Erbelding, "Male circumcision and risk of HIV infection among heterosexual African American men attending Baltimore sexually transmitted disease clinics," *Journal of Infectious Diseases*, vol. 199, no. 1, pp. 59-65, 2009.

[226] S. L. Sansom, V. S. Prabhu, A. B. Hutchinson, Q. An, H. I. Hall, R. K. Shrestha, et al., "Cost-effectiveness of newborn circumcision in reducing lifetime HIV risk among U.S. males," *PLoS One*, vol. 5, no. 1, article e8723 (8 pages), 2010.

[227] D. K. Smith, A. Taylor, P. H. Kilmarx, P. Sullivan, L. Warner, M. Kamb, et al., "Male circumcision in the United States for the prevention of HIV infection and other adverse health outcomes: report from a CDC consultation," *Public Health Reports*, vol. 125, Suppl 1, pp. 72-82, 2010.

[228] D. Chemtob, E. Op de Coul, A. van Sighem, Z. Mor, F. Cazein and C. Semaille, "Impact of male circumcision among heterosexual HIV cases: comparisons between three low HIV prevalence countries," *Israel Journal of Health Policy Research*, vol. 4, article 36, pp. 31-38, 2015.

[229] A. Chao, M. Bulterys, F. Musanganire, P. Habimana, P. Nawrocki, E. Taylor, et al., "Risk factors associated with prevalent HIV-1 infection among pregnant women in Rwanda. National University of Rwanda-Johns Hopkins University AIDS Research Team," *International Journal of Epidemiology*, vol. 23, no. 2, pp. 371-380, 1994.

[230] M. J. Wawer, F. Makumbi, G. Kigozi, D. Serwadda, S. Watya, F. Nalugoda, et al., "Circumcision in HIV-infected men and its effect on HIV transmission to female partners in Rakai, Uganda: a randomised controlled trial," *Lancet*, vol. 374, no. 9685, pp. 229-237, 2009.

[231] F. K. Lau, S. Jayakumar and S. K. Sgaier, "Understanding the socio-economic and sexual behavioural correlates of male circumcision across eleven voluntary medical male circumcision priority countries in southeastern Africa," *BMC Public Health*, vol. 15, no., pp. article 813 (811 pages), 2015.

[232] H. A. Weiss, C. A. Hankins and K. Dickson, "Male circumcision and risk of HIV infection in women: a systematic review and meta-analysis," *Lancet Infectious Diseases*, vol. 9, no. 11, pp. 669-677, 2009.

[233] K. Jean, P. Lissouba, D. Taljaard, R. Taljaard, B. Singh, J. Bouscaillou, et al., HIV incidence among women is associated with their partners' circumcision status in the township of Orange Farm (South Africa) where the male circumcision roll-out is ongoing (ANRS-12126). *International AIDS Conference*, Melbourne, Australia, Abstract FRAE0105LB, [accessed 2018 Jan 24]. Available from URL: http://pag.aids2014.org/Abstracts.aspx?AID=11010, 2014.

[234] G. Fatti, N. Shaikh, D. Jackson, A. Goga, J. B. Nachega, B. Eley, et al., "Low HIV incidence in pregnant and postpartum women receiving a community-based combination HIV prevention intervention in a high HIV incidence setting in South Africa," *PLoS One*, vol. 12, no. 7, article 0181691, 2017.

[235] C. S. Wiysonge, E. J. Kongnyuy, M. Shey, A. S. Muula, O. B. Navti, E. A. Akl, et al., "Male circumcision for prevention of homosexual acquisition of HIV in men," *Cochrane Database of Systemetic Reviews*, vol. 6, no. 6, article CD007496 (46 pages), 2011.

[236] D. J. Templeton, F. Jin, L. Mao, G. P. Prestage, B. Donovan, J. Imrie, et al., "Circumcision and risk of HIV infection in Australian homosexual men," *AIDS*, vol. 23, no. 17, pp. 2347-2351, 2009.

[237] R. S. Van Howe, "Sexually transmitted infections and male circumcision: a systematic review and meta-analysis," *ISRN Urology*, vol. 2013, article 109846 (42 pages), 2013.

[238] B. J. Morris, C. A. Hankins, A. A. Tobian, J. N. Krieger and J. D. Klausner, "Does male circumcision protect against sexually transmitted infections? Arguments and meta-analyses to the contrary fail to withstand scrutiny," *ISRN Urology*, vol. 2014, article 684706 (23 pages), 2014.

[239] R. S. Van Howe, "Genital ulcerative disease and sexually transmitted urethritis and circumcision: a meta-analysis," *International Journal of STD & AIDS*, vol. 18, no. 12, pp. 799-809, 2007.

[240] R. S. Van Howe, "Human papillomavirus and circumcision: a meta-analysis," *Journal of Infection*, vol. 54, no. 5, pp. 490-496, 2007.

[241] R. S. Van Howe, "Sampling bias explains association between human papillomavirus and circumcision," *Journal of Infectious Diseases*, vol. 200, no. 5, pp. 832, 2009.

[242] X. Castellsagué, G. Albero, R. Cleries and F. X. Bosch, "HPV and circumcision: A biased, inaccurate and misleading meta-analysis," *Journal of Infection*, vol. 55, no. 1, pp. 91-93, 2007.

[243] J. H. Waskett, B. J. Morris and H. A. Weiss, "Errors in meta-analysis by Van Howe.," *International Journal of STD & AIDS*, vol. 20, no. 3, pp. 216-218, 2009.

[244] Y. P. Zhu, Z. W. Jia, B. Dai, D. W. Ye, Y. Y. Kong, K. Chang, et al., "Relationship between circumcision and human papillomavirus infection: a systematic review and meta-analysis," *Asian Journal of Andrology*, vol. 19, no. 1, pp. 125-131, 2017.

[245] B. J. Morris, J. D. Klausner, J. N. Krieger, B. J. Willcox, P. D. Crouse and N. Pollock, "Canadian Paediatrics Society position statement on newborn circumcision: a risk-benefit analysis revisited," *Canadian Journal of Urology*, vol. 23, no. 5, pp. 8492-8502, 2016.

[246] B. J. Morris, S. E. Kennedy, A. D. Wodak, A. Mindel, D. Golovsky, L. Schrieber, et al., "Early infant male circumcision: Systematic review, risk-benefit analysis, and progress in policy," *World Journal of Clinical Pediatrics*, vol. 6, no. 1, pp. 89-102, 2017.

[247] X. Castellsague, F. X. Bosch, N. Munoz, C. J. Meijer, K. V. Shah, S. de Sanjose, et al., "Male circumcision, penile human papillomavirus infection, and cervical cancer in female partners," *New England Journal of Medicine*, vol. 346, no. 15, pp. 1105-1112, 2002.

[248] V. Homfray, C. Tanton, R. F. Miller, S. Beddows, N. Field, P. Sonnenberg, et al., "Male circumcision and STI acquisition in Britain: Evidence from a national probability sample survey," *PLoS One*, vol. 10, no. 6, article e0130396 (9 pages), 2015.

[249] D. M. Backes, M. C. Bleeker, C. J. Meijer, M. G. Hudgens, K. Agot, R. C. Bailey, et al., "Male circumcision is associated with a lower prevalence of human papillomavirus-associated penile lesions among Kenyan men," *International Journal of Cancer*, vol. 130, no. 8, pp. 1888-1897, 2012.

[250] A. A. Tobian, X. Kong, P. E. Gravitt, K. P. Eaton, G. Kigozi, D. Serwadda, et al., "Male circumcision and anatomic sites of penile high-risk human papillomavirus in Rakai, Uganda," *International Journal of Cancer*, vol. 129, no. 12, pp. 2970-2975, 2011.

[251] B. Y. Hernandez, Y. B. Shvetsov, M. T. Goodman, L. R. Wilkens, P. Thompson, X. Zhu, et al., "Reduced clearance of penile human papillomavirus infection in uncircumcised men," *Journal of Infectious Diseases*, vol. 201, no. 9, pp. 1340-1343, 2010.

[252] B. Lu, Y. Wu, C. M. Nielson, R. Flores, M. Abrahamsen, M. Papenfuss, et al., "Factors associated with acquisition and clearance of human papillomavirus infection in a cohort of US men: a prospective study," *Journal of Infectious Diseases*, vol. 199, no. 3, pp. 362-371, 2009.

[253] G. Albero, X. Castellsague, H. Y. Lin, W. Fulp, L. L. Villa, E. Lazcano-Ponce, et al., "Male circumcision and the incidence and clearance of genital human papillomavirus (HPV) infection in men: the HPV Infection in men (HIM) cohort study," *BMC Infectious Dieasess*, vol. 14, no., pp. article 75 (18 pages), 2014.

[254] L. A. Afonso, T. I. Cordeiro, F. N. Carestiato, A. A. Ornellas, G. Alves and S. M. Cavalcanti, "High risk human papillomavirus infection of the foreskin in asymptomatic men and patients with phimosis," *Journal of Urology*, vol. 195, no. 6, pp. 1784-1789, 2016.

[255] A. A. R. Tobian, V. Ssempijja, G. Kigozi, A. E. Oliver, D. Serwadda, F. Makumbi, et al., "Incident HIV and herpes simplex virus type 2 infection among men in Rakai, Uganda," *AIDS*, vol. 23, no. 12, pp. 1589-1594, 2009.

[256] A. A. R. Tobian, B. Charvat, V. Ssempijja, G. Kigozi, D. Serwadda, F. Makumbi, et al., "Factors Associated with the Prevalence and Incidence of Herpes Simplex Virus Type 2 Infection among Men in Rakai, Uganda," *Journal of Infectious Diseases*, vol. 199, no. 7, pp. 945-949, 2009.

[257] J. Sobngwi-Tambekou, D. Taljaard, P. Lissouba, K. Zarca, A. Puren, E. Lagarde, et al., "Effect of HSV-2 serostatus on acquisition of HIV by young men: results of a longitudinal study in Orange Farm, South Africa," *Journal of Infectious Diseases*, vol. 199, no. 7, pp. 958-964, 2009.

[258] S. D. Mehta, S. Moses, K. Agot, I. Maclean, E. Odoyo-June, H. Li, et al., "Medical male circumcision and HSV-2 acquisition: Post-trial surveillance in Kisumu, Kenya.," *Journal of Infectious Diseases* vol. 208, no., pp. 1869-1876, 2013.

[259] H. A. Weiss, S. L. Thomas, S. K. Munabi and R. J. Hayes, "Male circumcision and risk of syphilis, chancroid, and genital herpes: a systematic review and meta-analysis," *Sexually Transmitted Infections*, vol. 82, no. 2, pp. 101-109; discussion 110, 2006.

[260] J. Sobngwi-Tambekou, D. Taljaard, M. Nieuwoudt, P. Lissouba, A. Puren and B. Auvert, "Male circumcision and *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*: observations in the aftermath of a randomised controlled trial for HIV prevention," *Sexually Transmitted Infections*, vol. 85, no. 2, pp. 116-120, 2009.

[261] S. D. Mehta, C. Gaydos, I. Maclean, E. Odoyo-June, S. Moses, L. Agunda, et al., "The effect of medical male circumcision on urogenital *Mycoplasma genitalium* among men in Kisumu, Kenya," *Sexually Transmitted Diseases*, vol. 39, no. 4, pp. 276-280, 2012.

[262] J. Pintye, J. M. Baeten, L. E. Manhart, C. Celum, A. Ronald, N. Mugo, et al., "Association between male circumcision and incidence of syphilis in men and women: a prospective study in HIV-1 serodiscordant heterosexual African couples," *Lancet Global Health*, vol. 2, no. 11, pp. E664-E671, 2014.

[263] B. Otieno-Nyunya, E. Bennett, R. Bunnell, S. Dadabhai, A. A. Gichangi, N. Mugo, et al., "Epidemiology of syphilis in Kenya: results from a nationally representative serological survey," *Sexually Transmitted Infections*, vol. 87, no. 6, pp. 521-525, 2011.

[264] J. M. Nasio, N. J. D. Nagelkerke, A. Mwatha, S. Moses, J. O. NdinyaAchola and F. A. Plummer, "Genital ulcer disease among STD clinic attenders in Nairobi: Association with HIV-1 and circumcision status," *International Journal of STD & AIDS*, vol. 7, no. 6, pp. 410-414, 1996.

[265] S. D. Mehta, S. Moses, C. B. Parker, K. Agot, I. Maclean and R. C. Bailey, "Circumcision status and incident herpes simplex virus type 2 infection, genital ulcer disease, and HIV infection," *AIDS*, vol. 26, no. 9, pp. 1141-1149, 2012.

[266] M. R. Golden and J. N. Wasserheit, "Prevention of viral sexually transmitted infections -- Foreskin at the forefront," *New England Journal of Medicine*, vol. 360, no. 13, pp. 1349-1351, 2009.

[267] A. A. Tobian and T. C. Quinn, "Prevention of syphilis: another positive benefit of male circumcision," *Lancet Glob Health*, vol. 2, no. 11, pp. e623-624, 2014.

[268] R. Darby, "Syphilis 1855 and HIV-AIDS 2007: Historical reflections on the tendency to blame human anatomy for the action of micro-organisms," *Global Public Health*, vol. 10, no. 5-6, pp. 573-588, 2015.

[269] M. J. Wawer, A. A. R. Tobian, G. Kigozi, X. Kong, P. E. Gravitt, D. Serwadda, et al., "Effect of circumcision of HIV-negative men on transmission of human papillomavirus to HIV-negative women: a randomised trial in Rakai, Uganda," *Lancet*, vol. 377, no. 9761, pp. 209-218, 2011.

[270] S. M. Garland, S. K. Kjaer, N. Munoz, S. L. Block, D. R. Brown, M. J. DiNubile, et al., "Impact and effectiveness of the quadrivalent human papillomavirus vaccine: A systematic review of 10 years of real-world experience," *Clinical Infectious Diseases*, vol. 63, no. 4, pp. 519-527, 2016.

[271] B. J. Morris, J. L. Flanagan, K. J. McKinnon and B. N. Nightingale, "Papillomavirus screening of cervical lavages by polymerase chain reaction," *Lancet*, vol. 2, no. 8624, pp. 1368 [accessed 2018 Apr 13]. Available at URL: https://www.researchgate.net/publication/20252344_Papillomavirus_screening_of_cervical_lavages_by_polymerase_chain_reaction, 1988.

[272] R. H. Gray, G. Kigozi, D. Serwadda, F. Makumbi, F. Nalugoda, S. Watya, et al., "The effects of male circumcision on female partners' genital tract symptoms and vaginal infections in a randomized trial in Rakai, Uganda," *American Journal of Obstetrics and Gynecology*, vol. 200, no. 1, pp. 42 e41-47, 2009.

[273] A. E. Brankin, A. A. R. Tobian, O. Laeyendecker, T. R. Suntoke, A. Kizza, B. Mpoza, et al., "Aetiology of genital ulcer disease in female partners of male participants in a circumcision trial in Uganda," *International Journal of STD & AIDS*, vol. 20, no. 9, pp. 650-651, 2009.

[274] X. Castellsague, R. W. Peeling, S. Franceschi, S. de Sanjose, J. S. Smith, G. Albero, et al., "*Chlamydia trachomatis* infection in female partners of circumcised and uncircumcised adult men," *American Journal of Epidemiology*, vol. 162, no. 9, pp. 907-916, 2005.

[275] A. N. Turner, C. S. Morrison, N. S. Padian, J. S. Kaufman, F. M. Behets, R. A. Salata, et al., "Male circumcision and women's risk of incident chlamydial, gonococcal, and trichomonal infections," *Sexually Transmitted Diseases*, vol. 35, no. 7, pp. 689-695, 2008.

[276] J. Pintye, A. L. Drake, J. A. Unger, D. Matemo, J. Kinuthia, R. S. McClelland, et al., "Male partner circumcision associated with lower *Trichomonas vaginalis* incidence among pregnant and postpartum Kenyan women: a prospective cohort study," *Sexually Transmitted Infections*, vol. 93, no. 2, pp. 137-143, 2017.

[277] J. M. Grund, T. S. Bryant, I. Jackson, K. Curran, N. Bock, C. Toledo, et al., "Association between male circumcision and women's biomedical health outcomes: a systematic review," *Lancet Global Health*, vol. 5, no. 11, pp. e1113-e1122, 2017.

[278] B. J. Morris and C. A. Hankins, "Effect of male circumcision on risk of sexually transmitted infections and cervical cancer in women," *Lancet Global Health*, vol. 5, no. 11, pp. e1054-e1055, 2017.

[279] I. M. Poynten, F. Jin, D. J. Templeton, G. P. Prestage, B. Donovan, M. Pawlita, et al., "Prevalence, incidence, and risk factors for human papillomavirus 16 seropositivity in Australian homosexual men," *Sexually Transmitted Diseases*,, vol. 39, no. 9, pp. 726-732, 2012.

[280] D. J. Templeton, F. Jin, G. P. Prestage, B. Donovan, J. C. Imrie, S. C. Kippax, et al., "Circumcision and risk of sexually transmissible infections in a community-based cohort of HIV-negative homosexual men in Sydney, Australia," *Journal of Infectious Diseases*, vol. 200, no. 12, pp. 1813-1819, 2009.

[281] S. Weller and K. Davis, "Condom effectiveness in reducing heterosexual HIV transmission," *Cochrane Database of Systematic Reviews*, Issue 1, article CD003255, 2002.

[282] F. K. Giannou, C. G. Tsiara, G. K. Nikolopoulos, M. Talias, V. Benetou, M. Kantzanou, et al., "Condom effectiveness in reducing heterosexual HIV transmission: a systematic review and meta-analysis of studies on HIV serodiscordant couples," *Expert Review of Pharmacoeconomics & Outcomes Research*, vol. 16, no. 4, pp. 489-499, 2016.

[283] N. Hearst and S. Chen, "Condom promotion for AIDS prevention in the developing world: is it working?," *Studies in Family Planning*, vol. 35, no. 1, pp. 39-47, 2004.

[284] L. M. Lopez, C. Otterness, M. Chen, M. Steiner and M. F. Gallo, "Behavioral interventions for improving condom use for dual protection," *Cochrane Database of Systematic Reviews*, Issue 10, article CD010662, 2013.

[285] R. S. Van Howe, "Presumptions are not data and data are often not informative," *American Journal of Bioethics*, vol. 15, no. 2, pp. 40-58, 2015.

[286] J. S. Svoboda and R. S. Van Howe, "Out of step: fatal flaws in the latest AAP policy report on neonatal circumcision," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 434-441, 2013.

[287] B. J. Morris, J. H. Waskett, J. Banerjee, R. G. Wamai, A. A. Tobian, R. H. Gray, et al., "A 'snip' in time: what is the best age to circumcise?," *BMC Pediatrics*, vol. 12, no. 1, article 20 (15 pages), 2012.

[288] B. J. Morris, "Why circumcision is a biomedical imperative for the 21(st) century," *Bioessays*, vol. 29, no. 11, pp. 1147-1158, 2007.

[289] B. J. Morris, S. A. Bailis, X. Castellsague, T. E. Wiswell and D. T. Halperin, "RACP's policy statement on infant male circumcision is ill-conceived," *Australian and New Zealand Journal of Public Health*, vol. 30, no. 1, pp. 16-22, 2006.

[290] B. J. Morris, A. D. Wodak, A. Mindel, L. Schrieber, K. A. Duggan, A. Dilly, et al., "Infant male circumcision: An evidence-based policy statement.," *Open Journal of Preventive Medicine*, vol. 2, no., pp. 79-92, 2012.

[291] B. J. Morris, S. A. Bailis and T. E. Wiswell, "Circumcision rates in the United States: rising or falling? What effect might the new affirmative pediatric policy statement have?," *Mayo Clinic Proceedings*, vol. 89, no. 5, pp. 677-686, 2014.

[292] S. Moreton, "Babies don't have sex," *circfacts.org* [accessed 2018 Jan 31]. Available from URL: http://circfacts.org/general-information/ - med2, 2018.

[293] R. Merkel and H. Putzke, "After Cologne: male circumcision and the law. Parental right, religious liberty or criminal assault?," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 444-449, 2013.

[294] R. Darby, "Risks, benefits, complications and harms: neglected factors in the current debate on non-therapeutic circumcision," *Kennedy Institute of Ethics Journal*, vol. 25, no. 1, pp. 1-34, 2015.

[295] D. Benatar and M. Benatar, "How not to argue about circumcision," *American Journal of Bioethics*, vol. 3, no. 2, pp. W1-W9, 2003.

[296] P. A. Clark, J. Eisenman and S. Szapor, "Mandatory neonatal male circumcision in Sub-Saharan Africa: medical and ethical analysis," *Medical Science Monitor*, vol. 13, no. 12, pp. RA205-213, 2007.

[297] A. J. Jacobs, "The ethics of circumcision of male infants," *Israel Medical Association Journal*, vol. 15, no. 1, pp. 60-65, 2013.
[298] D. Benatar, "Evaluations of circumcision should be circumscribed by the evidence," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 431-432, 2013.
[299] J. Mazor, "The child's interests and the case for the permissibility of male infant circumcision," *Journal of Medical Ethics*, vol. 39, no. 7, pp. 421-428, 2013.
[300] A. J. Jacobs and K. S. Arora, "Ritual male infant circumcision and human rights," *American Journal of Bioethics*, vol. 15, no. 2, pp. 30-39, 2015.
[301] J. C. Bester, "Ritual male infant circumcision: the consequences and the principles say yes," *American Journal of Bioethics*, vol. 15, no. 2, pp. 56-58, 2015.
[302] M. Brusa and Y. M. Barilan, "Cultural circumcision in EU public hospitals - an ethical discussion," *Bioethics*, vol. 23, no. 8, pp. 470-482, 2009.
[303] M. Frisch and B. D. Earp, "Circumcision of male infants and children as a public health measure in developed countries: A critical assessment of recent evidence," *Global Public Health*, vol. 13, no. 5, pp. 626-641, 2018.
[304] B. J. Morris and J. N. Krieger, "Penile inflammatory skin disorders and the preventive role of circumcision," *International Journal of Preventive Medicine*, vol. 8, no., pp. 32, 2017.
[305] S. E. Folaranmi, H. J. Corbett and P. D. Losty, "Does application of topical steroids for lichen sclerosus (balanitis xerotica obliterans) affect the rate of circumcision? A systematic review," *Journal of Pediatric Surgery*, Epub ahead of print Jan 3, 2018.
[306] G. Kirtschig, K. Becker, A. Gunthert, D. Jasaitiene, S. Cooper, C. C. Chi, et al., "Evidence-based (S3) Guideline on (anogenital) Lichen sclerosus," *Journal of the European Academy of Dermatology and Venereology*, vol. 29, no. 10, pp. e1-43, 2015.
[307] B. J. Morris, R. H. Gray, X. Castellsague, F. X. Bosch, D. T. Halperin, J. H. Waskett, et al., "The strong protective effect of circumcision against cancer of the penis," *Advances in Urolology*, vol. 2011, article 812368 (21 pages), 2011.
[308] J. A. Ferris, J. Richters, M. K. Pitts, J. M. Shelley, J. M. Simpson, R. Ryall, et al., "Circumcision in Australia: further evidence on its effects on sexual health and wellbeing," *Australian and New Zealand Journal of Public Health*, vol. 34, no. 2, pp. 160-164, 2010.
[309] S. Iskit, M. Ilkit, A. Turc-Bicer, H. Demirhindi and M. Turker, "Effect of circumcision on genital colonization of Malassezia spp. in a pediatric population," *Medical Mycology*, vol. 44, no. 2, pp. 113-117, 2006.
[310] E. G. Severance, K. L. Gressitt, C. R. Stallings, E. Katsafanas, L. A. Schweinfurth, C. L. Savage, et al., "Candida albicans exposures, sex specificity and cognitive deficits in schizophrenia and bipolar disorder," *NPJ Schizophrenia*, vol. 2, article 16018 (7 pages), 2016.
[311] E. N. Preston, "Whither the foreskin? A consideration of routine neonatal circumcision," *JAMA*, vol. 213, no. 11, pp. 1853-1858, 1970.
[312] R. S. Van Howe and F. M. Hodges, "The carcinogenicity of smegma: debunking a myth," *Journal of the European Academy of Dermatology and Venereology* vol. 20, no. 9, pp. 1046-1054, 2006.
[313] R. Dagher, M. L. Selzer and J. Lapides, "Carcinoma of the penis and the anti-circumcision crusade," *Journal of Urology*, vol. 110, no. 1, pp. 79-80, 1973.
[314] J. H. Waskett and B. J. Morris, "Re: 'RS Van Howe, FM Hodges. The carcinogenicity of smegma: debunking a myth.' An example of myth and mythchief making?," *Journal of the European Academy of Dermatology and Venereology*, vol. 22, no. 1, pp. 131, 2008.
[315] B. J. Morris, J. N. Krieger, J. D. Klausner and B. E. Rivin, "The ethical course is to recommend infant male circumcision – Arguments disparaging American Academy of Pediatrics affirmative policy do not withstand scrutiny," *Journal of Law, Medicine & Ethics*, vol. 45, no. 4, pp. 647-663, 2017.

[316] M. Kochen and S. McCurdy, "Circumcision and the risk of cancer of the penis. A life-table analysis," *Am J Dis Child*, vol. 134, no. 5, pp. 484-486, 1980.
[317] T. E. Wiswell, "Neonatal circumcision: a current appraisal," *Focus Opinion in Pediatrics*, vol. 1, no. 2, pp. 93-99, 1995.
[318] T. E. Wiswell, "Circumcision circumspection.," *New England Journal of Medicine*, vol. 36, no., pp. 1244-1245, 1997.
[319] E. J. Schoen, M. Oehrli, C. Colby and G. Machin, "The highly protective effect of newborn circumcision against invasive penile cancer," *Pediatrics*, vol. 105, no. 3, pp. E36, 2000.
[320] G. Albero, X. Castellsague, A. R. Giuliano and F. X. Bosch, "Male circumcision and genital human papillomavirus: a systematic review and meta-analysis," *Sexually Transmitted Diseases*, vol. 39, no. 2, pp. 104-113, 2012.
[321] B. J. Morris and B. R. Rose, "Cervical screening in the 21st century: the case for human papillomavirus testing of self-collected specimens.," *Clinical Chemistry and Laboratory Medicine*, vol. 45, no. 5, pp. 577-591, 2007.
[322] E. P. F. Chow, D. A. Machalek, S. N. Tabrizi, J. A. Danielewski, G. Fehler, C. S. Bradshaw, et al., "Quadrivalent vaccine-targeted human papillomavirus genotypes in heterosexual men after the Australian female human papillomavirus vaccination programme: a retrospective observational study," *Lancet Infectious Diseases*, vol. 17, no. 1, pp. 68-77, 2017.
[323] N. Pabalan, E. Singian, H. Jarjanazi and A. Paganini-Hill, "Association of male circumcision with risk of prostate cancer: a meta-analysis," *Prostate Cancer and Prostatic Diseases*, vol. 18, no. 4, pp. 352-357, 2015.
[324] J. L. Wright, D. W. Lin and J. L. Stanford, "Circumcision and the risk of prostate cancer," *Cancer*, vol. 118, no. 18, pp. 4437-4443, 2012.
[325] A. R. Spence, M. C. Rousseau, P. I. Karakiewicz and M. E. Parent, "Circumcision and prostate cancer: a population-based case-control study in Montreal, Canada," *BJU International*, vol. 114, no. 6b, pp. E90-98, 2014.
[326] B. J. Morris and J. H. Waskett, "Circumcision reduces prostate cancer risk," *Asian Journal of Andrology*, vol. 14, no. 5, pp. 661-662, 2012.
[327] M. S. Wachtel, S. Yang and B. J. Morris, "Countries with high circumcision prevalence have lower protate cancer mortality," *Asian Journal of Andrology*, vol. 18, no., pp. 39-42, 2016.
[328] B. J. Morris, J. Waskett and S. A. Bailis, "Case number and the financial impact of circumcision in reducing prostate cancer," *BJU International*, vol. 100, no. 1, pp. 5-6, 2007.
[329] American Cancer Society, "Prostate cancer risk factors," [accessed 2018 Apr 9]. Available from URL: https://www.cancer.org/cancer/prostate-cancer/causes-risks-prevention/risk-factors.html, 2016.
[330] M. Frisch, Y. Aigrain, V. Barauskas, R. Bjarnason, S. A. Boddy, P. Czauderna, et al., "Cultural bias in the AAP's 2012 Technical Report and Policy Statement on male circumcision," *Pediatrics*, vol. 131, no. 4, pp. 796-800, 2013.
[331] B. D. Earp, "Do the benefits of male circumcision outweigh the risks? A critique of the proposed CDC guidelines," *Frontiers in Pediatrics*, vol. 3, no., pp. 18, 2015.
[332] L. W. Green, R. G. McAllister, K. W. Peterson and J. W. Travis, "Medicaid coverage of circumcision spreads harm to the poor," *American Journal of Public Health*, vol. 99, no. 4, pp. 584.
[333] Tasmanian Law Reform Institute, "Non-therapeutic male circumcision," Final report no 17, (109 pp) [accessed Feb 13, 2018]. Available from URL: http://www.utas.edu.au/__data/assets/pdf_file/0006/302829/Non-Therapuetic-Circ_Final-Report-August-2012.pdf, 2012.
[334] G. Hill, G. J. Boyle and J. V. Geisheker, "'Circumcision of infant males' must warn doctors of possible criminal assault charges," *Internal Medicine Journal*, vol. 42, no. 11, pp. 1280-1281, 2012.

[335] J. S. Svoboda, "Circumcision is a religious/cultural procedure, not a medical procedure," *JAMA Pediatrics*, vol. 168, no. 3, pp. 293-294, 2014.
[336] S. Blank, C. M. Brady, E. Buerk, W. Carlo, D. Diekema, A. Freedman, et al., "Cultural Bias and Circumcision: The AAP Task Force on Circumcision Responds," *Pediatrics*, vol. 131, no. 4, pp. 801-804, 2013.
[337] B. J. Morris, A. A. Tobian, C. A. Hankins, J. D. Klausner, J. Banerjee, S. A. Bailis, et al., "Veracity and rhetoric in paediatric medicine: a critique of Svoboda and Van Howe's response to the AAP policy on infant male circumcision," *Journal of Medical Ethics*, vol. 40, no. 7, pp. 463-470, 2014.
[338] B. J. Morris, "Commentary: Do the benefits of male circumcision outweigh the risks? A critique of the proposed CDC guidelines," *Frontiers in Pediatrics*, vol. 3, no., pp. article 88 (83 pages), 2015.
[339] B. E. Rivin, D. E. Diekema, A. C. Mastroianni, J. N. Krieger, J. D. Klausner and B. J. Morris, "Critical evaluation of Adler's challenge to the CDC's male circumcision recommendations," *International Journal of Children's Rights*, vol. 24, no. 2, pp. 265-303, 2016.
[340] B. J. Morris, J. N. Krieger and J. D. Klausner, "Critical evaluation of unscientific arguments disparaging affirmative infant male circumcision policy," *World Journal of Clinical Pediatrics*, vol. 5, no. 3, pp. 251-261, 2016.
[341] B. J. Morris, J. N. Krieger and J. D. Klausner, "CDC's male circumcision recommendations represent a key public health measure," *Global Health: Science and Practice*, vol. 5, no. 1, pp. 15-27, 2017.
[342] A. A. Leibowitz, K. Desmond and T. Belin, "Leibowitz et al. respond," *American Journal of Public Health*, vol. 99, no. 4, pp. 584-585, 2009.
[343] B. J. Morris, S. A. Bailis, J. H. Waskett, T. E. Wiswell and D. T. Halperin, "Medicaid coverage of newborn circumcision: a health parity right of the poor," *American Journal of Public Health*, vol. 99, no. 6, pp. 969-971, 2009.
[344] M. J. Bates, J. B. Ziegler, S. E. Kennedy, A. Mindel, A. D. Wodak, L. S. Zoloth, et al., "Recommendation by a law body to ban infant male circumcision has serious worldwide implications for pediatric practice and human rights," *BMC Pediatrics*, vol. 13, no., pp. article 136 (139 pages), 2013.
[345] B. Bates and B. J. Morris, "Legal arguments opposing infant male circumcision are flawed," *Internal Medicine Journal*, vol. 42, no. 11, pp. 1281-1282, 2012.
[346] B. J. Morris and A. A. Tobian, "Circumcision is a religious/cultural procedure, not a medical procedure-reply," *JAMA Pediatrics*, vol. 168, no. 3, pp. 294, 2014.
[347] B. J. Morris, J. N. Krieger and B. E. Rivin, "The ethical course is to recommend infant male circumcision – Arguments disparaging American Academy of Pediatrics affirmative policy do not withstand scrutiny," *Journal of Law, Medicine & Ethics*, vol. 45, no., pp. 647-663, 2017.
[348] I. Jenkins, "Bias and male circumcision," *Mayo Clinic Proceedings*, vol. 89, no. 11, pp. 1588, 2014.
[349] R. Darby, "To avoid circumcision complications, avoid circumcision," *Canadian Urological Association Journal*, vol. 8, no. 7-8, pp. 231, 2014.
[350] B. J. Morris, S. A. Bailis and T. E. Wiswell, "In reply--Bias and male circumcision," *Mayo Clinic Proceedings*, vol. 89, no. 11, pp. 1588-1589, 2014.
[351] B. J. Morris, "Scientific evidence dispels false claims about circumcision," *Canadian Urological Association Journal*, vol. 8, no. 11-12, pp. 396-397, 2014.
[352] M. T. Brady, "Newborn male circumcision with parental consent, as stated in the AAP circumcision policy statement, is both legal and ethical," *Journal of Law, Medicine & Ethics*, vol. 44, no. 2, pp. 256-262, 2016.
[353] M. Benatar and D. Benatar, "Between prophylaxis and child abuse: The ethics of neonatal male circumcision," *American Journal of Bioethics*, vol. 3, no. 2, pp. 35-48, 2003.

[354] R. Kelishadi, "To the readers," *International Journal of Preventive Medicine*, vol. 1, no. 1, pp. i, 2010.
[355] Johns Hopkins University, "Hippocratic Oath, Modern version," [accessed 2018, Mar 15]. Available from URL: http://guides.library.jhu.edu/c.php?g=202502&p=1335759," 2015.
[356] J. S. Svoboda, "A treatise from the trenches: Why are circumcision lawsuits so hard to win?," in: G. Denniston, F. Hodges, M. Milos, M. Fayre (Editors), *Circumcision and Human Rights*, Springer, Berlin, Germany, pp. 201-217, [accessed 2018 Jun 2017]. Available from URL: https://link.springer.com/chapter/2010.1007/2978-2011-4020-9167-2014_2019, 2009
[357] S. Moreton, "Why not remove breast buds (or appendix, etc.)?," *circfacts.org* [accessed 2018 Jan 31]. Available from URL: http://circfacts.org/debunking-corner/ - debk3, 2017.
[358] Anonymous, "Circumscience – Evidence-based annihilation of anti-circumcision pseudoscience," [accessed 2018 Jan 31]. Available from URL: https://circumscience.wordpress.com/2015/03/12/prophylactic-mastectomy-should-never-be-compared-to-routine-infant-circumcision/, 2015.
[359] C. F. McDonald, "Circumcision of the female," *GP*, vol. 18, no. 3, pp. 98-99, 1958.
[360] W. G. Rathmann, "Female circumcision, indications and a new technique," *GP*, vol. 20, no. 3, pp. 115-120, 1959.
[361] C. Ezzel, "Anatomy and sexual dysfunction," *Scientific American*, Oct 31, 2000 [accessed 2018 Feb 20] Available from URL: https://www.scientificamerican.com/article/anatomy-and-sexual-dysfun/, 2000.
[362] R. Darby, "*A Surgical Temptation: The Demonization of the Foreskin and the Rise in Circumcision in Britain*," University of Chicago Press, Chicago, 2005.
[363] E. Abram, "*De la circoncision*," Jean Martel Ainé, Imprimeur de la Faculté de Medicine: Montpellier (115 pages), 1864.
[364] W. Whitla, "*A Dictionary of Treatment - Including Medical and Surgical Therapeutics*," 50th ed., Bailli'ere, Tindall and Cox, London, 1912.
[365] F. A. Silby, "Part II: boys.," in: M. Scharlieb and F. A. Silby (Editors), *Youth and Sex. Dangers and Safeguards for Girls and Boys*, Dodge Publishing Co., London, pp. 44-92, 1913.
[366] J. C. Angulo and M. Garcia-Diez, "Male genital representation in Paleolithic art: Erection and circumcision before history," *Urology*, vol. 74, no. 1, pp. 10-14, 2009.
[367] G. Cox and B. J. Morris, "Why circumcision: From pre-history to the twenty-first century, Chapter 21," In: D. A. Bolnick, M. A. Koyle and A. Yosha (Editors), *Surgical Guide to Circumcision*, Springer, London, 2012, pp. 243-259 [accessed 2018 Apr 2019]. Available from URL: https://www.researchgate.net/publication/278660669_Why_Circumcision_From_Prehistory_to_the_Twenty-First_Century.
[368] I. Hershkovitz, G. W. Weber, R. Quam, M. Duval, R. Grun, L. Kinsley, et al., "The earliest modern humans outside Africa," *Science*, vol. 359, no. 6374, pp. 456-459, 2018.
[369] J. Hutchinson, "On the influence of circumcision in preventing syphilis," *Medical Times and Gazette*, vol. II, no., pp. 542-543, 1855.
[370] Anonymous, "Circumcision," *Edinburgh medical journal*, vol. 20, no. 3, pp. 282, 1874.
[371] B. J. Morris, R. G. Wamai, E. B. Henebeng, A. A. R. Tobian, J. D. Klausner, J. Banerjee, et al., "Estimation of country-specific and global prevalence of male circumcision," *Population Health Metrics*, vol. 14, no., pp. article 4 (13 pages), 2016.
[372] S. Kacker, K. D. Frick, C. A. Gaydos and A. A. Tobian, "Costs and effectiveness of neonatal male circumcision," *Archives of Pediatric and Adolescent Medicine*, vol. 166, no. 10, pp. 910-918, 2012.
[373] A. L. Andrews, G. B. Lazenby, E. R. Unal and K. N. Simpson, "The cost of Medicaid savings: the potential detrimental public health impact of neonatal circumcision defunding," *Infectious Diseases in Obstetrics and Gynecology*, vol. 2012, article 540295 (7 pages), 2012.

[374] J. Ortenberg and C. C. Roth, "Projected financial impact of noncoverage of elective circumcision by Louisiana medicaid in boys 0 to 5 years old," *Journal of Urology*, vol. 190, no. 4 Suppl, pp. 1540-1544, 2013.

[375] L. G. Gutwein, J. F. Alvarez, J. L. Gutwein, D. W. Kays and S. Islam, "Allocation of healthcare dollars: analysis of nonneonatal circumcisions in Florida," *The American Surgeon*, vol. 79, no. 9, pp. 865-869, 2013.

[376] A. A. Leibowitz, K. Desmond and T. Belin, "Determinants and policy implications of male circumcision in the United States.," *American Journal of Public Health*, vol. 99, no. 1, pp. 138-145, 2009.

[377] B. J. Morris, A. Mindel, A. A. R. Tobian, C. A. Hankins, R. H. Gray, R. C. Bailey, et al., "Should male circumcision be advocated for genital cancer prevention?," *Asian Pacific Journal of Cancer Prevention*, vol. 13, no. 9, pp. 4839-4842, 2012.

[378] A. B. Hutchinson, P. G. Farnham, H. D. Dean, D. U. Ekwueme, C. del Rio, L. Kamimoto, et al., "The economic burden of HIV in the United States in the era of highly active antiretroviral therapy: evidence of continuing racial and ethnic differences," *Journal of Acquired Immune Deficiency Syndromes*, vol. 43, no. 4, pp. 451-457, 2006.

[379] Attorneys for the Rights of the Child, " June update: Florida and Norway," [accessed 2018 Apr 6]. Available from URL: http://www.arclaw.org/news/june-update-florida-and-norway, 2014.

[380] T. Barnighausen, D. E. Bloom and S. Humair, "Economics of antiretroviral treatment vs. circumcision for HIV prevention," *Proc Natl Acad Sci U S A*, vol. 109, no. 52, pp. 21271-21276, 2012.

[381] J. Z. Hines, O. C. Ntsuape, K. Malaba, T. Zegeye, K. Serrem, E. Odoyo-June, et al., "Scale-up of voluntary medical male circumcision services for HIV prevention -- 12 countries in Southern and Eastern Africa, 2013-2016," *MMWR Morbidity and Mortality Weekly Report*, vol. 66, no. 47, pp. 1285-1290, 2017.

[382] B. J. Morris, J. D. Klausner, J. N. Krieger, B. J. Willcox, P. D. Crouse and N. Pollock, "Reply by Authors - Re: Canadian Pediatrics Society position statement on newborn circumcision: a risk-benefit analysis revisited," *Canadian Journal of Urology*, vol. 24, no. 1, pp. 8687-8692, 2017.

[383] B. J. Morris, A. D. Wodak, A. Mindel, L. Schrieber, K. A. Duggan, A. Dilly, et al., "The 2010 Royal Australasian College of Physicians policy statement 'Circumcision of infant males' is not evidence based.," *Internal Medicie Journal*, vol. 42, no. 7, pp. 822-828, 2012.

[384] B. J. Morris, A. D. Wodak, A. Mindel, L. Schrieber, K. A. Duggan, A. Dilly, et al., "Reply to Forbes: Evidence-based policy: circumcision of infant males," *Internal Medicine Journal*, vol. 42, no. 11, pp. 1279-1280, 2012.

[385] M. Jansen, "Routine circumcision of infant boys: It's time to make progress through the common ground," *Journal of Paediatrics and Child Health*, vol. 52, no. 5, pp. 477-479, 2016.

[386] A. D. Wodak, J. B. Ziegler and B. J. Morris, "Infant circumcision: Evidence, policy, and practice," *Journal of Paediatrics and Child Health*, vol. 53, no. 1, pp. 93, 2017.

[387] J. Conte, "Jonathan Conte: Motivations of an Intactivist," *Intact News* [accessed 2018 Mar 15]. Available at URL: http://intactnews.org/node/134/1318099689/jonathon-conte-motivations-intactivist, 2011.

[388] Bay Area Intactivists, "Incredibly sad news: Jonathon Conte has taken his own life," [accessed 2018 Jun 6]. Available at URL: http://www.bayareaintactivists.org/node/334, 2016.

[389] P. Chigwedere, G. R. Seage, 3rd, S. Gruskin, T. H. Lee and M. Essex, "Estimating the lost benefits of antiretroviral drug use in South Africa," *Journal of Acquired Immune Deficiency Syndromes*, vol. 49, no. 4, pp. 410-415, 2008.

[390] B. Auvert, D. Taljaard, D. Rech, P. Lissouba, B. Singh, J. Bouscaillou, et al., "Association of the ANRS-12126 male circumcision project with HIV levels among men in a South African township: Evaluation of effectiveness using cross-sectional surveys," *PloS Medicine*, vol. 10, no. 9, article e1001509 (12 pages), 2013.

[391] S. D. Mehta, S. Moses, K. Agot, E. Odoyo-June, H. Li, I. Maclean, et al., "The long-term efficacy of medical male circumcision against HIV acquisition," *AIDS*, vol. 27, no. 18, pp. 2899-2907, 2013.

[392] R. Gray, G. Kigozi, X. Kong, V. Ssempiija, F. Makumbi, S. Wattya, et al., "The effectiveness of male circumcision for HIV prevention and effects on risk behaviors in a posttrial follow-up study," *AIDS*, vol. 26, no. 5, pp. 609-615, 2012.

[393] A. A. R. Tobian, S. Kacker and T. C. Quinn, "Male circumcision: a globally relevant but under-utilized method for the prevention of HIV and other sexually transmitted infections," *Annual Review of Medicine*, vol. 65, no., pp. 293-306, 2014.

[394] E. L. Glaeser and C. R. Sunstein, "Does more speech correct falsehoods?," *Journal of Legal Studies*, vol. 43, no. 1, pp. 65-93, 2014.

[395] R. M. Barnes, H. M. Johnston, N. MacKenzie, S. J. Tobin and C. M. Taglang, "The effect of *ad hominem* attacks on the evaluation of claims promoted by scientists," *PLoS One*, vol. 13, no. 1, pp. e0192025, 2018.

[396] J. L. Brown, "Medical-legal risks associated with circumcision of newborn males: need for revised consent," *AAP News*, vol 34, issue 4, [accessed 2018 Apr 5]. Available from URL: http://www.aappublications.org/content/34/4/1.1?sso=1&sso_redirect_count=1&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token, 2013.

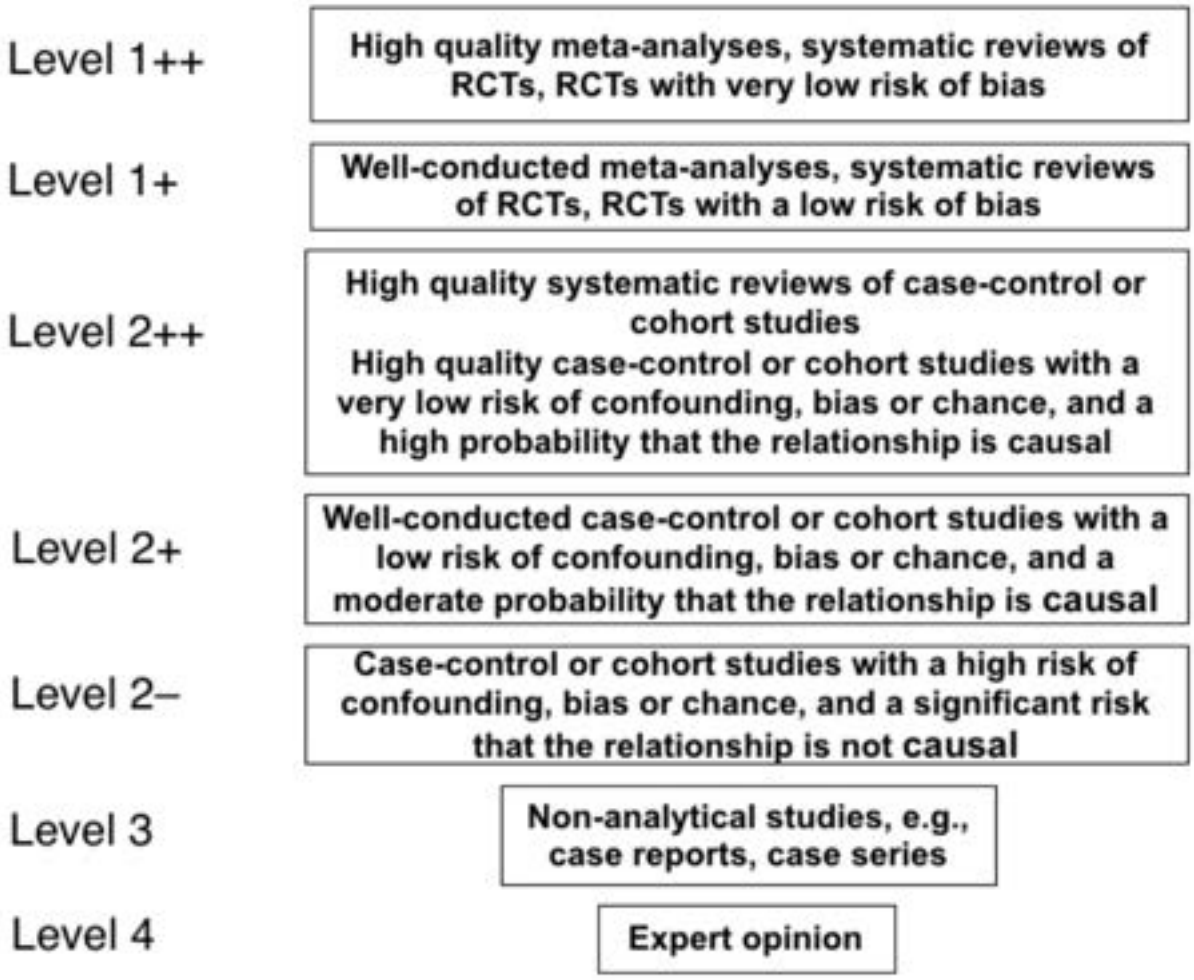

FIGURE 1: The hierarchy of quality of evidence used in science to evaluate claims, as specified by the Scottish Intercollegiate Guidelines Network (SIGN) [24].

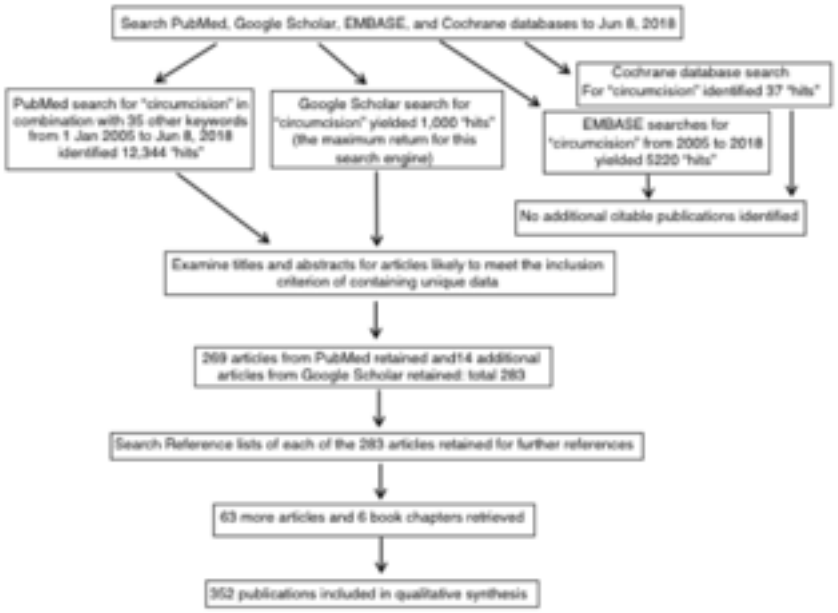

FIGURE 2: Search strategy diagram as required by PRISMA guidelines [25].

TABLE 1: Organizations opposed to non-therapeutic MC of boys.

Non-US medical bodies having formal policy statements
British Medical Association (2006)[1] [5]
Royal Australasian College of Physicians – Paediatrics & Child Health Division (2010)[1] [6]
Royal Dutch Medical Association (KNMG) (2010) [7]
Canadian Pediatric Society (2015)[2] [8]
Small fringe professional organizations
Doctors Opposing Circumcision (DOC)
Attorneys for the Rights of the Child (ARC)
Lay lobby groups
National Organization of Circumcision Information Research Centers (NOCIRC)
National Organization to Halt the Abuse and Routine Mutilation of Males (NOHARMM)
National Organization for Restoring Men (NORM)
International Coalition for Genital Integrity
Intact America
Bloodstained Men (BSM)
Mothers Against Circumcision
The VMMC Experience Project[3]

[1]Policy is currently in the process of being updated
[2]Only recommends non-therapeutic MC for "*boys in high-risk populations and circumstances*"
[3]Opposition by this group is directed at MC irrespective of age, with a particular focus on the voluntary medical male circumcision (VMMC) programs currently underway in sub-Saharan Africa

TABLE 2: Arguments used in opposing non-therapeutic MC of minors

• MC for prevention of urinary tract infections in infancy is unnecessary as these are rare, of minor consequence, and easily treated with oral antibiotics
• MC causes physical harm, including a high rate of surgical complications, numerous deaths, disrupts breastfeeding, commonly results in meatal stenosis and glans keritinization
• MC "pain" can result in permanent brain damage, autism, alexithymia, and post-traumatic stess disorder
• MC reduces sexual function in men
• MC reduces sexual pleasure in men and their female sexual partners
• MC does not protect against infection with HIV or other sexually transmitted infections during heterosexual intercourse with an infected partner
• Condoms afford complete protection against HIV and other STIs, so obviating the need for MC
• MC is not needed for prevention of phimosis and penile inflammatory conditions since these can be easily treated with steroid creams
• Penile cancer is so rare that prevention by MC is not worth the effort
• MC should be delayed until the boy is old enough to make the decision for himself
• Non-therapeutic MC of minors should be deemed unethical and illegal
• Early infant MC is a waste of money

TABLE 3: The "16 Functions of the Foreskin" claim [144]

1. Erotic pleasure especially via the ridged band and 20,000 nerve endings (Meissner's corpuscles)
2. Acts as a rolling bearing in intercourse and masturbation
3. Prevents dyspareunia (painful intercourse)
4. Simulates partner's genitalia, giving her erotic pleasure
5. Supplies skin to cover the shaft in erection and prevent tightness
6. Stores pheromones and releases them on arousal
7. Stores, releases and helps distribute natural lubricants ("smegma" and pre-ejaculatory fluid)
8. Makes the glans a visual signal of sexual arousal
9. Provides a seal against the vaginal wall to contain semen
10. Prevents the glans becoming keratinized, and keeps it soft and moist.
11. Protects the thin-skinned glans against injury
12. Protects the nerves of the glans and their erotic function
13. In infancy, it protects the urethra against contamination, UTIs and meatal stenosis
14. Provides lysosomes for bacteriostatic action around the glans
15. Pigmented, it protects the unpigmented glans against sunburn
16. Vascular (rich in blood vessels that bring heat to the tissues), it protects the less vascular glans against frostbite and other weather-related conditions

TABLE 4: PubMed search results, showing number of "hits" each year using as keyword "circumcision", together with the additional keyword shown in left-hand column.

Keyword	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015 ...cont.
Public health	162	187	240	237	248	266	258	295	277	195	189
Urinary tract infection	13	17	13	11	13	19	13	29	23	11	16
Sexually transmitted infection	67	100	174	147	135	163	162	174	152	90	95
Human papillomavirus	6	12	8	8	23	29	23	32	26	10	10
HPV	5	10	8	7	17	23	22	30	22	12	14
HSV-2	6	6	12	5	20	15	15	10	6	6	5
Syphilis	3	5	14	2	8	8	7	6	4	10	10
Trichomonas	1	0	2	4	3	5	0	4	2	0	0
Chancroid	1	2	4	0	0	2	0	2	1	1	6
Mycoplasma	0	1	0	0	0	2	0	3	1	1	1
HIV	63	92	182	159	151	172	184	191	171	147	146
Chlamydia	3	9	6	4	3	8	2	4	2	2	3
Bacterial vaginosis	2	0	0	2	1	6	1	7	5	3	4
Microbiome	0	0	0	0	0	2	2	4	1	1	1
Hygiene	8	12	18	11	13	16	15	23	13	14	19
Phimosis	29	36	27	34	33	28	28	37	39	20	18
Paraphimosis	4	3	3	5	2	4	4	7	3	0	2
Balanitis	10	11	13	12	12	10	11	16	13	7	4
Balanoposthitis	2	3	0	1	0	3	4	7	2	0	2
Lichen sclerosus/is	5	1	2	4	7	4	11	4	7	3	0
Penile cancer	14	32	17	17	21	20	27	29	24	7	16
Penis cancer	11	28	16	15	18	15	25	21	17	7	12
Prostate cancer	2	2	4	1	4	0	0	5	4	3	1
Cervical cancer	1	8	5	0	6	8	7	16	14	6	5
Sexual function	12	14	22	20	20	31	28	34	27	20	19
Sensation	9	7	11	4	6	8	3	9	15	9	8
Sensitivity	7	13	10	9	11	9	11	12	13	5	3
Satisfaction	15	12	19	23	20	25	24	29	29	22	18
Pleasure	3	3	2	6	9	5	3	10	9	3	9
Complications	66	84	76	86	84	101	83	108	121	90	82
Adverse events	4	3	9	7	13	14	19	24	17	24	18
Risk-benefit	17	13	23	23	27	33	20	33	27	19	32
Cost effectiveness	6	7	7	10	13	20	11	16	12	16	10
Timing	4	0	2	3	3	2	3	2	5	3	0
Best time	1	4	2	1	1	0	2	5	1	1	1
Policy	16	23	38	23	27	38	42	52	39	40	51

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… continued:

Keyword	2016	2017	Jun 2018	Total
Public health	234	164	36	2968
Urinary tract infection	14	12	3	207
Sexually transmitted infection	96	62	4	1621
Human papillomavirus	7	12	6	212
HPV	8	10	3	192
HSV-2	2	2	1	112
Syphilis	3	3	0	83
Trichomonas	0	3	0	24
Chancroid	0	0	0	19
Mycoplasma	0	0	0	9
HIV	147	87	36	1912
Chlamydia	2	4	1	47
Bacterial vaginosis	0	1	0	32
Microbiome	1	2	0	14
Hygiene	16	19	3	200
Phimosis	25	27	8	586
Paraphimosis	1	1	0	39
Balanitis	9	14	3	145
Balanoposthitis	1	2	1	28
Lichen sclerosus	4	10	4	66
Penile cancer	11	13	4	252
Penis cancer	6	11	3	205
Prostate cancer	5	3	0	34
Cervical cancer	6	5	1	88
Sexual function	16	21	2	286
Sensation	7	11	1	108
Sensitivity	14	6	3	126
Satisfaction	33	23	7	299
Pleasure	4	6	0	72
Complications	76	67	18	1142
Adverse events	20	18	5	195
Risk-benefit	29	20	6	322
Cost effectiveness	25	12	3	168
Timing	6	5	2	40
Best time	2	3	2	26
Policy	42	26	8	465

Grand total = 12,344 "hits"*

*The numbers shown do not take into account duplication of publication in different searches.

TABLE 5: Quality rating [24] of published studies that have shown negligible physical and psychological effects of MC and studies claiming a detrimental effect.

Rating	Studies showing no adverse effect
2++	El Bcheraoui *et al.* [52], Fergusson *et al.* [65], Morris & Krieger [76], Calnan *et al.* [86], Bauer & Kriebel [95]
2+	Christakis *et al.* [53], Wiswell & Geschke[32], Ben Chaim *et al.*[54], Mondzelewski *et al.* [66], Halata & Munger [78], Stenram *et al.* [85], Schlosberger *et al.* [87], Sneppen & Thorup [97]

Rating	Studies claiming a detrimental effect
2+	Taddio *et al.* [81]
2–	Frisch *et al.* [129], Frisch & Simonsen[69], Bollinger & Van Howe[103]
4	Bollinger[55], Adler[67], Van Howe[71], Tinari[86], Boyle *et al.*[126]

TABLE 6: Pain during sexual intercourse for circumcised vs. uncircumcised men, and for women.

Reference	Type of study	n	More (+), Less (–), No difference (0)
Men			
Kigozi *et al*. 2008[120]	RCT	1,500	0
Krieger *et al*. 2008[121]	RCT	1,995	0
Morris & Krieger 2013[114]	Systematic review	8288 vs. 6894 (6 studies)	0 (all 6 studies)
Tian *et al*. 2013[115]	Systematic review & meta-analysis	7349 vs. 6407 (5 studies)	0 (4 studies); – (1 study)
Shabanzadeh *et al*. 2016[117]	Systematic review	8 studies	0 (7 studies); – (1 study)
Brito *et al*. 2017[122]	Cohort study	500	– (p <0.001; fewer coital injuries)
Galukande *et al*. 2017[157]	Cohort study	304	– (42%); 0 (58%)
Nordstrom *et al*. 2017[119]	Case-control	>3,000	– (p <0.001).
Yang *et al*. 2017[116]	Systematic review & meta-analysis	6736 vs. 4201 (6 studies)	0 (3 studies); – (3 studies)
Women:			
Kigozi *et al*. 2009[143]	RCT	455	0 (99.8%); + (0.2%) (p=NS)

TABLE 7: Conventional quality rating[24] of published studies that have shown no adverse effect of MC on sexual function and pleasure and studies finding a detrimental effect.

Rating	Studies showing no adverse effect
1+	Tian *et al.* [115], Nordstrom *et al.* [119], Kigozi *et al.* [120, 143], Krieger *et al.* [121]
1–	Morris & Krieger [114], Cox *et al.* [137], Yang *et al.* [116], Shabanzadeh *et al.* [117], Payne *et al.* [160]
2++	Homfray *et al.* [118], Brito *et al.* [122], Galukande *et al.* [157], Bossio *et al.* [138]
2+	Cortés-González *et al.* [140, 141], Zulu *et al.* [142]

Rating	Studies showing a detrimental effect
2–	O'Hara & O'Hara [125], Boyle & Bensley [126], Kim & Pang [127], Sorrells *et al.* [128], Frisch *et al.* [129], Bronsalaer *et al.* [130]

TABLE 8: Quality rating[24] of studies that have found MC protects against HIV and several other STIs and studies showing no protective effect.

HIV

Rating	*Studies supporting a protective effect of MC*
1++	Auvert *et al.* [185], Bailey *et al.* [186], Gray *et al.* [187], Siegfried *et al.* [189]
1+	Weiss *et al.* [188], Morris *et al* .[207], Lei *et al.* [211], Sharma *et al.* [212], Freeman *et al.* [219], Weiss *et al.* [232], Wiysonge *et al.* [235]
2++	Morris *et al.* [206], Gray *et al.* [218], Boily *et al.* [209, 220]
2+	Warner *et al.[225]*, Sansom *et al.* [226], Chemtob *et al.* [228], Templeton *et al.* [236]
2–	Wawer *et al.* [230]

Rating	*Studies disputing the protective effect of MC*
2–	Van Howe [167, 183, 184]

Other STIs

Rating	*Studies supporting a protective effect of MC*
1+	Waskett *et al.* [243], Zhu *et al.* [244], Mehta *et al.* [261, 265], Weiss *et al.* [269], Gray *et al.* [272], Brankin *et al.* [273]
2++	Morris *et al.* [246], Castellsagué *et al.* [247, 274], Homfray *et al.* [248], Backes *et al.* [249], Hernandez *et al.* [251], Lu *et al.* [252], Albero *et al.* [253], Tobian *et al.* [255, 256], Sobngwi-Tambekou *et al.* [257, 260], Mehta *et al.* [258], Pintye *et al.* [262, 276], Otieno-Nyunya *et al.* [263], Nasio *et al.* [264], Poynten *et al.* [279], Templeton *et al.* [280]
2+	Turner *et al.* [275]

Rating	*Studies disputing the protective effect of MC*
2–	Van Howe[237, 239-241]

TABLE 9: Reasons why early infancy is the preferred time for MC

EIMC	MC of older boys and men
• Simple	• More complex
• Quick (takes several minutes)	• Half an hour or more to perform
• Cost is lower	• Much more expensive (often unaffordable)
• Low risk (adverse events 0.4%)	• Moderate risk (adverse events 4–8%)
• Bleeding (uncommon) is minimal and easily stopped	• Bleeding more common, requiring cautery or other interventions
• Sutures not needed	• Sutures or tissue glue needed
• Convenient for patient (sleeps mostly)	• Inconvenient (time off school or work)
• Local anesthesia for < 2 months	• General anesthesia for > 2 months to age 9 years. Local anesthesia for men, although general anesthesia sometimes preferred by surgeon
• Healing is fast (< 2 weeks)	• Healing takes 6 weeks or more
• Cosmetic outcome usually good	• If stitches used stitch marks may be seen
• No long-term memory of procedure	• Fear of undergoing an operation
• Does not disrupt (breast) feeding or other day-today activities	• Abstinence from sexual intercourse for the 6-week healing period

TABLE 10: Risk-benefit analyses of EIMC and medical conditions over the lifetime

Benefit-to-risk ratio	Uncircumcised males affected	Publication
> 100:1	~1 in 3	Morris *et al.* 2006 *ANZ J Public Health* [289]
> 100:1	~1 in 3	Morris 2007 *BioEssays* [288]
"very favourable"	~1 in 2	Morris *et al.* 2012 *Open J Prevent Med* [290]
"strongly favors"	~1 in 2	Morris et al. 2012 *BMC Pediatr* [287]
> 100:1	~1 in 2	Morris *et al.* 2014 *Mayo Clin Proc* [291]
~ 100:1	~2 in 3	Morris *et al.* 2016 *Can J Urol* [245]
~ 200:1	~2 in 3	Morris *et al.* 2017 *World J Clin Pediatr* [246]

TABLE 11: PRISMA-required summary of the key publications on each topic cited in this systematic review

Topic	
Data and arguments opposing MC	Critique(s) of each respective article
Urinary tract infections	
Singh-Grewal *et al.* 2005 [34]	Schoen 2005 [36], Morris & Wiswell 2013 [26]
Van Howe 2005 [35]	Simforoosh *et al.* 2012 [37]
Deaths from infant MC	
Bollinger 2010 [55]	Morris et al 2012 [56]
Meatal stenosis	
Van Howe 2006 [71]	Schoen 2007 [72]
Frisch & Simonsen 2018 [69]	Morris & Krieger 2017 [76], Morris & Krieger 2018 [70]
Van Howe 2018 [73]	Morris & Krieger 2018 [75]
Alexithymia	
Bollinger & Van Howe 2011 [103]	Morris et al. 2012 [106]
Anesthesia	
Paix 2012 [90]	Dilley & Morris 2012 [92]
Autism spectrum disorder	
Frisch & Simonsen 2015 [88]	Bauer 2015 [96], Morris & Wiswell 2015 [89], Sneppen & Thorup 2016 [97]
Sexual function and pleasure	
O'Hara & O'Hara 1999 [125]	Cortéz-González *et al.* 2008 [140], Kigozi *et al.* 2009 [143], Zulu *et al.* 2015 [142]
Boyle & Bensley 200 [126]	Morris & Krieger 2013 [114]
Kim & Pang 2007 [127]	Willcourt 2007 [132]
Sorrells *et al.* 2007 [128]	Waskett & Morris 2007 [133], Morris & Krieger 2013 [114], Cox *et al.* 2015 [137], Bossio *et al.* 2016 [138]
Frisch *et al.* 2011 [129]	Morris *et al.* 2012 [134], Morris *et al.* 2013 [114]
Bronselaer *et al.* 2013 [130]	Morris et al. 2013 [135]
Boyle 2015 [131]	Morris & Krieger 2015 [136]
HIV	
Van Howe 1999 [167]	Moses *et al.* 1999 [193]
	O'Farrell & Egger 2000 [194]
Green *et al.* 2008 [168]	Wamai *et al.* 2008 [195]
Gisselquist *et al.* 2009 [169]	Wamai *et al.* 2011 [198]
Green et al. 2010 [170]	Banerjee *et al.* 2011 [196]
Boyle & Hill 2011 [171]	Wamai *et al.* 2012 [201]
Boyle & Hill 2011 [172],	Cooper *et al.* 2011[208], Morris *et al.* 2012 [56]
Chin 2011 [173], Conroy 2011 [174],	Cooper *et al.* 2011 [208], Morris *et al.* 2012 [56]

Darby 2011 [175], Darby & Van Howe 2011 [176], Forbes 2011 [177], Paix 2011 [178], Travis *et al.* 2011 [179]

Van Howe & Storms 2011 [180]
de Camargo *et al.* 2013 [181]
de Camargo *et al.* 2015 [182]
Van Howe 2015 [183]
Van Howe 2018 [184]

Other STIs
Van Howe 2007 [240]
Van Howe 2007 [239]
Van Howe 2009 [241]
Van Howe 2013 [237]
Darby 2015 [268]

MC can be delayed ("self-determination")
Darby 2013 [19]
Merkel & Putzke 2013 [293]
Darby 2015 [294]
Van Howe 2015 [285]

Treatment of inflammatory conditions
Frisch & Earp 201 [303]

Penile cancer
Preston 1970 [311]
Van Howe & Hodges 2008 [312]
Svoboda et al. 2016 [27]

Legal, ethical
Green *et al.* 2009 [332]

Tasmanian Law Reform Institute 2010 [333]
Hill *et al.* 201 [334]
Svoboda 2014 [335]
Darby 2015 [294]
Adler 2016 [67]
Svoboda *et al.* 2016 [27]

2012 AAP policy on EIMC
Frisch *et al.* 2013 [330]
Svoboda & Van Howe 2013 [286]
Jenkins 2014 [348]
Darby 2014 [349]
Darby 2015 [294]
Svoboda *et al.* 2016 [27]

Cooper *et al.* 2011 [208], Morris *et al.* 2012 [56]
Cooper *et al.* 2011 [208], Morris *et al.* 2012 [56]
Cooper *et al.* 2011 [208], Morris *et al.* 2012 [56]

Morris *et al.* 2011 [197]
Wamai *et al.* 2015 [203]
Wamai *et al.* 2015 [204]
Morris *et al.* 2018 [206]
Morris *et al.* 2017 [207]

Castellsague *et al.* 2007 [242]
Waskett *et al.* 2009 [243]
Morris *et al.* 2014 [238]
Morris *et al.* 2014 [238]
Morris *et al.* 2017 [205]

Morris *et al.* 2012 [287]
Morris *et al.* 2012 [287]
Morris *et al.* 2012 [287]
Morris *et al.* 2012 [287]

Morris & Krieger 2017 [304], Folaranmi *et al.* 2018 [305]

Dagher et al. 1973 [313]
Waskett & Morris 2008 [314]
Morris *et al.* 2017 [315]

Leibowitz *et al.* 2009 [342]
Morris *et al.* 2009 [343]
Bates *et al.* [344]

Bates & Morris 2012 [345]
Morris 2014 [346]
Morris *et al.* 2016 [340]
Rivin *et al.* 2016 [339]
Morris *et al.* 2017 [347]

AAP Task Force 2013 [336]
Morris *et al.* 2014 [337]
Morris *et al.* 2014 [350]
Morris 2014 [351]
Morris *et al.* 2016 [340]
Brady 2016 [352]
Morris *et al.* 2017 [347]

2014 CDC MC draft policy
Earp 2015 [331]
Adler 2016 [67]
Frisch & Earp 201 [303]
Morris BJ. 2015 [338]
Rivin *et al*. 2016 [339]
Morris *et al*. 2017 [341]

2010 RACP policy on EIMC
RACP 2010 [6]
Forbes 2012 [177]
Jansen 2016 [385]
Morris *et al*. 2012[383]
Morris *et al*. 2012 [384]
Wodak *et al*. 2017 [386]

2015 CPS policy on EIMC
Sorokan *et al*. 2015 [8]
Robinson *et al*. 2017 [62]
Morris *et al*. 2016 [245]
Morris *et al*. 2017 [382]