Odprto pismo prenatalni medicinski stroki

Odziv na mnenje Združenja za perinatalno medicino glede cepljenja nosečnic proti Covid-19

Spoštovani zdravniki in profesorji prenatalne medicine,

Slovenska javnost in številne matere vas poznajo kot požrtvovalne zdravnike, ki se po najboljših močeh trudite v dobro nosečnic in njihovih otrok. Kot sami najbolje veste, je nosečnost izredno zapleten biološki proces, in primarna skrb nosečnic je, da se ne izpostavljajo aktivnostim ali snovem ali terapijam, ki bi lahko škodili materi ali plodu oziroma otroku. To zagotovo velja tudi za zdravila med nosečnostjo, ki morajo gotovo biti najprej preizkušena in potrjena, da so varna za splošno zdravo populacijo, šele potem pa se lahko sploh testirajo na nosečnicah, ali nimajo morebiti kakšnih posledic za nosečnost in zdravje ploda. Vsekakor mora tukaj najprej veljati načelo skrajne previdnosti, in načelo najprej ne škoditi pacientu, ter na splošno pravila medicinske etike.

Zaradi tega smo zelo presenečeni nad **mnenjem Združenja za perinatalno medicino Slovenije glede cepljenja nosečnic proti Covid-19.** Ali omenjena načela previdnosti in skrbi za zdravje nosečnice ter ploda več ne veljajo v primeru tega posega (cepljenja proti Covid-19)? Ali res omenjeno cepljenje lahko smatramo za neškodljivo nosečnici in plodu? Naše mnenje je, da so dokazi za to zelo neprepričljivi ter preliminarni, in da bi lahko dokončno o tem sklepali šele po večletni, znanstveno utemeljeni, neodvisni, primerjalni študiji na večji populaciji, ne pa samo na sprotnih prostovoljnih podatkih cepljenja v ZDA.

Obrazložitev mnenja se nam **ne zdi dovolj utemeljena**, da bi lahko smatrali te zaključke kot nedvoumno podprte z znanstvenimi dokazi ter v skladu z veljavno medicinsko etiko in praksami. Menimo, da tudi v obrazložitvi niste dovolj upoštevali nekaterih novih, vendar že znanih dejstev o samem virusu in nevarnostih delovanja spike proteina v cepivih, ter študij in podatkov o dejanskih učinkih cepljenja v drugih državah.

Kot največje pomanjkljivosti povzemamo tukaj, ter kasneje v diskusiji:

1. Kot **razlog za cepljenje** navajate samo relativno povečano tveganje nosečnic v primerjavi z nenosečimi ženskami za hujši potek bolezni. Ni pa podanih izračunov, kolikšno je dejansko absolutno tveganje nosečnic za tak potek, kakšni so realni podatki in izkušnje enega leta v Sloveniji glede teh potekov, ter kakšni so rezultati teh hujših potekov : kako vplivajo na nosečnico in na plod. V tem smislu so **tveganja Covid bolezni podana pomanjkljivo oz neustrezno**. Potrebno je točno navesti ali predvideti tveganja za posamezno pacientko glede različnih zaključkov poteka bolezni.

2. Sami navajate, da je **cepljenje svetovano, ko so koristi cepljenja večja od tveganj**. V mnenju pa **niste konkretno opredelili niti tveganj (zgoraj), niti koristi cepljenja**. Oziroma se kar predpostavlja korist sama po sebi, v kolikor se nekdo cepi (da je s tem že avtomatsko zaščiten pred težjo boleznijo, kar nikakor ne drži, saj lahko tudi samo cepljenje povzroči težjo bolezen ali smrt – spodaj).

3. **Niste opredelili tveganja za zdravje nosečnice v smislu lažjih in težkih stranskih učinkov cepljenja (adverse events),** ki so poznani že iz kliničnih raziskav, ter so že poznani iz poročil baz v ZDA, EU in VB.

Tveganje za zdravje nikakor ni enako nič, kot bi sklepali, ampak obstaja tudi možnost in verjetnost smrtnega izida po cepljenju. **Niste izračunali verjetnosti pojava vsakega od težjih stranskih učinkov cepljenja,** ter jo primerjali z verjetnostjo učinkov težjega poteka bolezni, **da bi lahko trdili, da je cepljenje manj nevarno od Covid-19 bolezni**. Poleg tega je znano, da s cepljenjem tveganje za Covid bolezen ne izgine, ampak je ta še vedno možna. Poleg tega obstajajo tudi **dolgoročna tveganja za nastanek degenerativnih bolezni kot posledica cepljenja**, ki jih obravnavamo spodaj, ter jih medicinska stroka v celoti ignorira, kot da jih ni.

4. **Niste dovolj natančno opredelili tveganja cepljenja za plod oz. otroka.** Po poročilih povsod opažajo izredno povečanje spontanih splavov, tudi iz študije navajate velik odstotek. Ker pa študija temelji na opazovanju podatkov med poskusom, niti ni zagotovljeno, da so podatki popolni, saj tudi zajemajo samo dva meseca. **Na podlagi te študije dokončno zaključiti, da je tveganje za plod kar enako kot brez cepljenja, je neutemeljeno.** Ni narejenih dolgoročnih študij, ki bi neodvisno potrdile, da ni tveganj za normalen razvoj ploda. Vaša izjava v točki 3, da "Observacijski podatki kažejo, da je cepljenje proti COVID-19 z mRNA cepivi učinkovito in varno za nosečnice in plodove/novorojenčke", ni z ničemer dokazana. Učinkovitosti študija sploh ni preverjala, varnost pa niste definirali, kaj pomeni za vas. **Da je cepljenje učinkovito in varno za nosečnice, na tej podlagi ni mogoče zaključiti**, drugih relevantnih in neodvisnih dolgoročnih študij pa sploh še ni.

5. V ničemer **niste opredelili tveganja cepljenja za normalen fizični in mentalni razvoj ploda oz. otroka**. Ali ni eden temeljnih ciljev vaše stroke, ter pričakovanje staršev, da naredite vse, da se otrok rodi zdrav? Ali je to za vas sprejemljiv rezultat, da se otrok sicer rodi živ, ima pa hude mentalne ali fizične okvare zaradi cepljenja? Boste naložili nosečnicam tveganje bremena doživljenjske skrbi za poškodovanega otroka zaradi nepotrebnega cepljenja? Očitno je to po novem sprejemljivo in normalno za stroko, glede na vaše podano mnenje. Nasprotno pa menimo, da **dokler niso opravljene neodvisne študije o posledicah cepljenja na razvoj ploda**, in dokler ne bodo pokazale rezultatov neškodljivosti cepiva za plod, **je predlagati cepljenje nosečnic v nasprotju z zdravniško etiko, prisego, in zakonodajo ter mednarodnimi konvencijami**. Navajamo spodaj mnenje pravnika dr. Andraža Terška.

6. Opredelili ste se, da je cepljenje nosečnic z mRNA cepivi upravičeno. **Niste pa poskrbeli oziroma predvideli, kako in na kakšen način mora biti vsaka posamezna nosečnica seznanjena z vsemi tveganji tega posega, da bo lahko podala svojo informirano privolitev v poseg.** Niste torej opredelili tveganj, ki jim je nosečnica izpostavljena s cepljenjem, da bo lahko o njih pravočasno obveščena in seznanjena pred posegom. **Brez objektivnega informiranja nosečnice ne more biti podano informirano soglasje**, ter je **poseg s cepljenjem v resnici nezakonit ter v nasprotju z mednarodnimi konvencijami** (Nurnberg). Na splošno se po mnenju dr. Terška celotno cepljenje izvaja brez pridobitve informiranega soglasja pacientov, saj jim niso objektivno predstavljena tveganja za njihovo zdravje zaradi tega posega.

7. Številni **ugledni svetovni znanstveniki in zdravniki so izrazili pomisleke** glede masovnega cepljenja z mRNA tehnologijo, **v odsotnosti trdnih dokazov o njenem delovanju** in dolgotrajnih učinkih, **in zahtevajo ustavitev cepljenja.** Navajajo številne nove študije, ki kažejo na **hudo patogenost Spike proteina**, ki ga telo izdeluje kot posledico cepljenja, ker sam ta protein povzroča številne okvare na različnih nivojih in organih, ter nevro-degenerativne bolezni. Že samo dejstvo, da **tehnologija mRNA**

še nikoli ni bila preizkušena na ljudeh, da jo je financirala ameriška vojska, da v 10 letih razvoja niso prejeli niti ene odobritve za uporabo razvitih mRNA genskih terapij (Moderna), nam narekuje skrajno previdnost pri njeni masovni uporabi, še posebno na najbolj ranljivi populaciji nosečnic. V prilogi navajamo kopijo članka, ki povzema najnovejše ugotovitve, ter zahteva preklic masovnega cepilnega programa, dokler ne bo trdnih dokazov o varnosti. Podatki iz številnih držav kažejo, da se po pričetku cepljenja prične povečevati število Covid-19 primerov in smrti (Indija, Madžarska, VB ..). Število smrtnih primerov in hudih reakcij, ki so sporočena v sisteme spremljanja, se je povečalo vsaj za 10x glede na predhodna cepljenja, pri čemer je ocena, da je sporočenih samo 1 % realnih dogodkov.

8. **Številni izredno hudi učinki cepljenja** se že kažejo v številnih državah po svetu, in tudi pri nas, kar v popolnosti potrjuje vnaprejšnja opozorila in trditve neodvisnih strokovnjakov. **Še nikoli v zgodovini namreč ni nobeno cepljenje povzročilo tako hudih stranskih učinkov, kot cepiva proti Covid-19.** Slovenska javnost ni s strani medicinske stroke v nobenem smislu informirana, da je v bazah stranskih učinkov navedenih že **več kot 13.000 smrtnih primerov po cepljenju**, ter pol milijona poškodb, ob tem, da je vpis prostovoljen, in da tako zajema samo 1% realnih primerov. **V ZDA je število žrtev cepljenja v treh mesecih (torej vpisanih, ne vseh) že preseglo skupno število v zadnjih 20 letih, torej so ta cepiva neprimerljivo bolj nevarna od klasičnih.** Leta 1976 so cepljenje proti "swine flu" ustavili pri 25 primerih smrti, sedaj pa je ta številka že čez 4.000, in se cepljenje nadaljuje povsod po svetu. **Ni bila narejena analiza učinkov dosedanjega cepljenja pri nas glede stranskih učinkov**. Na FB pa so objavljena alarmantna sporočila negovalcev iz DSO o nepričakovanih smrtih, medicinskih sester iz bolnišnic, medicinske sestre, poškodovane po izsiljenem cepljenju, sorodnikov umrlih po cepljenju, ter poškodovane dijakinje po cepljenju maturantov. Dokler niso raziskane in popolnoma jasne posledice cepiv, mora biti **upoštevana skrajna previdnost pri vseh skupinah, predvsem mladih, ženskah in nosečnicah.**

Zaključek

Zaradi tega prosimo, da preučite naše argumente in obrazložitve, ter podane dokaze.

V luči podanih obrazložitev in pozivov številnih uglednih znanstvenikov menimo, da je edini smotrn, etičen in odgovoren zaključek, da se s cepljenjem ranljive skupine nosečih žensk počaka, dokler ni varnost cepiv nedvoumno znanstveno utemeljena in potrjena z neodvisnimi študijami.

Obrazložitev in diskusija

1. **Razlog za cepljenje oziroma koristi cepljenja za pacienta**

Kot edini razlog oz. potrebo po cepljenju nosečnic navajate tveganje za hujši potek bolezni Covid-19. Pri tem izpostavljate : relativni faktor 2-4x povečanega tveganja za hujši potek bolezni glede na ženske enakih let, pogostejši sprejem v int.terapijo, pogostejša meh.ventilacija, povečano tveganje za smrt. Večje tveganje za carski rez in prezgodnji porod.

Študija je meta-analiza 192 drugih kliničnih študij, kar pomeni, da so rezultati samo do neke mere zanesljivi, ker vsaka od teh 192 študij lahko uporablja malo drugačno metodologijo. Iz študije lahko izluščimo povprečno stopnjo tveganja nosečnic za bolezen Covid-19 (ni jasno, ali je to samo PCR- pozitivno, ali klinični znaki bolezni), ki znaša 34047/576075 = 5,9 %.

Iz študije nikakor enoznačno ne izhaja, da bi bile nosečnice s Covid-19 veliko bolj ogrožene, kot neokužene, ali primerjalna skupina žensk.

Nasprotno:

- v primerjavi z ne-nosečimi ženskami s Covid-19, je pri nosečih zmanjšana verjetnost praktično vseh simptomov bolezni (vročina, dispneja, myalgia) – Tabela 2, Covid-19 so torej bile v večji meri asimptomatične.
- Pri nosečih s Covid-19 je v primerjavi z nenosečimi ženskami s Covid-19 rahlo, vendar minimalno povečana verjetnost sprejema na intenzivno nego (1,8% proti 1,7%) ter ventilacije (0,8% proti 0,6%), vendar pa je hkrati **polovično nižja smrtnost** (0,3% proti 0,6%). Skupna smrtnost nosečnic z Covid-19 preko 59 študij (41.664 oseb, 339 smrti) v vseh študijah je bila 0,8%.
- Študija tudi poudarja, da so v obravnavani analizi 192 študij zaznali bistvena odstopanja rezultatov glede izidov za zdravje (nosečnice, plod), kar je posledica različnih metodologij in vzorčenja, torej skupni rezultati še zdaleč niso popolnoma zanesljivi.

Table 1 | Outcomes in pregnant and recently pregnant women with coronavirus disease 2019 (covid-19)

Outcomes	No of studies	Women (No with event/No in group (%))		Odds ratio (95% CI)	I^2 (%)
		Pregnant women with covid-19	Comparison group		
Comparison group: non-pregnant women of reproductive age with covid-19					
All cause mortality	8	103/34 047 (0.3)	3388/567 075 (0.6)	0.96 (0.79 to 1.18)	0
ICU admission	7	616/34 035 (1.8)	9568/567 073 (1.7)	2.13 (1.54 to 2.95)	71.2
Invasive ventilation	6	270/34 001 (0.8)	3280/567 043 (0.6)	2.59 (2.28 to 2.94)	0
ECMO	2	17/30 446 (0.1)	120/431 490 (0.0)	2.02 (1.22 to 3.34)	0
Oxygen through nasal cannula	2	8/48 (16.7)	49/106 (46.2)	0.21 (0.04 to 1.13)	65.7
ARDS	1	0/17 (0)	0/26 (0)	1.51 (0.03 to 79.93)	NE
Major organ failure	1	0/17 (0)	0/26 (0)	1.51 (0.03 to 79.93)	NE
Comparison group: pregnant women without covid-19					
Maternal outcomes:					
All cause mortality	8*	8/1195 (0.7)	8/3625 (0.2)	2.85 (1.08 to 7.52)	0
ICU admission	7*	64/1508 (4.2)	4/3482 (0.1)	18.58 (7.53 to 45.82)	0
Preterm birth <37 weeks	18	147/1184 (12.4)	572/7365 (7.8)	1.47 (1.14 to 1.91)	18.6
Caesarean section	21*†	669/1854 (36.1)	4221/11842 (35.6)	1.12 (0.91 to 1.38)	57.6
Perinatal outcomes:					
Stillbirth	9*	9/1039 (0.9)	26/4755 (0.5)	2.84 (1.25 to 6.45)	0
Neonatal death	8*	4/970 (0.4)	5/3316 (0.2)	2.77 (0.92 to 8.37)	0
Admission to neonatal unit	10*	329/1285 (25.6)	519/4588 (11.3)	4.89 (1.87 to 12.81)	96.2
Abnormal Apgar score at 5 minutes	6	13/662 (2.0)	46/2823 (1.6)	1.38 (0.71 to 2.70)	0
Fetal distress	2	11/77 (14.3)	13/263 (4.9)	2.37 (0.77 to 7.31)	0

Iz Tabele 1, vsekakor ni razbrati 2-4x povečanega tveganja glede na ženske enakih let, kot trdite.

Navajate torej samo podatke iz tuje meta-študije, ne navajate pa klinične prakse pri nas, ali ste res zaznali bistveno povišanje tveganja nosečih s Covid-19.

Če bi sklepali po podatkih smrtnosti tega svetovnega pregleda študij kot smrtnost nosečih žensk brez Covid 0,2%, bi to pri nas pomenilo od 18.000 žensk kar 36 smrtnih primerov.

Glede smrtnosti okuženih s Covid-19, pa bi pri 5,9% okužbi to pomenilo 1062 okuženih nosečnic, in pri smrtnosti teh 0,7% bi to pomenilo 7 smrtnih primerov s Covid-19. Nismo zasledili, da bi pri nas obstajal tako velik problem bolezni in smrti s Covid-19 pri nosečnicah, torej uporaba teh rezultatov s celega sveta in **posploševanje na razmere pri nas ni možna,** saj so tudi zdravstveni sistemi in splošne razmere po svetu zelo različne. Omenjena (svetovna) meta-analiza **torej ne dokazuje, da so v Sloveniji nosečnice s Covid-19 pozitivnim PCR testom kaj posebno ogrožene, in da zaradi tega nujno potrebujejo poseg s cepljenjem proti Covid-19.**

2. Niste opredelili koristi cepljenja, da bi jih bilo možno sploh primerjati s tveganji, torej bistvenega pogoja za cepljenje sploh ne moremo preveriti, ker ne poznamo koristi.

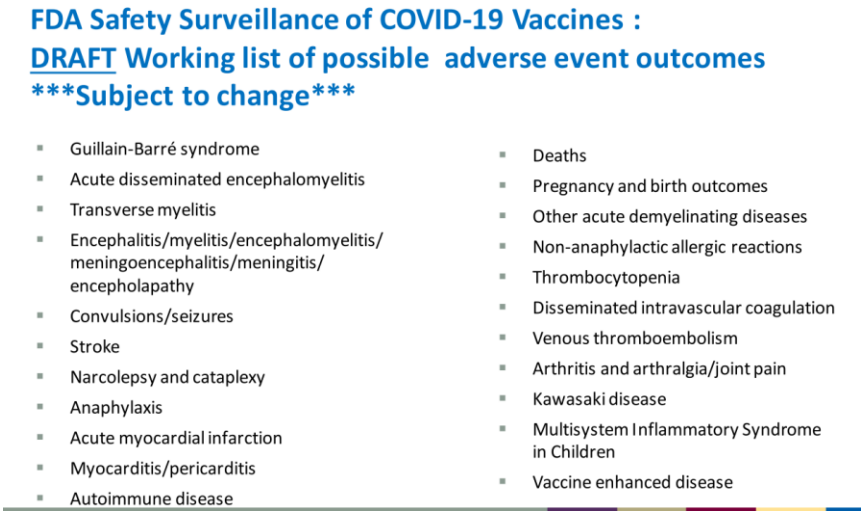
Kot vemo, cepljenje ne zagotavlja čudežnega zdravila proti vsem simptomom ali proti bolezni Covid-19, kar kažejo tudi podatki – številni namreč po cepljenju ravno tako zbolijo za enakimi simptomi.

3.

Niste opredelili tveganja za zdravje nosečnice v smislu lažjih in težkih stranskih učinkov cepljenja (adverse events). Niste izračunali, kakšne posledice bo imelo cepljenje populacije.

Tveganja za stranske učinke so realna in se kažejo v vpisih teh učinkov v sisteme spremljanja VAERS in sistem EMA. Tveganja vključujejo zelo hude zaplete, ki jih je predvidel že proizvajalec in tudi FDA.

V svoji predstavitvi oktobra 2020, "CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness", je Steve Anderson, PhD, MPP, Director, Office of Biostatistics & Epidemiology, CBER, navedel možna tveganja mRNA cepiv, tudi dolgoročna:



V študij Penn University pa so pregledali mRNA tehnologijo in obstoječe študije, predvsem stranske učinke, in navajamo rezultate.

ADVERSE EFFECTS OF MESSENGER RNA VACCINES

An Evidence Review from the Penn Medicine Center for Evidence-based Practice
December 2020

Project director: ..... Nikhil K. Mull, MD (CEP)
Lead analyst: ..... Matthew D. Mitchell, PhD (CEP)
Clinical review: ..... Patrick J. Brennan, MD. (CMO)

Keywords: COVID-19, vaccine, messenger RNA, adverse effects

EVIDENCE SUMMARY

- There are no specific guidelines for use of messenger RNA (mRNA) vaccines or contraindications to mRNA vaccines.
- No large trials of any mRNA vaccine have been completed yet.
- The only evidence on safety of mRNA vaccines comes from small phase I and phase II trials of SARS-CoV-2 vaccines, with follow-up typically less than two months.
- Systemic adverse events such as fatigue, muscle aches, headache, and chills are common.
- Severe systemic adverse events were reported by 5 to 10 percent of trial subjects.
- Localized adverse events such as pain at the injection side are common.
- Both systemic and local adverse events usually are resolved within one or two days.
- The rate and severity of adverse events appears to be higher for the second dose of vaccine than for the first.
- Higher vaccine doses appear to increase the rate and severity of adverse events.
- Larger trials of SARS-CoV-2 vaccines are in progress, with results expected in mid-2021.
- There is not sufficient evidence to support any conclusions on the comparative safety of different mRNA vaccines.
- Direct evidence on the comparative safety of mRNA vaccines and other vaccines is lacking.

Najpomembnejši rezultat je, da se pojavljajo **hudi sistemski stranski učinki** (severe systemic adverse events) pri **kar 5 do 10% testiranih oseb**. Hude stranske učinke zaznava tudi baza VAERS, čeprav z veliko zamudo, ter z zelo majhno stopnjo dejanskega vpisa podatkov, ki je okrog 1%.

Ti zaključki nikakor ne podpirajo mnenja, da je mRNA tehnologija varna.

Če bi predpostavili, da se cepi celotna populacija 18.000 nosečnic, bi torej **hudi stranski učinki**, ki so gotovo tudi nevarni za plod, nastopili pri **900 do 1800 nosečnicah**.

Če to primerjamo s prej navedenih potencialno 1062 okuženih nosečnic, od katerih pa večina nima posebnih zapletov, je torej **tveganje stranskih učinkov cepljenja bistveno višje (zaradi večje populacije) kot tveganje Covid-19 pozitivnosti za težje zaplete.**

Ni bilo torej dokazano, da je tveganje cepljenja celotne populacije nosečnic manjše kot tveganje okužbe in bolezni Covid-19, ampak ravno nasprotno.

S cepljenjem je torej na kocki življenje in zdravje tako nosečnice kot otroka. Ali so koristi cepljenja za posamezno nosečnico znane in jasne, da opravičujejo tako veliko, praktično največje možno tveganje posega?

Tega niste dokazali ali pokazali, da je tveganje smrti za nosečnico opravičljivo s stališča njenih koristi. V kolikor to ni jasno dokazano, se tak poseg za ceno zdravja pacienta po načelu previdnosti ne sme izvršiti, saj je prvo pravilo : ne škodi pacientu.

Zmanjševanje pomena ali verjetnosti za znane težje zaplete, ki jih sami omenjate v mnenju, ni primerno, saj jim bodo izpostavljene tako nosečnice kot plod.

5.

V ničemer **niste opredelili tveganja cepljenja za normalen fizični in mentalni razvoj ploda oz. otroka**.

Sama študija, na katero se sklicujete, v zaključku ugotavlja, navajam:

> **Preliminary findings** did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines. However, **more longitudinal follow-up**, including follow-up of large numbers of women vaccinated earlier in pregnancy, **is necessary to inform maternal**, **pregnancy**, and **infant outcomes.**

Študija podaja preliminarne rezultate, in ne omogoča nobenega sklepanja, da je cepljenje varno za otroka. **Ni torej znanstveno dokazano**, da je cepljenje **nenevarno** in **neškodljivo za normalen razvoj otroka**, zato princip previdnosti narekuje, **da se takšne intervencije ne smejo izvajati** (razen v kolikor gre za poskus z inf. soglasjem), še posebno, **ker tudi koristi tega posega niso v ničemer dokazane**.

6. Informirano soglasje nosečnic ter njihovo objektivno informiranje ni v ničemer zagotovljeno.

Pravnik Dr. Andraž Teršek je objavil "**Memorandum o očitni in pravno nedopustni prisili ljudi v medicinske posege in o pravno prepovedanem eksperimentiranju z ljudmi**". Povzetek njegovega mnenja:

https://andraz-tersek.si/memorandum-o-ocitni-in-pravno-nedopustni-prisili-ljudi-v-medicinske-posege-in-o-pravno-prepovedanem-eksperimentiranju-z-ljudmi/

> *18. člen Ustave RS: 2 (prepoved mučenja) : Na človeku je prepovedano delati medicinske ali druge znanstvene poskuse brez njegove svobodne privolitve.*
>
> *Posameznika se ne sme »žrtvovati« s sklicevanjem na javni ali znanstveni interes. To ne bi bilo samo protipravno in neetično, ampak tudi nemoralno (op.: treba je razumeti razliko med etiko in moralo, zlasti pa razlago koncepta »normativna etika«). Medicina mora biti zavezana k resnici, resnicoljubnosti in poštenju.*
>
> *Zapisal bom še eno vprašanje: je ob vsem, kar javnost ve o cepivih, predvsem pa ob vsem, kar javnost ne ve o cepivih, pa ob vsem, kar se o njih že ve in je to zaskrbljujoče, predvsem pa ob tistem, kar se o njih ne ve, ali še ne ve in kar o njih ne vedo, ali še ne vedo niti predstavniki medicinske znanosti, dogaja »medicinski, politični in socialni eksperiment« z ljudmi? Trdim, da se. Je ta eksperiment »vsiljen«, izsiljen, smo ljudje v to prisiljeni? Trdim, da smo.*
>
> ***Je to medicinsko, etično, moralno in pravno dopustno? Trdim, da ni.***

7. Ozadja in rezultati masovnega cepljenja proti Covid-19

Ugledni zdravniki, npr. dr. McCullough, ki je razvil uspešno metodo zgodnjega zdravljenja Covid (https://aapsonline.org/) , ter objavil najbolj citiran članek o zdravljenju, opozarjajo in zahtevajo strokovne odgovore od pristojnih inštitucij, o dejanskih učinkih in varnosti masovne cepilne kampanije po svetu (priloga A). Opozarjajo na **visoko stopnjo pojavljanja hudih stranskih učinkov, ter nepoznane dolgoročne učinke nove tehnologije mRNA na človekovo telo, ter reprodukcijsko sposobnost**. Uradna medicina in politika namreč minimizirata tveganja, povezana s cepljenjem, ter cepljenje prestavljata kot edino rešitev za epidemijo.

Cepilna kampanija oziroma obstoječa cepiva v uporabi (mRNA, adenovirusna) so sporna v naslednjih točkah:

- **mRNA tehnologija v 10-letnem razvoju ni uspela pridobiti niti ene odobritve za uporabo na ljudeh** (Moderna, razvoj genskih terapij), ker niso uspeli zadovoljivo pojasniti, kakšen bo dolgoročen vpliv

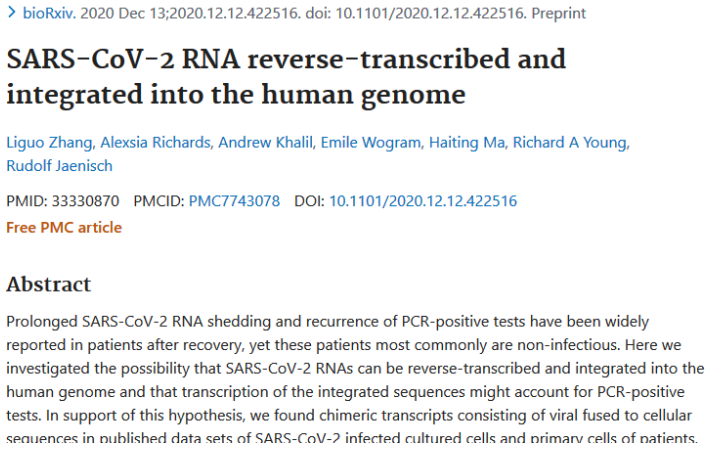
mRNA na celice organizma. V letu 2021 pa to očitno ni več potrebno, ampak se lahko z nepreverjeno tehnologijo cepi celotna svetovna populacija, kar je eksperiment z zdravjem ljudi.

- **Razvoj mRNA cepiv v 2020 je v celoti z 10 milijardami dolarjev financirala vojska ZDA**, in celotno operacijo "Warp speed" razvoja in distribucije cepiv so vodili generali ameriške vojske. Kakšni so cilji ameriške vojske, lahko samo ugibamo. V vojaških laboratorijih razvijajo mnoge patogene viruse za biološko vojskovanje. https://articles.mercola.com/sites/articles/archive/2020/11/15/operation-warp-speed.aspx

- **Raziskave in razvoj vedno bolj patogenih in infektivnih virusov (etično izredno sporni gain-of-function research)** je v zadnjih 20 letih večinsko financirala ameriška vojska, preostalo pa inštituti kot NIH. Raziskave so potekale na ameriških univerzah (dr Baric) in v laboratoriju v Wuhanu (Zhengli), katerega znanstveniki so objavili izboljšane variante koronavirusov. Zgodovina teh raziskav je znana, ter je pripeljala do izredno nevarnega in človeku prilagojenega spike proteina, ki je del virusa SARS-COV-2, hkrati pa tudi nastaja v telesu kot posledica cepljenja.

- **Masovna kampanja cepljenja v EU je bila načrtovana dolgoročno in že leta 2019**, torej pred epidemijo, torej pred pojavom vzroka, zaradi katerega je potrebna?? To dokazujejo uradni dokumenti Evropske komisije, ter organizacija **Global Vaccination Summit, septembra 2019 v Bruslju**, kjer so se srečali vsi proizvajalci in promotorji cepiv, WHO in EU. **Sklenjeno je bilo, da je potrebno uvesti cepljenja celotnega prebivalstva**, kljub temu, da za to ni nikakršne potrebe. Ravno tako je uvedba Zelenih certifikatov že nekaj let planirana v Bruslju. To vse dokazuje, da gre v celotni zgodbi cepljenja za neke vrste zaroto birokratov s farma industrijo in drugimi zakulisnimi lobiji, kajti o teh odločitvah niso odločali ljudje in države. https://ec.europa.eu/health/vaccination/ev_20190912_en

- **Virusna RNA se reverzno prepiše v človekov genom, in ga tako trajno spreminja**. Še zdaleč torej ni resnica, da cepljenje nima dolgoročnih posledic na človeka in njegovo genetiko. (članek: bioRxiv doi: 10.1101/2020.12.12.422516. : SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome), https://pubmed.ncbi.nlm.nih.gov/33330870/



› bioRxiv. 2020 Dec 13;2020.12.12.422516. doi: 10.1101/2020.12.12.422516. Preprint

SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome

Liguo Zhang, Alexsia Richards, Andrew Khalil, Emile Wogram, Haiting Ma, Richard A Young, Rudolf Jaenisch

PMID: 33330870 PMCID: PMC7743078 DOI: 10.1101/2020.12.12.422516

Free PMC article

Abstract

Prolonged SARS-CoV-2 RNA shedding and recurrence of PCR-positive tests have been widely reported in patients after recovery, yet these patients most commonly are non-infectious. Here we investigated the possibility that SARS-CoV-2 RNAs can be reverse-transcribed and integrated into the human genome and that transcription of the integrated sequences might account for PCR-positive tests. In support of this hypothesis, we found chimeric transcripts consisting of viral fused to cellular sequences in published data sets of SARS-CoV-2 infected cultured cells and primary cells of patients.

- **Številni znanstveniki opozarjajo na možnost hudih in trajnih posledic za reproduktivno zdravje**, ker je spike protein zelo podoben telesnim proteinom, ter zato zahtevajo prekinitev cepljenja. Nobena

študija ni potrdila, da se to ne more zgoditi, nasprotno, obstaja čedalje več poročil o 400% povečanju spontanih splavov in nezmožnosti oploditve.

> Janci Chunn Lindsay: **Covid vaccines could induce cross-reactive antibodies to syncytin, and impair fertility as well as pregnancy outcomes**
>
> **First, there is a credible reason to believe that the Covid vaccines will cross-react with the syncytin and reproductive proteins in sperm, ova, and placenta, leading to impaired fertility and impaired reproductive and gestational outcomes.**
>
> Respected virologist Dr. Bill Gallaher, Ph.D., made excellent arguments as to why you would expect cross reaction. Due to beta sheet conformation similarities between spike proteins and syncytin-1 and syncytin-2.
>
> I have yet to see a single immunological study which disproves this. Despite the fact that it would literally take the manufacturers a single day to do these syncytin studies to ascertain this [once they had serum from vaccinated individuals]. It's been over a year since the assertions were first made that this [the body attacking its own syncytin proteins due to similarity in spike protein structure] could occur.
>
> https://www.jennifermargulis.net/halt-covid-vaccine-research-scientist-urges-cdc/

- **Dr. Wodarg in dr. Fleming** (pripeto na koncu)**, pa tudi dr. Bhakdi, pojasnjujeta razlike in podobnosti med delovanjem infekcije z SARS-COV-2 po respiratorni poti, ter vnosom cepiva direktno v mišico in v kri.** Pri naravni infekciji s koronavirusom preko respiratornih poti bo 99% teh infekcij potekalo brez težav, saj bo imunski sistem preko T-celic, ki so križno imune na koronaviruse, zaustavil infekcijo že v dihalih, in ne bo prišlo do vnosa spike proteina v kri in sistemskih zapletov, razen v redkih primerih hujše bolezni.

  Nasprotno pa je pri Covid-19 cepljenju ta naravni obrambni mehanizem preskočen, saj pride do direktnega **vnosa genetsko modificiranih nano-delcev v mišice** (13 milijard delcev). Ko pričnejo celice mišice proizvajati spike protein, pride do boleče lokalne imunske reakcije. Povsem verjetno pa je, da cepivo doseže kri in se razširi po telesu, ter bodo endotelijske celice pričele po vsem telesu proizvajati škodljivi spike protein. Spike protein v krvi pa se veže na ACE2 receptorje rdečih krvnih telesc, kar vodi k strjevanju in trombozi.
  Oba znanstvenika v svojih analizah zaključujeta, da je cepljenje proti COVID-19 s to tehnologijo reprogramiranja celic za proizvodnjo spike proteina, izredno in veliko bolj nevarno kot sama naravna okužba preko dihalnih poti. Tako ustvarjena proti-telesa pa niti približno ne zagotavljajo tako široke, trajne ter učinkovite imunosti v primerjavi z naravno okužbo in T-celicami. V tem smislu **so cepiva tudi neučinkovita**, ko protitelesa upadejo (po treh mesecih), ter neučinkovita proti mutacijam.

  https://www.wodarg.com/english/

  https://www.flemingmethod.com/

  https://www.globalresearch.ca/dr-sucharit-bhakdi-interview-covid-vaccine-blood-clot-risk-known-ignored-buried/5744010

https://www.globalresearch.ca/new-report-sheds-light-vaccine-doomsday-cult/5744267

Povzeto iz članka: Now there is solid evidence that:

> **Covid-19 is primarily a disease of the vascular system** (The vascular system, also called the circulatory system, is made up of the vessels that carry blood and lymph through the body.) and not the respiratory system.
>
> **The main culprit is the spike protein**. (Spike protein–"a glycoprotein that protrudes from the envelope of some viruses" Merriam-Webster "Like a key in a lock, these spike proteins fuse to receptors on the surface of cells, allowing the virus's genetic code to invade the host cell, take over its machinery and replicate." Bruce Lieberman)

- **Spike protein**, katerega proizvodnjo povzročijo cepiva, je tisti **ključni patogeni element virusa**, ki dejansko povzroča težko bolezen (kardio-vaskularno bolezen, nevrološke bolezni ..). To pomeni, **da so cepiva, ki generirajo proizvodnjo spike, proteina, nedvomno škodljiva za zdravje oziroma povzročajo bolezen, nekateri pa jih označujejo za biološko orožje.**

  https://www.salk.edu/news-release/the-novel-coronavirus-spike-protein-plays-additional-key-role-in-illness/

  SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE2

  The paper, published on April 30, 2021, in *Circulation Research*, also shows conclusively that COVID-19 is a vascular disease, demonstrating exactly how the SARS-CoV-2 virus damages and attacks the vascular system on a cellular level. The findings help explain COVID-19's wide variety of seemingly unconnected complications, and could open the door for new research into more effective therapies.

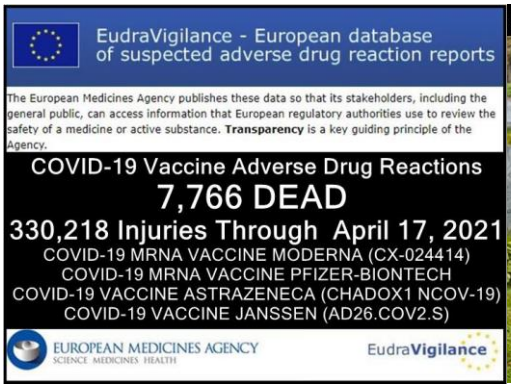
- **Spike protein, torej tudi Covid-19 cepiva,** lahko povzročijo nevrološke spremembe oziroma **prionske nevrodegenerativne bolezni**, kot je neozdravljiva in smrtna Creutzfeldt-Jakob bolezen (CJD) oziroma bolezen norih krav. **Cepljenje torej predstavlja tveganje za smrtonosno bolezen možganov.**

  https://greatgameindia.com/mrna-vaccines-degenerate-brain-prion/

8. Dosedaj poznani podatki o številnih stranskih učinkih in žrtvah cepljenja po svetu in pri nas

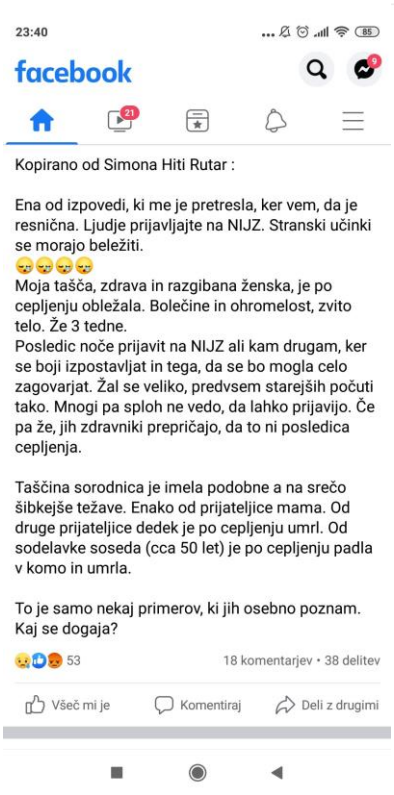
Po svetu so v okviru sistemov spremljanja Vaers in Eduvigilance na voljo delni podatki o stranskih učinkih po cepljenju, **ki pa so izredno alarmantni**. V ZDA beležijo že **več žrtev cepljenja v treh mesecih kot v zadnjih 20 letih,** skupaj več kot 4.000, študije pa kažejo, da se v resnici v sistem vpiše samo 1% posledic cepiv.

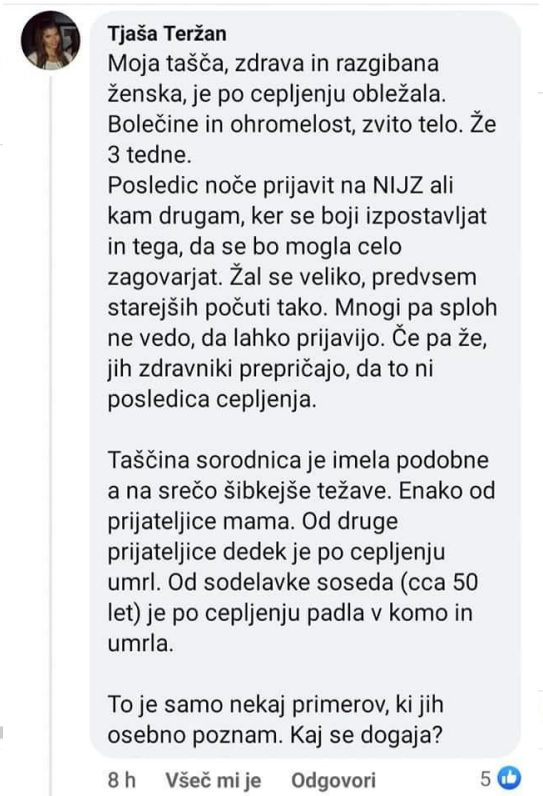
V Evropi več kot 330.000 poškodovanih, zelo verjetno pa mnogo več, saj države zelo različno vpisujejo podatke v sistem (največ Nizozemska, velike države pa malo vpisov, Slovenija praktično nič).

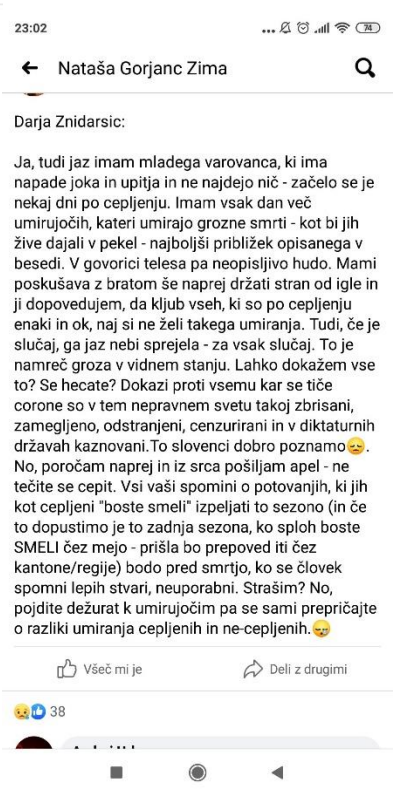


Vir: https://healthimpactnews.com

Posledice pri nas so, smrti in hude poškodbe, vendar ne pridejo v medije in v javnost. Ljudje, ki pa osebno poznajo primere posledic cepljenja in žrtve, **pa se upravičeno sprašujejo "kaj se dogaja"**, in pričakujejo argumentirane odgovore od slovenske medicinske stroke.







9. Vloga slovenske uradne medicine in njenih predstavnikov

Predstavniki medicinske stroke, ki odločajo in govorijo v javnosti, predvsem **profesorji Ihan, Štrukelj, Jerala, Beović, Logar, Čakš-Jager,** in vsi ostali (NIJZ), od jeseni 2020 do sedaj povsem zanikajo kakršnekoli nevarnosti, tveganja cepljenja, **in izključno ponavljajo eno in isto zgodbo o "varnih in učinkovitih cepivih".** Priložena študija DoctorsForCovidEthics pa navaja povsem drugačno zgodbo, in s številnimi viri dokazuje, **da je cepljenje nepotrebno, ni učinkovo in je izredno nevarno predvsem za mlade.** Enako trdijo Dr. Williams, Dr. McCollugh, Dr. Wodarg, Dr. Fleming, ki so na svojih področjih po znansvenih rezultatih eminence v svetovnem merilu, daleč pred slovensko stroko.

Ob znanih in utemeljenih pomislekih svetovne stroke, ob znanih podatkih o hudih poškodbah in posledicah po svetu, lahko to ocenjujemo **samo kot namerno prikrivanje in zavajanje laične javnosti**. S tem se ljudem odvzema možnost objektivne in nepristranske informiranosti, ki bi vodila njihovo odločitev o cepljenju, ki mora biti izključno v korist zdravja posameznika, ne pa za neke interese države, medicine, farme ali koga drugega. **S tem se ljudi zavaja, da sprejemajo nek poseg, ki ima lahko daljnoročne in hude posledice za zdravje, in o tem niso objektivno informirani,** kar je, kot ugotavlja dr.Teršek, v absolutnem nasprotju z zakonodajo.

Profesor Štrukelj je celo zaslovel s svojo strokovno izjavo, sicer nepodprto z znanstvenimi dokazi, da so mRNA cepiva 1000x varnejša od kontracepcijskih tablet. Vendar pa javnost nekako ni opazila te hude smrtnosti kontracepcije, da bi v nekaj mesecih umrlo kakšnih 10 milijonov žensk v Evropi, če jih je za cepivi 10.000.

Kakšni so pri tem skriti cilji in nameni slovenske uradne medicine, kdo in kako na predstavnike vpliva ter s kakšnimi sredstvi, kakšna so pri tem nasprotja interesov, lahko samo ugibamo. Predvidevamo, da raziskovalne projekte MF, FF, KI, večinsko financirata farmacevstka industrija in država prek ARRS. Država oziroma politika pa se je odločila, da je cepljenje nujno in koristno. O neodvisnosti predstojnikov in profesorjev od države tako težko govorimo, zato je vprašljiva tudi objektivnost glede vprašanj cepljenja. **Glede na stotine milijone evrov, ki pa se namenjajo zdravstvu v Sloveniji,** ter glede na dejstvo, da imajo zdravniki kot poklic daleč najvišje plače v državi, **pa si slovenska javnost glede cepljenja in vseh ostalih ukrepov stroke**, ki v največji meri krojijo življenje, delo in možnost zaslužka in preživetja, **zasluži izključno objektivne in nepristranske informacije, v korist pacientu, in ne morebitnim skritim lobijem.**

Mnenje Združenja za perinatalno medicino

ZDRUŽENJE ZA PERINATALNO MEDICINO SLOVENIJE

CEPLJENJE NOSEČNIC PROTI COVID-19

Mnenje Združenja za perinatalno medicino Slovenije:

- Ob okužbi s SARS-CoV-2 imajo nosečnice po trenutnih podatkih dva do štirikrat večje tveganje za hujši potek bolezni kot enako stare nenoseče ženske.
- Nosečnice niso bile vključene v randomizirane raziskave učinkovitosti in varnosti cepiv proti COVID-19.
- Observacijski podatki kažejo, da je cepljenje proti COVID-19 z mRNA cepivi učinkovito in varno za nosečnice in plodove/novorojenčke.
- Ni trdnih podatkov o večjem tveganju za trombotične trombocitopenične zaplete po cepljenju z vektorskimi cepivi pri nosečnicah. Vendar do danes objavljeni prikazi primerov kažejo na morebitno večje tveganje pri ženskah v reproduktivni dobi. Poleg tega je opisano mesto tromboz (npr. tromboza venskega sinusa) pogostejše pri nosečnicah in otročnicah kot pri nenosečih ženskah.
- Menimo, da je na podlagi trenutnih dokazov strokovno upravičeno cepljenje nosečnic proti COVID-19 z mRNA cepivi.

Obrazložitev:

Ob okužbi s SARS-CoV-2 imajo nosečnice dva do štirikrat večje tveganje za hujši potek bolezni kot enako stare nenoseče ženske. Pogosteje so sprejete v enoto intenzivne terapije, pogosteje potrebujejo mehansko ventilacijo in imajo povečano tveganje za smrt (1). Pri okužbi COVID-19 v nosečnosti je po podatkih iz literature večje tveganje za carski rez in za prezgodnji porod, predvsem pri hujšem poteku bolezni (1,2).

V času testiranja cepiv proti COVID-19, so bile nosečnice izključene iz randomiziranih kliničnih preiskav tretje faze in priporočila o cepljenju so bila izdana na podlagi načina delovanja cepiv ter posameznih opisanih primerov. Nacionalna in mednarodna združenja so svetovala cepljenje nosečnic v primerih, ko so koristi cepljenja večja od tveganj. Cepljenje v nosečnosti je strokovno upravičeno pri nosečnicah z večjim tveganjem za okužbo (npr. zdravstvene delavke) in pri nosečnicah z večjim tveganjem za hujši potek bolezni (višji ITM, starejše od 35 let, s pridruženimi obolenji kot so sladkorna bolezen, arterijska hipertenzija, astma…) (3,4).

Od pričetka cepljenja se zbirajo podatki o cepljenju nosečnic. Spremlja se tako učinkovitost cepiv proti COVID-19 v nosečnosti, kot tudi stranske učinke cepljenja pri materi in plodu/novorojenčku. 21.aprila 2021 so bili v NEJM (5) objavljeni trenutni podatki o varnosti cepljenja z mRNA cepivi v nosečnosti na ameriški populaciji. Podatki so bili zbrani od 14. decembra 2020 do 28. februarja 2021 in vključujejo 35 691 nosečnic, starih 16 do 54 let. Nosečnice so pogosteje poročale o bolečini na mestu injiciranja cepiva, medtem ko so imele redkeje glavobol, bolečino v mišicah, vročino in mrzlico kot enako stare nenoseče ženske. V tem času se je zaključilo 827 nosečnosti; do splava je prišlo pri 115 (13,9%), rodilo je 712 (86,1%) žensk. Pojavnost zapletov v nosečnosti in pri novorojencu je bila pri cepljenih nosečnicah, ki so rodile, primerljiva s splošno populacijo in historičnimi podatki izpred pandemije COVID-19 . Med 221 z nosečnostjo povezanih stranskih učinkih cepljenja je bil najpogosteje poročan spontan splav (46 primerov). Zaključek raziskave je, da je po trenutnih obseracijskih podatkih cepljenje z mRNA cepivi v nosečnosti učinkovito in varno.

Pri vektorskih cepivih (AstraZeneca, Johnson & Johnson) se je poročalo o pogostejših trombozah v kombinaciji s trombocitopenijo po cepljenju. Tako evropska kot ameriška agencija za zdravila (EMA,

FDA) sta natančno preučili opisane primere in ugotovili, da koristi pri preprečevanju COVID-19 in povezana tveganja za hospitalizacijo in smrt pretehtajo morebitna tveganja (6,7). Povezavo cepljenja s trombozo v kombinaciji s trombocitopenijo so ocenili kot možno, čeprav zelo redko. EMA po pregledu poročil o trombotičnih trombocitopeničnih zapletih po cepljenju z vektorskimi cepivi proti COVID-19 ni ugotovila povečanega tveganja v določenih populacijah (npr. mlajše ženske, nosečnice…). Vendar se je večina primerov, ki so bili do danes opisani v literaturi, zgodila pri mlajših ženskah. Raziskovalci iz Avstrije in Nemčije so opisali 11 primerov trombotičnih trombocitopeničnih zapletov po cepljenju s cepivom Astra Zenece. Med temi je bilo 9 žensk starih od 22 do 49 let (10). Tudi v norveški seriji so bile štiri od petih opisanih bolnikov ženske, med njimi tri mlajše od 45 let (11). Tudi edini tovrstni v literaturi opisani zaplet po cepljenju s cepivom Johnson & Johnson se je zgodil pri 48 letni ženski (12). V več primerih je opisana tromboza cerebralnega venskega sinusa (7), ki je po podatkih iz literature pogostejša v nosečnosti in po porodu (8,9). Do sedaj je bila cepljena predvsem bolj ogrožena starejša populacija, podatki na mlajših odraslih so redkejši. Prav tako ni bilo do sedaj objavljenih obsežnejših podatkov o cepljenju nosečnic z vektorskimi cepivi.

Glede na trenutno znane podatke menimo, da bi bilo upravičeno cepljenje nosečnic z mRNA COVID-19 cepivi.

Skupina za pripravo in posodabljanje COVID-19 priporočil v porodništvu:

Marijana Vidmar Šimic, dr. med., prof. dr. Miha Lučovnik, dr. med., doc. dr. Tanja Premru Sršen, dr. med., Mirjam Druškovič, dr. med., mag. Lili Steblovnik, dr. med., mag. Gorazd Kavšek, dr. med., svetnik, doc. dr. Andreja Trojner Bregar, dr. med., prof. dr. Alojz Ihan, dr. med.

Ljubljana, 25.4.2021

1. Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, et al; for PregCOV-19 Living Systematic Review Consortium. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ. 2020 Sep 1;370:m3320. doi: 10.1136/bmj.m3320. PMID: 32873575; PMCID: PMC7459193.
2. Knight M, Bunch K, Vousden N, Morris E, Simpson N, et al; UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study. BMJ. 2020 Jun 8;369:m2107. doi: 10.1136/bmj.m2107. PMID: 32513659; PMCID: PMC7277610.
3. Dostopno na: COVID19_cepljenje.pdf (kclj.si)
4. Dostopno na: Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination, 30 December 2020 - GOV.UK (www.gov.uk)
5. Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, et al; CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. N Engl J Med. 2021 Apr 21. doi: 10.1056/NEJMoa2104983. Epub ahead of print. PMID: 33882218.
6. Dostopno na: VAXZEVRIA/COVID-19 Vaccine AstraZeneca: link between the vaccine and the occurrence of thrombosis in combination with thrombocytopenia (europa.eu)

7. Dostopno na: FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review | FDA
8. Nasr DM, Brinjikji W, Cloft HJ, Saposnik G, Rabinstein AA. Mortality in cerebral venous thrombosis: results from the national inpatient sample database. Cerebrovasc Dis. 2013;35(1):40-4. doi: 10.1159/000343653. Epub 2013 Feb 14. PMID: 23428995Alet M,
9. Ciardi C, Alemán A, Bandeo L, Bonardo P, et al.; Argentinian Stroke and Cerebrovascular Diseases Study Group - Argentine Neurological Society. Cerebral venous thrombosis in Argentina: clinical presentation, predisposing factors, outcomes and literature review. J Stroke Cerebrovasc Dis. 2020 Oct;29(10):105145. doi: 10.1016/j.jstrokecerebrovasdis.2020.105145. Epub 2020 Jul 28. PMID: 32912503.
10. Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, et al. Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination. N Engl J Med. 2021 Apr 9. doi: 10.1056/NEJMoa2104840. Epub ahead of print. PMID: 33835769.
11. Schultz NH, Sørvoll IH, Michelsen AE, Munthe LA, Lund-Johansen F, et al. Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination. N Engl J Med. 2021 Apr 9. doi: 10.1056/NEJMoa2104882. Epub ahead of print. PMID: 33835768.
12. Muir KL, Kallam A, Koepsell SA, Gundabolu K. Thrombotic Thrombocytopenia after Ad26.COV2.S Vaccination. N Engl J Med. 2021 Apr 14. doi: 10.1056/NEJMc2105869. Epub ahead of print. PMID: 33852795.

Cepljenje proti COVID-19: analiza znanstvenikov in zdravnikov

57 uglednih znanstvenikov na čelu z dr. Petrom McCulloughom, povzema številna odprta vprašanja cepljenja COVID-19, ki odpirajo dvom v smotrnost in predvsem varnost masovnega programa cepljenja, in pričakujejo jasne odgovore od pristojnih inštitucij.

Vir: https://en-volve.com/2021/05/08/57-top-scientists-and-doctors-release-shocking-study-on-covid-vaccines-and-demand-immediate-stop-to-all-vaccinations/

SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers

Roxana Bruno[1], Peter McCullough[2], Teresa Forcades i Vila[3], Alexandra Henrion-Caude[4], Teresa García-Gasca[5], Galina P. Zaitzeva[6], Sally Priester[7], María J. Martínez Albarracín[8], Alejandro Sousa-Escandon[9], Fernando López Mirones[10], Bartomeu Payeras Cifre[11], Almudena Zaragoza Velilla[10], Leopoldo M. Borini[1], Mario Mas[1], Ramiro Salazar[1], Edgardo Schinder[1], Eduardo A Yahbes[1], Marcela Witt[1], Mariana Salmeron[1], Patricia Fernández[1], Miriam M. Marchesini[1], Alberto J. Kajihara[1], Marisol V. de la Riva[1], Patricia J. Chimeno[1], Paola A. Grellet[1], Matelda Lisdero[1], Pamela Mas[1], Abelardo J. Gatica Baudo[12], Elisabeth Retamoza[12], Oscar Botta[13], Chinda C. Brandolino[13], Javier Sciuto[14], Mario Cabrera Avivar[14], Mauricio Castillo[15], Patricio Villarroel[15], Emilia P. Poblete Rojas[15], Bárbara Aguayo[15], Dan I. Macías Flores[15], Jose V. Rossell[16], Julio C. Sarmiento[17], Victor Andrade-Sotomayor[17], Wilfredo R. Stokes Baltazar[18], Virna Cedeño Escobar[19], Ulises Arrúa[20], Atilio Farina del Río[21], Tatiana Campos Esquivel[22], Patricia Callisperis[23], María Eugenia Barrientos[24], Karina Acevedo-Whitehouse[5],*

* Correspondence: Karina Acevedo-Whitehouse, karina.acevedo.whitehouse@uaq.mx

Abstract

Since the start of the COVID-19 outbreak, the race for testing new platforms designed to confer immunity against SARS-CoV-2, has been rampant and unprecedented, leading to emergency authorization of various vaccines. Despite progress on early multidrug therapy for COVID-19 patients, the current mandate is to immunize the world population as quickly as possible. The lack of thorough testing in animals prior to clinical trials, and authorization based on safety data generated during trials that lasted less than 3.5 months, raise questions regarding the safety of these vaccines. The recently identified role of SARS-CoV-2 glycoprotein Spike for inducing endothelial damage characteristic of COVID-19, even in absence of infection, is extremely relevant given that most of the authorized vaccines induce the production of Spike glycoprotein in the recipients. Given the high rate of occurrence of adverse effects, and the wide range of types of adverse effects that have been reported to date, as well as the potential for vaccine-driven disease enhancement, Th2-immunopathology, autoimmunity, and immune evasion, there is a need for a better understanding of the benefits and risks of mass vaccination, particularly in the groups that were excluded in the clinical trials. Despite calls for caution, the risks of SARS-CoV-2 vaccination have been minimized or ignored by health organizations and government authorities. We appeal to the need for a pluralistic dialogue in the context of health policies, emphasizing critical questions that require urgent answers if we wish to avoid a global erosion of public confidence in science and public health.

Introduction

Since COVID-19 was declared a pandemic in March 2020, over 150 million cases and 3 million deaths have been reported worldwide. Despite progress on early ambulatory, multidrug-therapy for high-risk patients, resulting in 85% reductions in COVID-19 hospitalization and death [1], the current paradigm for control is mass-vaccination. While we recognize the effort involved in development, production and emergency authorization of SARS-CoV-2 vaccines, we are concerned that risks have been minimized or ignored by health organizations and government authorities, despite calls for caution [2-8].

Vaccines for other coronaviruses have never been approved for humans, and data generated in the development of coronavirus vaccines designed to elicit neutralizing antibodies show that they may worsen COVID-19 disease via antibody-dependent enhancement (ADE) and Th2 immunopathology, regardless of the vaccine platform and delivery method [9-11]. Vaccine-driven disease enhancement in animals vaccinated against SARS-CoV and MERS-CoV is known to occur following viral challenge, and has been attributed to immune complexes and Fc-mediated viral capture by macrophages, which augment T-cell activation and inflammation [11-13].

In March 2020, vaccine immunologists and coronavirus experts assessed SARS-CoV-2 vaccine risks based on SARS-CoV-vaccine trials in animal models. The expert group concluded that ADE and immunopathology were a real concern, but stated that their risk was insufficient to delay clinical trials, although continued monitoring would be necessary [14]. While there is no clear evidence of the occurrence of ADE and vaccine-related immunopathology in volunteers immunized with SARS-CoV-2 vaccines [15], safety trials to date have not specifically addressed these serious adverse effects (SAE). Given that the follow-up of volunteers did not exceed 2-3.5 months after the second dose [16-19], it is unlikely such SAE would have been observed. Despite92 errors in reporting, it cannot be ignored that even accounting for the number of vaccines administered, according to the US Vaccine Adverse Effect Reporting System (VAERS), the number of deaths per million vaccine doses administered has increased more than 10-fold. We believe there is an urgent need for open scientific dialogue on vaccine safety in the context of large-scale immunization. In this paper, we describe some of the risks of mass vaccination in the context of phase 3 trial exclusion criteria and discuss the SAE reported in national and regional adverse effect registration systems. We highlight unanswered questions and draw attention to the need for a more cautious approach to mass vaccination.

SARS-CoV-2 phase 3 trial exclusion criteria

With few exceptions, SARS-CoV-2 vaccine trials excluded the elderly [16-19], making it impossible to identify the occurrence of post-vaccination eosinophilia and enhanced inflammation in elderly people. Studies of SARS-CoV vaccines showed that immunized elderly mice were at particularly high risk of life-threatening Th2 immunopathology [9,20]. Despite this evidence and the extremely limited data on safety and efficacy of SARS-CoV-2 vaccines in the elderly, mass-vaccination campaigns have focused on this age group from the start. Most trials also excluded pregnant and lactating volunteers, as well as those with chronic and serious conditions such as tuberculosis, hepatitis C, autoimmunity, coagulopathies, cancer, and immune suppression [16-29], although these recipients are now being offered the vaccine under the premise of safety.

Another criterion for exclusion from nearly all trials was prior exposure to SARS-CoV-2. This is unfortunate as it denied the opportunity of obtaining extremely relevant information concerning post-vaccination ADE in people that already have anti-SARS-Cov-2 antibodies. To the best of our knowledge,

ADE is not being monitored systematically for any age or medical condition group currently being administered the vaccine. Moreover, despite a substantial proportion of the population already having antibodies [21], tests to determine SARS-CoV-2-antibody status prior to administration of the vaccine are not conducted routinely.

Will serious adverse effects from the SARS-CoV-2 vaccines go unnoticed?

COVID-19 encompasses a wide clinical spectrum, ranging from very mild to severe pulmonary pathology and fatal multi-organ disease with inflammatory, cardiovascular, and blood coagulation dysregulation [22-24]. In this sense, cases of vaccine-related ADE or immunopathology would be clinically-indistinguishable from severe COVID-19 [25]. Furthermore, even in the absence of SARS-CoV-2 virus, Spike glycoprotein alone causes endothelial damage and hypertension in vitro and in vivo in Syrian hamsters by down-regulating angiotensin-converting enzyme 2 (ACE2) and impairing mitochondrial function [26]. Although these findings need to be confirmed in humans, the implications of this finding are staggering, as all vaccines authorized for emergency use are based on the delivery or induction of Spike glycoprotein synthesis. In the case of mRNA vaccines and adenovirus-vectorized vaccines, not a single study has examined the duration of Spike production in humans following vaccination. Under the cautionary principle, it is parsimonious to consider vaccine-induced Spike synthesis could cause clinical signs of severe COVID-19, and erroneously be counted as new cases of SARS-CoV-2 infections. If so, the true adverse effects of the current global vaccination strategy may never be recognized unless studies specifically examine this question. There is already non-causal evidence of temporary or sustained increases138 in COVID-19 deaths following vaccination in some countries (Fig. 1) and in light of Spike's pathogenicity, these deaths must be studied in depth to determine whether they are related to vaccination.

Unanticipated adverse reactions to SARS-CoV-2 vaccines

Another critical issue to consider given the global scale of SARS-CoV-2 vaccination is autoimmunity. SARS-CoV-2 has numerous immunogenic proteins, and all but one of its immunogenic epitopes have similarities to human proteins [27]. These may act as a source of antigens, leading to autoimmunity [28]. While it is true that the same effects could be observed during natural infection with SARS-CoV-2, vaccination is intended for most of the world population, while it is estimated that only 10% of the world population has been infected by SARS-CoV-2, according to Dr. Michael Ryan, head of emergencies at the World Health Organization. We have been unable to find evidence that any of the currently authorized vaccines screened and excluded homologous immunogenic epitopes to avoid potential autoimmunity due to pathogenic priming.

Some adverse reactions, including blood-clotting disorders, have already been reported in healthy and young vaccinated people. These cases led to the suspension or cancellation of the use of adenoviral vectorized ChAdOx1-nCov-19 and Janssen vaccinesin some countries. It has now been proposed that vaccination with ChAdOx1-nCov-19 can result in immune thrombotic thrombocytopenia (VITT) mediated by platelet-activating antibodies against Platelet factor-4, which clinically mimics autoimmune heparin-induced thrombocytopenia [29]. Unfortunately, the risk was overlooked when authorizing these vaccines, although adenovirus-induced thrombocytopenia has been known for more than a decade, and has been a consistent event with adenoviral vectors [30]. The risk of VITT would presumably be higher in those already at risk of blood clots, including women who use oral contraceptives [31], making it imperative for clinicians to advise their patients accordingly.

At the population level, there could also be vaccine-related impacts. SARS-CoV-2 is a fast-evolving RNA virus that has so far produced more than 40,000 variants [32,33] some of which affect the antigenic domain of Spike glycoprotein [34,35]. Given the high mutation rates, vaccine-induced synthesis of high levels of anti-SARS-CoV-2-Spike antibodies could theoretically lead to suboptimal responses against subsequent infections by other variants in vaccinated individuals [36], a phenomenon known as "original antigenic sin" [37] or antigenic priming [38]. It is unknown to what extent mutations that affect SARS-CoV-2 antigenicity will become fixed during viral evolution [39], but vaccines could plausibly act as selective forces driving variants with higher infectivity or transmissibility. Considering the high similarity between known SARS-CoV-2 variants, this scenario is unlikely [32,34] but if future variants were to differ more in key epitopes, the global vaccination strategy might have helped shape an even more dangerous virus. This risk has recently been brought to the attention of the WHO as an open letter [40].

Discussion

The risks outlined here are a major obstacle to continuing global SARS-CoV-2 vaccination. Evidence on the safety of all SARS-CoV-2 vaccines is needed before exposing more people to the risk of these experiments, since releasing a candidate vaccine without time to fully understand the resulting impact on health could lead to an exacerbation of the current global crisis [41]. Risk-stratification of vaccine recipients is essential. According to the UK government, people below 60 years of age have an extremely low risk of dying from COVID-191 187 . However, according to Eudravigillance, most of the serious adverse effects following SARS-CoV-2 vaccination occur in people aged 18-64. Of particular concern is the planned vaccination schedule for children aged 6 years and older in the United States and the UK. Dr. Anthony Fauci recently anticipated that teenagers across the country will be vaccinated in the autumn and younger children in early 2022, and the UK is awaiting trial results to commence vaccination of 11 million children under 18. There is a lack of scientific justification for subjecting healthy children to experimental vaccines, given that the Centers for Disease Control and Prevention estimates that they have a 99.997% survival rate if infected with SARS-CoV-2. Not only is COVID-19 irrelevant as a threat to this age group, but there is no reliable evidence to support vaccine efficacy or effectiveness in this population or to rule out harmful side effects of these experimental vaccines. In this sense, when physicians advise patients on the elective administration of COVID-19 vaccination, there is a great need to better understand the benefits and risk of administration, particularly in understudied groups.

In conclusion, in the context of the rushed emergency-use-authorization of SARS-CoV-2 vaccines, and the current gaps in our understanding of their safety, the following questions must be raised:

- Is it known whether cross-reactive antibodies from previous coronavirus infections or vaccine induced antibodies may influence the risk of unintended pathogenesis following vaccination with COVID-19?
- Has the specific risk of ADE, immunopathology, autoimmunity, and serious adverse reactions been clearly disclosed to vaccine recipients to meet the medical ethics standard of patient understanding for informed consent? If not, what are the reasons, and how could it be implemented?
- What is the rationale for administering the vaccine to every individual when the risk of dying from COVID-19 is not equal across age groups and clinical conditions and when the phase 3 trials excluded the elderly, children and frequent specific conditions?
- What are the legal rights of patients if they are harmed by a SARS-CoV-2 vaccine? Who will cover the costs of medical treatment? If claims were to be settled with public money, has the public been made aware that the vaccine manufacturers have been granted immunity, and their

responsibility to compensate those harmed by the vaccine has been transferred to the tax-payers?

In the context of these concerns, we propose halting mass-vaccination and opening an urgent pluralistic, critical, and scientifically-based dialogue on SARS-CoV-2 vaccination among scientists, medical doctors, international health agencies, regulatory authorities, governments, and vaccine developers. This is the only way to bridge the current gap between scientific evidence and public health policy regarding the SARS-CoV-2 vaccines. We are convinced that humanity deserves a deeper understanding of the risks than what is currently touted as the official position. An open scientific dialogue is urgent and indispensable to avoid erosion of public confidence in science and public health and to ensure that the WHO and national health authorities protect the interests of humanity during the current pandemic. Returning public health policy to evidence-based medicine, relying on a careful evaluation of the relevant scientific research, is urgent. It is imperative to follow the science.

1 https://www.gov.uk/government/publications/covid-19-reported-sars-cov-2-deaths-in-england/covid-19-confirmed-deaths-in-england-report

Conflict of Interest Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

References

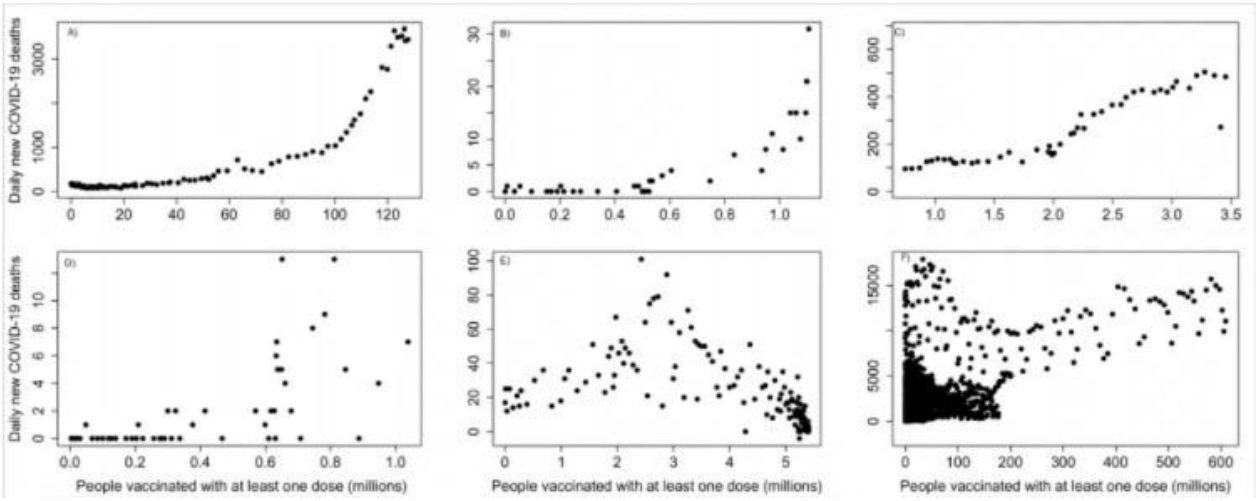
1. McCullough PA, Alexander PE, Armstrong R, et al. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med (2020) 21:517–530. doi:10.31083/j.rcm.2020.04.264
2. Arvin AM, Fink K, Schmid MA, et al. A perspective on potential antibody- dependent enhancement of SARS-CoV-2. Nature (2020) 484:353–363. doi:10.1038/s41586-020-2538-8
3. Coish JM, MacNeil AJ. Out of the frying pan and into the fire? Due diligence warranted for ADE in COVID-19. Microbes Infect (2020) 22(9):405-406. doi:10.1016/j.micinf.2020.06.006
4. Eroshenko N, Gill T, Keaveney ML, et al. Implications of antibody-dependent enhancement of infection for SARS-CoV-2 countermeasures. Nature Biotechnol (2020) 38:788–797. doi:10.1038/s41587-020-0577-1
5. Poland GA. Tortoises, hares, and vaccines: A cautionary note for SARS-CoV-2 vaccine development. Vaccine (2020) 38:4219–4220. doi:10.1016/j.vaccine.2020.04.073
6. Shibo J. Don't rush to deploy COVID-19 vaccines and drugs without sufficient safety guarantees. Nature (2000) 579,321. doi:10.1038/d41586-020-00751-9
7. Munoz FA, Cramer JP, Dekker CL, et al. Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine (2021) https://doi.org/10.1016/j.vaccine.2021.01.055
8. Cardozo T, Veazey R. Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease. Int J Clin Pract (2020) 28:e13795. doi: 10.1111/ijcp.13795
9. Bolles D, Long K, Adnihothram S, et al. A double-inactivated severe acute respiratory syndrome coronavirus vaccine provides incomplete protection in mice and induces increased eosinophilic proinflammatory pulmonary response upon challenge. J Virol (2001) 85:12201–12215. doi:10.1128/JVI.06048-11

10. Weingartl H, Czub M, Czub S, et al. Immunization with modified vaccinia virus Ankarabased recombinant vaccine against severe acute respiratory syndrome is associated with enhanced hepatitis in ferrets. J Virol (2004) 78:12672–12676. doi:10.1128/JVI.78.22.12672-12676.2004272
11. Tseng CT, Sbrana E, Iwata-Yoshikawa N, et al. Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus. PLoS One (2012) 7(4):e35421. doi: 10.1371/journal.pone.0035421
12. Iwasaki A, Yang Y. The potential danger of suboptimal antibody responses in COVID-19. Nat Rev Immunol (2020) 20:339–341. doi:10.1038/s41577-020-0321-6
13. Vennema H, de Groot RJ, Harbour DA, et al. Early death after feline infectious peritonitis virus challenge due to recombinant vaccinia virus immunization. J Virol (1990) 64:1407-1409
14. Lambert PH, Ambrosino DM, Andersen SR, et al. Consensus summary report for CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. Vaccine (2020) 38(31):4783-4791. doi:10.1016/j.vaccine.2020.05.064
15. de Alwis R, Chen S, Gan S, et al. Impact of immune enhancement on Covid-19 polyclonal hyperimmune globulin therapy and vaccine development. EbioMedicine (2020) 55:102768. doi:10.1016/j.ebiom.2020.102768
16. Folegatti PM, Ewer KJ, Aley PK, et al. Safety and immunogenicity of the ChAdOx1 nCoV287 19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. Lancet (2020) 396:467–783. doi:10.1016/S0140-6736(20)31604-4
17. Polack FP, Thomas SJ, Kitchin N. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med (2020) 383:2603–2615. doi:10.1056/NEJMoa2034577
18. Ramasamy MN, Minassian AM, Ewer KJ, et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. Lancet (2021) 396:1979–93. doi: 10.1016/S0140-6736(20)32466-1
19. Chu L, McPhee R, Huang W, et al. mRNA-1273 Study Group. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine. Vaccine (2021) S0264-410X(21)00153-5. doi:10.1016/j.vaccine.2021.02.007
20. Liu L, Wei Q, Lin Q, et al. Anti-spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection. JCI Insight (2019) 4(4):e123158. doi:10.1172/jci.insight.123158.
21. Ioannidis PA. Infection fatality rate of COVID-19 inferred from seroprevalence data. Bull WHO (2021) 99:19–33F. http://dx.doi.org/10.2471/BLT.20.265892
22. Martines RB, Ritter JM, Matkovic E, et al. Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease, United States Emerg Infect Dis (2020) 26:2005-2015. doi:10.3201/eid2609.202095
23. Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA (2020) 323:1239-1242. doi:10.1001/jama.2020.2648
24. Xu Z, Shi L, Wang Y, et al. Pathological findings of COVID-19 associated with acute respiratory distress syndrome. Lancet Respiratory Med (2020) 8:420-422 doi:10.1016/S2213-2600(20)30076-X
25. Negro F. Is antibody-dependent enhancement playing a role in COVID-19 pathogenesis? Swiss Medical Weekly (2020) 150:w20249. doi:10.4414/smw.2020.20249317
26. Lei Y, Zhang J, Schiavon CR et al., Spike Protein Impairs Endothelial Function via Downregulation of ACE 2. Circulation Res (2021) 128:1323–1326. https://doi.org/10.1161/CIRCRESAHA.121.318902
27. Lyons-Weiler J. Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity, J Translational Autoimmunity (2020) 3:100051. doi:10.1016/j.jtauto.2020.100051

28. An H, Park J. Molecular Mimicry Map (3M) of SARS-CoV-2: Prediction of potentially immunopathogenic SARS-CoV-2 epitopes via a novel immunoinformatic approach. bioRxiv [Preprint]. 12 November 2020 [cited 2020 April 19] https://doi.org/10.1101/2020.11.12.344424
29. Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, Eichinger S. Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination. N Engl J Med (2021). doi: 10.1056/NEJMoa2104840
30. Othman M, Labelle A, Mazzetti I et al. Adenovirus-induced thrombocytopenia: the role of von Willebrand factor and P-selectin in mediating accelerated platelet clearance. Blood (2007) 109:2832–2839. doi:10.1182/blood-2006-06-032524
31. Ortel TL. Acquired thrombotic risk factors in the critical care setting. Crit Care Med (2010) 38(2 Suppl):S43-50. doi:10.1097/CCM.0b013e3181c9ccc8
32. Grubaugh ND, Petrone ME, Holmes EC. We shouldn't worry when a virus mutates during disease outbreaks. Nat Microbiol (2020) 5:529–530. https://doi.org/10.1038/s41564-020-0690-4
33. Greaney AJ, Starr TN, Gilchuk P, et al. Complete Mapping of Mutations to the SARS-CoV339 2 Spike Receptor-Binding Domain that Escape Antibody Recognition. Cell Host Microbe (2021) 29:44–57.e9. doi:10.1016/j.chom.2020.11.007.
34. Lauring AS, Hodcroft EB. Genetic Variants of SARS-CoV-2—What Do They Mean? JAMA (2021) 325:529–531. doi:10.1001/jama.2020.27124
35. Zhang L, Jackson CB, Mou H, et al. The D614G mutation in the SARS-CoV-2 spike protein reduces S1 shedding and increases infectivity. bioRxiv [Preprint]. June 12 2020 [cited 2021 Apr 19] https://doi.org/10.1101/2020.06.12.148726
36. Korber B, Fischer WM, Gnanakaran S et al. Sheffield COVID-19 Genomics Group. Tracking changes in SARS-CoV-2 spike: evidence that D614G increases infectivity of the COVID-19 virus. Cell (2020) 182:812-827.e19. doi:10.1016/j.cell.2020.06.043
37. Francis T. On the doctrine of original antigenic sin. Proc Am Philos Soc (1960) 104:572–578.
38. Vibroud C, Epstein SL. First flu is forever. Science (2016) 354:706–707. doi:10.1126/science.aak9816
39. Weisblum Y, Schmidt F, Zhang F, et al. Escape from neutralizing antibodies by SARS354 CoV-2 spike protein variants. Elife (2020) 9:e61312. doi:10.7554/eLife.61312
40. Vanden Bossche G (March 6, 2021) https://dryburgh.com/wp-356content/uploads/2021/03/Geert_Vanden_Bossche_Open_Letter_WHO_March_6_2021.pdf
41. Coish JM, MacNeil AJ. Out of the frying pan and into the fire? Due diligence warranted for ADE in COVID-19. Microbes Infect (2020) 22(9):405-406. doi:10.1016/j.micinf.2020.06.006

Figure legends

Figure 1. Number of new COVID-19 deaths in relation to number of people that have received at least one vaccine dose for selected countries. Graph shows data from the start of vaccination to May 3rd 365 , 2021. A) India (9.25% of population vaccinated), B) Thailand (1.58% of population vaccinated), C) Colombia (6.79% of population vaccinated), D) Mongolia (31.65% of population vaccinated), E) Israel (62.47% of population vaccinated), F) Entire world (7.81% of population vaccinated). Graphs were built using data from Our World in Data (accessed 4 May 2021) https://github.com/owid/covid-19-data/tree/master/public/data/vaccinations


A)
B)
C)
D)
E)
F)
Daily new COVID-19 deaths
Daily new COVID-19 deaths
People vaccinated with at least one dose (millions)
People vaccinated with at least one dose (millions)
People vaccinated with at least one dose (millions)

COVID cepiva: potrebnost, učinkovitost in varnost

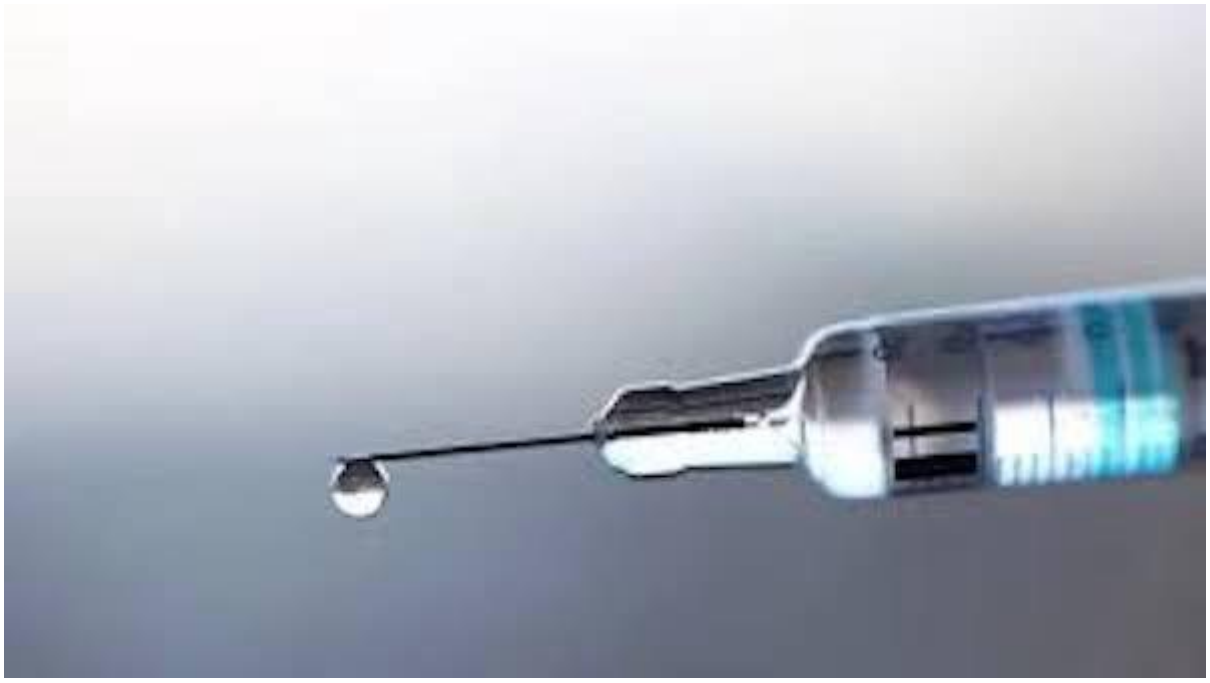
https://johnplatinumgoss.com/2021/05/01/experts-explain-why-vaccines-against-covid-19-are-unnecessary-and-dangerous/

COVID Vaccines: Necessity, Efficacy and Safety

Doctors for Covid Ethics1 day ago·14 min read

Abstract: COVID-19 vaccine manufacturers have been exempted from legal liability for vaccine-induced harm. It is therefore in the interests of all those authorising, enforcing and administering COVID-19 vaccinations to understand the evidence regarding the risks and benefits of these vaccines, since liability for harm will fall on them.

In short, the available evidence and science indicate that COVID-19 vaccines are unnecessary, ineffective and unsafe.



Necessity: Immunocompetent individuals are protected against SARS-CoV-2 by cellular immunity. Vaccinating low-risk groups is therefore unnecessary. For immunocompromised individuals who do fall ill with COVID-19 there is a range of medical treatments that have been proven safe and effective. Vaccinating the vulnerable is therefore equally unnecessary. Both immunocompetent and vulnerable groups are better protected against variants of SARS-CoV-2 by naturally acquired immunity and by medication than by vaccination.

Efficacy: Covid-19 vaccines lack a viable mechanism of action against SARS-CoV-2 infection of the airways. Induction of antibodies cannot prevent infection by an agent such as SARS-CoV-2 that invades through the respiratory tract. Moreover, none of the vaccine trials have provided any evidence that vaccination prevents transmission of the infection by vaccinated individuals; urging vaccination to “protect others” therefore has no basis in fact.

Safety: The vaccines are dangerous to both healthy individuals and those with pre-existing chronic disease, for reasons such as the following: risk of lethal and non-lethal disruptions of blood clotting including bleeding disorders, thrombosis in the brain, stroke and heart attack; autoimmune and allergic reactions; antibody-dependent enhancement of disease; and vaccine impurities due to rushed manufacturing and unregulated production standards.

The **risk-benefit calculus** is therefore clear: the experimental vaccines are needless, ineffective and dangerous. Actors authorising, coercing or administering experimental COVID-19 vaccination are exposing populations and patients to serious, unnecessary, and unjustified medical risks.

1. The vaccines are unnecessary

Multiple lines of research indicate that immunocompetent people display **"robust" and lasting** cellular (T cell) immunity to SARS-CoV viruses [1], including SARS-CoV-2 and its variants [2]. T cell protection stems not only from exposure to SARS-CoV-2 itself, but from cross-reactive immunity following previous exposure to common cold and SARS coronaviruses [1,3–10]. Such immunity was detectable after infections up to 17 years prior [1,3]. Therefore, immunocompetent people do not need vaccination against SARS-CoV-2.

Natural T-Cell immunity provides stronger and more comprehensive protection against all SARS-CoV-2 strains than vaccines, because naturally primed immunity recognises multiple virus epitopes and costimulatory signals, not merely a single (spike) protein. Thus, immunocompetent people are better protected against SARS-CoV-2 and any variants that may arise by their own immunity than by the current crop of vaccines.

The vaccines have been touted as a means to prevent asymptomatic infection [11], and by extension "asymptomatic transmission." However, **"asymptomatic transmission" is an artefact** of invalid and unreliable PCR test procedures and interpretations, leading to high false-positive rates [12–15]. Evidence indicates that PCR-positive, asymptomatic people are healthy false-positives, not carriers. A comprehensive study of **9,899,828** people in China found that asymptomatic individuals testing positive for COVID-19 never infected others [16]. In contrast, the papers cited by the Centre for Disease Control [17,18] to justify claims of asymptomatic transmission are based on hypothetical models, not empirical studies; they present assumptions and estimates rather than evidence. Preventing asymptomatic infection is not a viable rationale for promoting vaccination of the general population.

In most countries, **most people now have immunity to SARS-CoV-2** [19]. Depending on their degree of previously acquired cross-immunity, they will have had no symptoms, mild and uncharacteristic symptoms, or more severe symptoms, possibly including anosmia (loss of sense of smell) or other somewhat characteristic signs of the COVID-19 disease. Regardless of disease severity, they will now have sufficient immunity to be protected from severe disease in the event of renewed exposure. This majority of the population will not benefit at all from being vaccinated.

Population survival of COVID-19 exceeds 99.8% globally [20–22]. In countries that have been intensely infected over several months, less than 0.2% of the population have died and had their deaths classified as 'with covid19'. COVID-19 is also typically a mild to moderately severe illness. Therefore, the overwhelming majority of people are not at risk from COVID-19 and do not require vaccination for their own protection.

In those susceptible to severe infection, **Covid-19 is a treatable illness**. A convergence of evidence indicates that early treatment with existing drugs reduces hospitalisation and mortality by ~85% and 75%, respectively [23–27]. These drugs include many tried and true antiinflammatory, antiviral, and anticoagulant medications, as well as monoclonal antibodies, zinc, and vitamins C and D. Industry and government decisions to sideline such proven treatments through selective research support [24], regulatory bias, and even outright sanctions against doctors daring to use such treatments on their own initiative, have been out of step with existing laws, standard medical practice, and research; the legal requirement to consider real world evidence has fallen by the wayside [28]. The systematic denial and denigration of these effective therapies has underpinned the spurious justification for the emergency use authorisation of the vaccines, which requires that "no standard acceptable treatment is available" [29]. Plainly stated, vaccines are not necessary to prevent severe disease.

2. The vaccines lack efficacy

At a mechanistic level, the concept of immunity to COVID-19 via antibody induction, as per **COVID-19 vaccination, is medical nonsense**. Airborne viruses such as SARS-CoV-2 enter the body via the airways and lungs, where antibody concentrations are too low to prevent infection. Vaccine-induced antibodies primarily circulate in the bloodstream, while concentrations on the mucous membranes of lungs and airways is low. Given that COVID-19 primarily spreads and causes disease by infecting these mucous membranes, vaccines miss the immunological mark. The documents submitted by the vaccine manufacturers to the various regulatory bodies contain no evidence that vaccination prevents airway infection, which would be crucial for breaking the chain of transmission. Thus, vaccines are immunologically inappropriate for COVID-19.

Medium to long-term vaccine efficacy is unknown. Phase 3, medium term, 24-month trials will not be complete until 2023: There is no medium-term or long term longitudinal data regarding COVID-19 vaccine efficacy.

Short term data has not established prevention of severe disease. The European Medicines Agency has noted of the Comirnaty (Pfizer mRNA) vaccine that severe COVID-19 cases "were rare in the study, and statistically certain conclusion cannot be drawn" from it [30]. Similarly, the Pfizer document submitted to the FDA [31] concludes that efficacy against mortality could not be demonstrated. Thus, the vaccines have not been shown to prevent death or severe disease even in the short term.

The **correlates of protection against COVID-19 are unknown.** Researchers have not yet established how to measure protection against COVID-19. As a result, efficacy studies are stabbing around in the dark. After completion of Phase 1 and 2 studies, for instance, a paper in the journal Vaccine noted that "without understanding the correlates of protection, it is impossible to currently address questions regarding vaccine-associated protection, risk of COVID-19 reinfection, herd immunity, and the possibility of elimination of SARS-CoV-2 from the human population" [32]. Thus, Vaccine efficacy cannot be evaluated because we have not yet established how to measure it.

3. The vaccines are dangerous

1. Just as smoking could be and was predicted to cause lung cancer based on first principles, **all gene-based vaccines can be expected to cause blood clotting and bleeding disorders** [33], based on their molecular mechanisms of action. Consistent with this, diseases of this kind have been observed across age groups, leading to temporary vaccine suspensions around the world — The vaccines are not safe.

2. Contrary to claims that blood disorders post-vaccination are "rare", many **common vaccine side effects** (headaches, nausea, vomiting and haematoma-like "rashes" over the body) **may indicate thrombosis and other severe abnormalities**. Moreover, vaccine-induced diffuse micro-thromboses in the lungs can mimic pneumonia and may be misdiagnosed as COVID-19. Clotting events currently receiving media attention are likely just the "tip of a huge iceberg" [34] — The vaccines are not safe.

3. Due to immunological priming, **risks of clotting, bleeding and other adverse events can be expected to increase with each re-vaccination** and each intervening coronavirus exposure. Over time, whether months or years [35], this renders both vaccination and coronaviruses dangerous to young and healthy age groups, for whom without vaccination COVID-19 poses no substantive risk.

Since vaccine roll-out, COVID-19 incidence has risen in numerous areas with high vaccination rates [36–38]. Furthermore, multiple series of COVID-19 fatalities have occurred shortly after the onset vaccinations in senior homes [39,40]. These cases may have been due not only to antibody-dependent enhancement but also to a general immunosuppressive effect of the vaccines, which is suggested by the increased occurrence of Herpes zoster in certain patients [41]. Immunosuppression may have caused a previously asymptomatic infection to become clinically manifest. Regardless of the exact mechanism responsible for these reported deaths, we must expect that the vaccines will increase rather than decrease lethality of COVID-19 — The vaccines are not safe.

4. **The vaccines are experimental by definition**. They will remain in Phase 3 trials until 2023. Recipients are human subjects entitled to free informed consent under Nuremberg and other protections, including the Parliamentary Assembly of the Council of Europe's resolution 2361 [42] and the FDA's terms of emergency use authorisation [29]. With respect to safety data from Phase 1 and 2 trials, in spite of initially large sample sizes the journal Vaccine reports that, "the vaccination strategy chosen for further development may have only been given to as few as 12 participants" [32]. With such extremely small sample sizes, the journal notes that, "larger Phase 3 studies conducted over longer periods of time will be necessary" to establish safety. The risks that remain to be evaluated in Phase 3 trials into 2023, with entire populations as subjects, include not only thrombosis and bleeding abnormalities, but other autoimmune responses, allergic reactions, unknown tropisms (tissue destinations) of lipid nanoparticles [35], antibody-dependent enhancement [43–46] and the impact of rushed, questionably executed, poorly regulated [47] and reportedly inconsistent manufacturing methods, conferring risks of potentially harmful impurities such as uncontrolled DNA residues [48]. The vaccines are not safe, either for recipients or for those who administer them or authorise their use.

5. Initial experience might suggest that the adenovirus-derived vaccines (AstraZeneca/Johnson & Johnson) cause graver adverse effects than the mRNA (Pfizer/Moderna) vaccines. However, upon repeated injection, the former will soon induce antibodies against the proteins of the adenovirus vector. These antibodies will then neutralize most of the vaccine virus particles and cause their disposal before they can infect any cells, thereby limiting the intensity of tissue damage.

In contrast, in the mRNA vaccines, there is no protein antigen for the antibodies to recognize. Thus, regardless of the existing degree of immunity, the vaccine mRNA is going to reach its target — the body cells. These will then express the spike protein and subsequently suffer the full onslaught of the immune system. **With the mRNA vaccines, the**

risk of severe adverse events is virtually guaranteed to increase with every successive injection. In the long term, they are therefore even more dangerous than the vector vaccines. Their apparent preferment over the latter is concerning in the highest degree; these vaccines are not safe.

4. Ethics and legal points to consider

Conflicts of interest abound in the scientific literature and within organisations that recommend and promote vaccines, while demonising alternate strategies (reliance on natural immunity and early treatment). Authorities, doctors and medical personnel need to protect themselves by evaluating the sources of their information for conflicts of interest extremely closely.

Authorities, doctors and medical personnel need to be similarly careful not to ignore the credible and independent literature on vaccine necessity, safety and efficacy, given the foreseeable mass deaths and harms that must be expected unless the vaccination campaign is stopped.

Vaccine manufacturers have exempted themselves from legal liability for adverse events for a reason. When vaccine deaths and harms occur, liability will fall to those responsible for the vaccines' authorisation, administration and/or coercion via vaccine passports, none of which can be justified on a sober, evidence-based risk-benefit analysis.

All political, regulatory and medical actors involved in COVID-19 vaccination should familiarise themselves with the Nuremberg code and other legal provisions in order to protect themselves.

References

Le Bert, N.; Tan, A.T.; Kunasegaran, K.; Tham, C.Y.L.; Hafezi, M.; Chia, A.; Chng, M.H.Y.; Lin, M.; Tan, N.; Linster, M.; Chia, W.N.; Chen, M.I.; Wang, L.; Ooi, E.E.; Kalimuddin, S.; Tambyah, P.A.; Low, J.G.; Tan, Y. and Bertoletti, A. (2020) SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls. ***Nature*** **584:457–462**

Tarke, A.; Sidney, J.; Methot, N.; Zhang, Y.; Dan, J.M.; Goodwin, B.; Rubiro, P.; Sutherland, A.; da Silva Antunes, R.; Frazier, A. and al., e. (2021) Negligible impact of SARS-CoV-2 variants on CD4+ and CD8+ T cell reactivity in COVID-19 exposed donors and vaccinees. ***bioRxiv*** **-:x-x**

Anonymous, (2020) **Scientists uncover SARS-CoV-2-specific T cell immunity in recovered COVID-19 and SARS patients**.

Beasley, D. (2020) **Scientists focus on how immune system T cells fight coronavirus in absence of antibodies**.

Bozkus, C.C. (2020) SARS-CoV-2-specific T cells without antibodies. ***Nat. Rev. Immunol.*** **20:463**

Grifoni, A.; Weiskopf, D.; Ramirez, S.I.; Mateus, J.; Dan, J.M.; Moderbacher, C.R.; Rawlings, S.A.; Sutherland, A.; Premkumar, L.; Jadi, R.S. and al., e. (2020) Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals. ***Cell*** **181:1489–1501.e15**

Mateus, J.; Grifoni, A.; Tarke, A.; Sidney, J.; Ramirez, S.I.; Dan, J.M.; Burger, Z.C.; Rawlings, S.A.; Smith, D.M.; Phillips, E. and al., e. (2020) Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans. ***Science*** **370:89–94**

McCurry-Schmidt, M. (2020) **Exposure to common cold coronaviruses can teach the immune system to recognize SARS-CoV-2**.

Palmer, S.; Cunniffe, N. and Donnelly, R. (2021) COVID-19 hospitalization rates rise exponentially with age, inversely proportional to thymic T-cell production. ***J. R. Soc. Interface*** **18:20200982**

Sekine, T.; Perez-Potti, A.; Rivera-Ballesteros, O.; Strålin, K.; Gorin, J.; Olsson, A.; Llewellyn-Lacey, S.; Kamal, H.; Bogdanovic, G.; Muschiol, S. and al., e. (2020) Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19. ***Cell*** **183:158–168.e14**

Drake, J. (2021) **Now We Know: Covid-19 Vaccines Prevent Asymptomatic Infection, Too**.

Bossuyt, P.M. (2020) Testing COVID-19 tests faces methodological challenges. ***Journal of clinical epidemiology*** **126:172–176**

Jefferson, T.; Spencer, E.; Brassey, J. and Heneghan, C. (2020) Viral cultures for COVID-19 infectivity assessment. Systematic review. ***Clin. Infect. Dis.*** **ciaa1764:x-x**

Borger, P.; Malhotra, R.K.; Yeadon, M.; Craig, C.; McKernan, K.; Steger, K.; McSheehy, P.; Angelova, L.; Franchi, F.; Binder, T.; Ullrich, H.; Ohashi, M.; Scoglio, S.; Doesburg-van Kleffens, M.; Gilbert, D.; Klement, R.J.; Schrüfer, R.; Pieksma, B.W.; Bonte, J.; Dalle Carbonare, B.H.; Corbett, K.P. and Kämmer, U. (2020) **External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results**.

Mandavilli, A. (2020) **Your Coronavirus Test Is Positive. Maybe It Shouldn't Be**.

Cao, S.; Gan, Y.; Wang, C.; Bachmann, M.; Wei, S.; Gong, J.; Huang, Y.; Wang, T.; Li, L.; Lu, K.; Jiang, H.; Gong, Y.; Xu, H.; Shen, X.; Tian, Q.; Lv, C.; Song, F.; Yin, X. and Lu, Z. (2020) Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. ***Nat. Commun.*** **11:5917**

Moghadas, S.M.; Fitzpatrick, M.C.; Sah, P.; Pandey, A.; Shoukat, A.; Singer, B.H. and Galvani, A.P. (2020) The implications of silent transmission for the control of COVID-19 outbreaks. ***Proc. Natl. Acad. Sci. U. S. A.*** **117:17513–17515**

Johansson, M.A.; Quandelacy, T.M.; Kada, S.; Prasad, P.V.; Steele, M.; Brooks, J.T.; Slayton, R.B.; Biggerstaff, M. and Butler, J.C. (2021) SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. ***JAMA network open*** **4:e2035057**

Yeadon, M. (2020). What SAGE got wrong. ***Lockdown Skeptics***.

Ioannidis, J.P.A. (2020) Global perspective of COVID-19 epidemiology for a full-cycle pandemic. ***Eur. J. Clin. Invest.*** **50:x-x**

Ioannidis, J.P.A. (2021) Reconciling estimates of global spread and infection fatality rates of COVID-19: An overview of systematic evaluations. ***Eur. J. Clin. Invest.*** **-:x-x**

CDC, (2020) **Science Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2**.

Orient, J.; McCullough, P. and Vliet, E. (2020) **A Guide to Home-Based COVID Treatment**.

McCullough, P.A.; Alexander, P.E.; Armstrong, R.; Arvinte, C.; Bain, A.F.; Bartlett, R.P.; Berkowitz, R.L.; Berry, A.C.; Borody, T.J.; Brewer, J.H.; Brufsky, A.M.; Clarke, T.; Derwand, R.; Eck, A.; Eck, J.; Eisner, R.A.; Fareed, G.C.; Farella, A.; Fonseca, S.N.S.; Geyer, C.E.; Gonnering, R.S.; Graves, K.E.; Gross, K.B.V.; Hazan, S.; Held, K.S.; Hight, H.T.; Immanuel, S.; Jacobs, M.M.; Ladapo, J.A.; Lee, L.H.; Littell, J.; Lozano, I.; Mangat, H.S.; Marble, B.; McKinnon, J.E.; Merritt, L.D.; Orient, J.M.; Oskoui, R.; Pompan, D.C.; Procter, B.C.; Prodromos, C.; Rajter, J.C.; Rajter, J.; Ram, C.V.S.; Rios, S.S.; Risch, H.A.; Robb, M.J.A.; Rutherford, M.; Scholz, M.; Singleton, M.M.; Tumlin, J.A.; Tyson, B.M.; Urso, R.G.; Victory, K.; Vliet, E.L.; Wax, C.M.; Wolkoff, A.G.; Wooll, V. and Zelenko, V. (2020) Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). ***Reviews in cardiovascular medicine*** **21:517–530**

Procter, {.B.C.; {APRN}, {.C.R.{.; {PA}-C, {.V.P.; {PA}-C, {.E.S.; {PA}-C, {.C.H. and McCullough, {.{.P.A. (2021) Early Ambulatory Multidrug Therapy Reduces Hospitalization and Death in High-Risk Patients with SARS-CoV-2 (COVID-19). ***International journal of innovative research in medical science*** **6:219–221**

McCullough, P.A.; Kelly, R.J.; Ruocco, G.; Lerma, E.; Tumlin, J.; Wheelan, K.R.; Katz, N.; Lepor, N.E.; Vijay, K.; Carter, H.; Singh, B.; McCullough, S.P.; Bhambi, B.K.; Palazzuoli, A.; De Ferrari, G.M.; Milligan, G.P.; Safder, T.; Tecson, K.M.; Wang, D.D.; McKinnon, J.E.; O'Neill, W.W.; Zervos, M. and Risch, H.A. (2021) Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. ***Am. J. Med.*** **134:16–22**

Anonymous, (2020) **Real-time database and meta analysis of 588 COVID-19 studies**.

Hirschhorn, J.S. (2021) **COVID scandal: Feds ignored 2016 law requiring use of real world evidence**.

Anonymous, (1998) **Emergency Use of an Investigational Drug or Biologic: Guidance for Institutional Review Boards and Clinical Investigators**.

Anonymous, (2021) **EMA assessment report: Comirnaty**.

Anonymous, (2020) **FDA briefing document: Pfizer-BioNTech COVID-19 Vaccine**.

Giurgea, L.T. and Memoli, M.J. (2020) Navigating the Quagmire: Comparison and Interpretation of COVID-19 Vaccine Phase 1/2 Clinical Trials. ***Vaccines*** **8:746**

Bhakdi, S.; Chiesa, M.; Frost, S.; Griesz-Brisson, M.; Haditsch, M.; Hockertz, S.; Johnson, L.; Kämmerer, U.; Palmer, M.; Reiss, K.; Sönnichsen, A.; Wodarg, W. and Yeadon, M. (2021) **Urgent Open Letter from Doctors and Scientists to the European Medicines Agency regarding COVID-19 Vaccine Safety Concerns**.

Bhakdi, S. (2021) **Rebuttal letter to European Medicines Agency from Doctors for Covid Ethics, April 1, 2021**.

Ulm, J.W. (2020) **Rapid response to: Will covid-19 vaccines save lives? Current trials aren't designed to tell us**.

Reimann, N. (2021) **Covid Spiking In Over A Dozen States — Most With High Vaccination Rates**.

Meredith, S. (2021) **Chile has one of the world's best vaccination rates. Covid is surging there anyway**.

Bhuyan, A. (2021) Covid-19: India sees new spike in cases despite vaccine rollout. ***BMJ*** **372:n854**

Morrissey, K. (2021) **Open letter to Dr. Karina Butler**.

Anonymous, (2021) **Open Letter from the UK Medical Freedom Alliance: Urgent warning re Covid-19 vaccine-related deaths in the elderly and Care Homes**.

Furer, V.; Zisman, D.; Kibari, A.; Rimar, D.; Paran, Y. and Elkayam, O. (2021) Herpes zoster following BNT162b2 mRNA Covid-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series. ***Rheumatology*** **-:x-x**

Anonymous, (2021) **Covid-19 vaccines: ethical, legal and practical considerations**.

Tseng, C.; Sbrana, E.; Iwata-Yoshikawa, N.; Newman, P.C.; Garron, T.; Atmar, R.L.; Peters, C.J. and Couch, R.B. (2012) Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus. ***PLoS One*** **7:e35421**

Bolles, M.; Deming, D.; Long, K.; Agnihothram, S.; Whitmore, A.; Ferris, M.; Funkhouser, W.; Gralinski, L.; Totura, A.; Heise, M. and Baric, R.S. (2011) A double-inactivated severe acute respiratory syndrome coronavirus vaccine provides incomplete protection in mice and induces increased eosinophilic proinflammatory pulmonary response upon challenge. ***J. Virol.*** **85:12201–15**

Weingartl, H.; Czub, M.; Czub, S.; Neufeld, J.; Marszal, P.; Gren, J.; Smith, G.; Jones, S.; Proulx, R.; Deschambault, Y.; Grudeski, E.; Andonov, A.; He, R.; Li, Y.; Copps, J.; Grolla, A.; Dick, D.; Berry, J.; Ganske, S.; Manning, L. and Cao, J. (2004) Immunization with modified vaccinia virus Ankara-based recombinant vaccine against severe acute respiratory syndrome is associated with enhanced hepatitis in ferrets. ***J. Virol.*** **78:12672–6**

Czub, M.; Weingartl, H.; Czub, S.; He, R. and Cao, J. (2005) Evaluation of modified vaccinia virus Ankara based recombinant SARS vaccine in ferrets. ***Vaccine*** **23:2273–9**

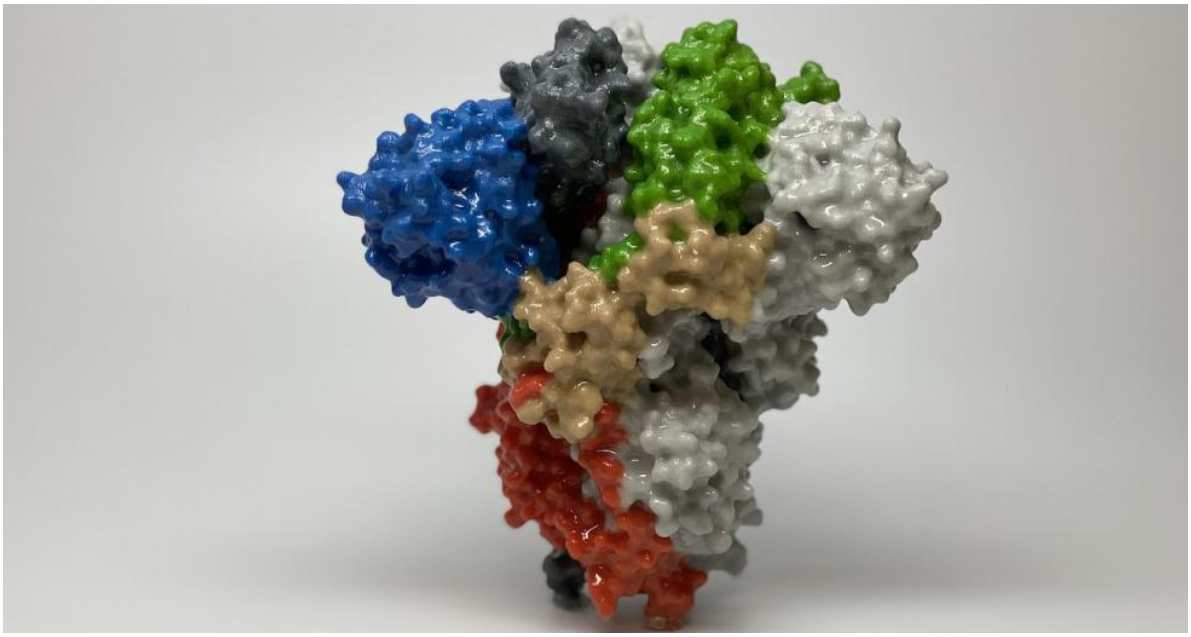
Tinari, S. (2021) The EMA covid-19 data leak, and what it tells us about mRNA instability. ***BMJ*** **372:n627**

Anonymous, (2021) **Interview with Dr. Vanessa Schmidt-Krüger**.

Doctors for Covid Ethics

We are doctors and scientists from 30 countries, seeking to uphold medical ethics, patient safety and human rights in response to COVID-19. t: @Drs4CovidEthics

Dr. Mike Williams: Analiza znanst.spoznanj v zvezi z mRNA cepivom in njegovimi posledicami (posledice so bile pričakovane)



https://www.ukcolumn.org/article/clotting-and-covid-science

Clotting and Covid Vaccine "Science"

Dr Mike Williams

Sunday, 2nd May 2021

Even a cursory look at social media demonstrates that there are three main areas of concern around Covid vaccines at the moment: clotting disorders; abnormal menses; and the possibility that those that are vaccinated are shedding that vaccine material.

There are of course other significant concerns not least neurological damage following receipt of the vaccine but, as you will see, that may be as a consequence of one of the other three.

Only one of these concerns is recognised by governments and health agencies at the moment – clotting disorders; the other two are not.

I'm going to try and sketch out what we know about the first; the other two will be for later articles. I'll attempt to use the scientific and medical literature to help me to do that.

Clotting Disorders

The problem of clots after Covid vaccination was taken more seriously when a preprint paper appeared in Research Square investigating reports "of some vaccine recipients developing unusual thrombotic events and thrombocytopenia".

The researchers "investigated whether such patients could have a prothrombotic disorder caused by platelet-activating antibodies directed against platelet factor 4 (PF4), as is known to be caused by heparin and sometimes other environmental triggers".

In short: some of the patients were positive for antibodies to PF4 and the authors concluded that "The AZD1222 [AstraZeneca] vaccine is associated with development of a prothrombotic disorder that clinically resembles heparin-induced thrombocytopenia but which shows a different serological profile".

They proposed calling this new problem *vaccine-induced prothrombotic immune thrombocytopenia* (VIPIT). Something tells me that name is going to be changed ASAP.

The authors' conflict(s) of interest included receiving fees from AstraZeneca's competitor, Pfizer. This is something we may have to forgive them for, as any help in unravelling this problem is much needed.

Effectively we have two opposing problems here: thrombosis forming a clot that can block a vessel supplying blood to an organ; and thrombocytopenia reducing the number of platelets that are needed to form a clot, causing bleeding, aka haemorrhage. Either of these problems can be very difficult to manage and extremely dangerous, even lethal for the patient -- but to have both at the same time!

The combined thrombosis and thrombocytopenia linked to Covid vaccination is being considered as something new and very rare, and if clotting happens in a vital organ … well, we're seeing the results: young people that should **not** be dying, are.

At the time of writing this article, Reuters reported:

In a weekly update on side effects from COVID-19 vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) said there were a total of 209 clots with low platelet counts following vaccination with AstraZeneca's shot, compared to a total of 168 reported last week.

Considering that adverse events are generally accepted to be massively underreported, that is very concerning.

Clotting following vaccination — A surprise?

If we were to rely on mainstream news and government reports, we might be led to believe that clotting problems with Covid vaccines were entirely unexpected and rare.

Yet the first warnings about the Astrazeneca clotting disorder came before the preprint (above) was published: and long before they even started making the current Covid 'vaccines'. Well over a decade before, to be precise.

Adenoviral viral vector delivery systems that are being employed by Astrazeneca, Sputnik and Johnson & Johnson, for example, were known to be problematic in the past. In 2007 a research paper laid it out very clearly:

Thrombocytopenia has been consistently reported following the administration of adenoviral gene transfer vectors. The mechanism underlying this phenomenon is currently unknown. In this study, we have assessed the influence of von Willebrand Factor (VWF) and P-selectin on the clearance of platelets following adenovirus administration. In mice, thrombocytopenia occurs between 5 and 24 hours after adenovirus delivery. The virus activates platelets and induces platelet-leukocyte aggregate formation. There is an associated increase in platelet and leukocyte-derived microparticles. Adenovirus-induced endothelial cell activation was shown by VCAM-1 expression on virus-treated, cultured endothelial cells and by the release of ultra-large molecular weight multimers of VWF within 1 to 2 hours of virus administration with an accompanying elevation of endothelial microparticles.

Consistently reported? In 2007?

It was known in 2007 that the same vector used for many of the Covid vaccines consistently caused thrombocytopenia. But apparently, that did not deter the UK regulatory authorities from allowing an emergency authorisation for that technology to be released not just on the UK population but also many other countries around the world.

In September 2020, another paper was published **SARS-CoV-2 binds platelet ACE2 to enhance thrombosis in COVID-19**, that outlined a problem with SARS-CoV-2:

Our findings uncovered a novel function of SARS-CoV-2 on platelet activation via binding of Spike to ACE2. SARS-CoV-2-induced platelet activation may participate in thrombus formation and inflammatory responses in COVID-19 patients.

Specifically, they noted:

SARS-CoV-2 and its Spike protein directly stimulated platelets to facilitate the release of coagulation factors, the secretion of inflammatory factors, and the formation of leukocyte–platelet aggregates.

But what has that got to do with the vaccine?

This paper identified a spike protein as causal factor in clotting. And, of course, a spike protein is what is being produced by most of the Covid vaccines. Alarm bells should have been ringing with regulators, but nothing was done.

It should also be noted that **platelet-leukocyte aggregation** was mentioned in both the 2007 and 2020 papers. How did the authorities and drug manufacturers miss that?

Pseudovirons

Of more concern was the fantastic work of Margo et al, available as early as October 2020, in a paper entitled **Severe COVID-19: A multifaceted viral vasculopathy syndrome.**

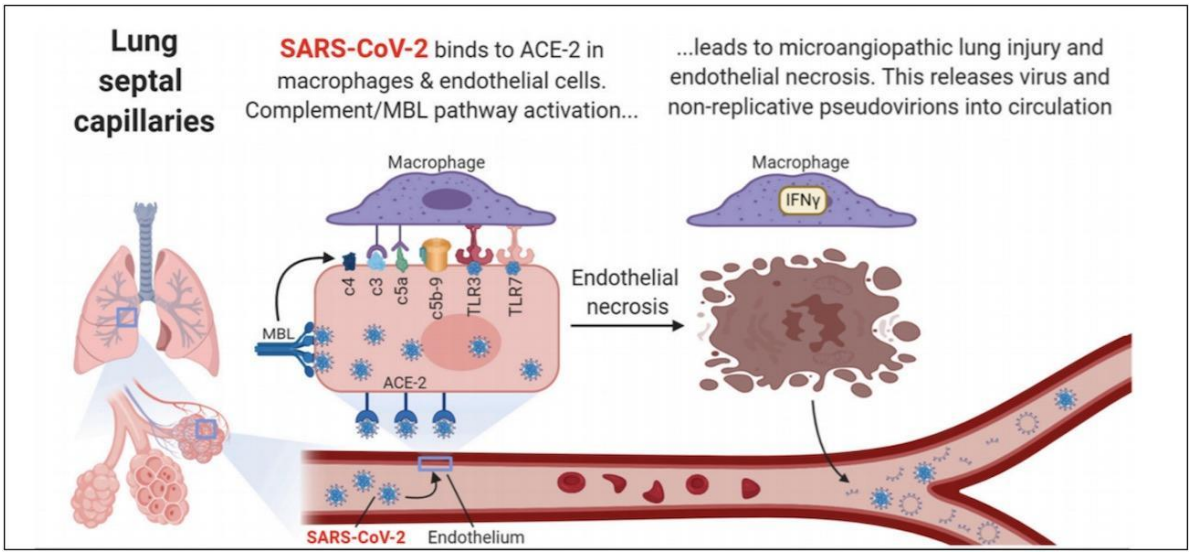
They demonstrated brilliantly that in small blood vessels the spike protein, all by itself, can induce clotting by docking in various tissues.

[V]iral spike protein without viral RNA localized to ACE2+ endothelial cells in microvessels that were most abundant in the subcutaneous fat and brain.

We see immediately a reason why overweight people have a higher risk of a poorer outcome from SARS-CoV-2 infection. We also get a prophetic warning of what was to come post vaccination — brain clots and death.

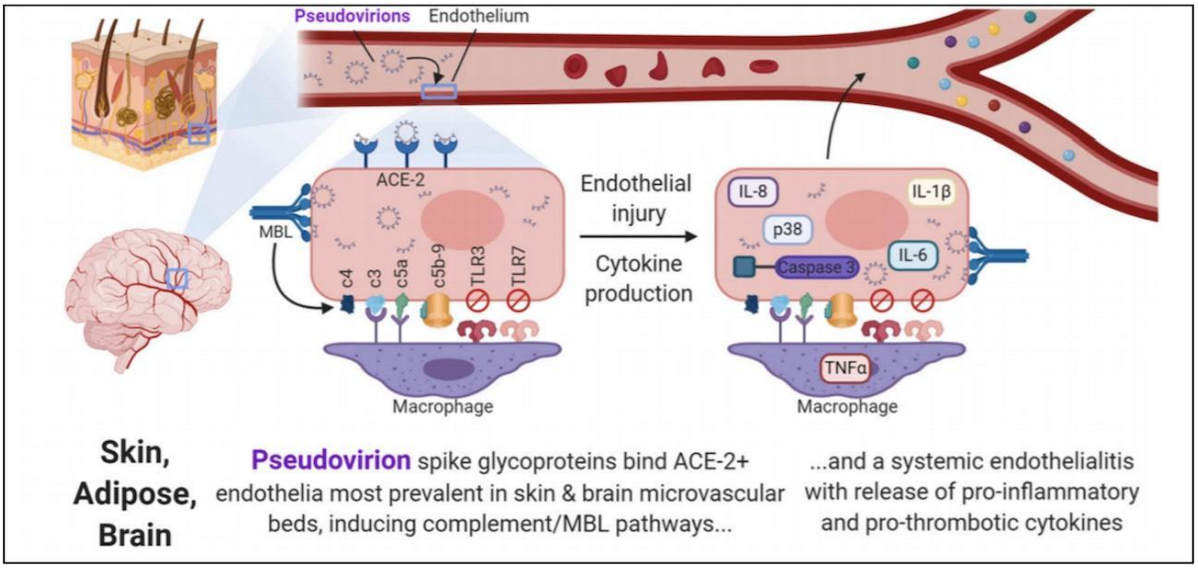
Dr Magro and her colleagues exquisitely demonstrated that the spike protein, even absent viral RNA, could cause thrombosis:

It is concluded that serious COVID-19 infection has two distinct mechanisms: 1) a microangiopathy of pulmonary capillaries associated with a high infectious viral load where endothelial cell death releases pseudovirions into the circulation, and 2) the pseudovirions dock on ACE2+ endothelial cells most prevalent in the skin/subcutaneous fat and brain that activates the complement pathway/coagulation cascade resulting in a systemic procoagulant state as well as endothelial expression of cytokines that produce the cytokine storm.



The above diagram depicts the virus attaching to the inner lining of small blood vessels, causing an immune reaction and destruction of the infected cells. That results in debris being released — pseudovirions — that travel to other areas, where the process repeats itself with some modifications.

In the brain (below), those viral-free pseudovirions (including spike protein) induce a clotting response initiated by a part of the immune system called Complement. Specifically, the Mannose Binding Lectin Complement pathway.



The key point to this paper in relation to Covid vaccines is that the spike protein, devoid of viral RNA travels to the brain and causes clotting. Once again, in case you needed reminding: Covid vaccines produce such a spike protein.

Another paper by Nuovo et al, entitled **Endothelial cell damage is the central part of COVID-19 and a mouse model induced by injection of the S1 subunit of the spike protein**, which also featured Dr Magro, was available online from 24 December 2020.

It concluded that:

ACE2+ endothelial damage is a central part of SARS-CoV2 pathology and may be induced by the spike protein alone ... including neurological damage in test animals.

There seems to be a common theme developing here.

Resistant clots

The journey doesn't end there. **SARS-CoV-2 spike protein S1 induces fibrin(ogen) resistant to fibrinolysis: Implications for microclot formation in COVID-19**:

Here we suggest that, in part, the presence of spike protein in circulation may contribute to the hypercoagulation in COVID-19 positive patients and may cause substantial impairment of fibrinolysis. Such lytic impairment may result in the persistent large microclots we have noted here and previously in plasma samples of COVID-19 patients. This observation may have important clinical relevance in the treatment of hypercoagulability in COVID-19 patients.

Loosely translated: the spike protein may contribute to clotting and those clots may be resistant to be being broken up by the body.

Another one: **The SARS-CoV-2 spike protein alters barrier function in 2D static and 3D microfluidic in-vitro models of the human blood-brain barrier**:

[in vitro] [e]vidence provided suggests that the SARS-CoV-2 spike proteins trigger a pro-inflammatory response on brain endothelial cells that may contribute to an altered state of BBB function. Together, these results are the first to show the direct impact that the SARS-CoV-2 spike protein could have on brain endothelial cells; thereby offering a plausible explanation for the neurological consequences seen in COVID-19 patients.

Not only can the spike protein cause clots all by itself, that may well be resistant to being broken up, it also looks like it also may alter the blood-brain barrier, causing neurological damage.

As if mocking the intelligence of those that still believe in science this, just published — **SARS-CoV-2 spike protein alone may cause lung damage**:

"These findings show that the genetically modified mouse together with just a segment of the spike protein can be used to study SARS-CoV-2 lung injury," said Solopov. "We can use this tool to develop a better understanding of how the spike protein causes lung symptoms—even without the intact virus—in order to develop new targets and therapeutics for COVID-19.

Using a newly developed mouse model of acute lung injury, researchers found that exposure to the SARS-CoV-2 spike protein alone was enough to induce COVID-19-like symptoms including severe inflammation of the lungs.

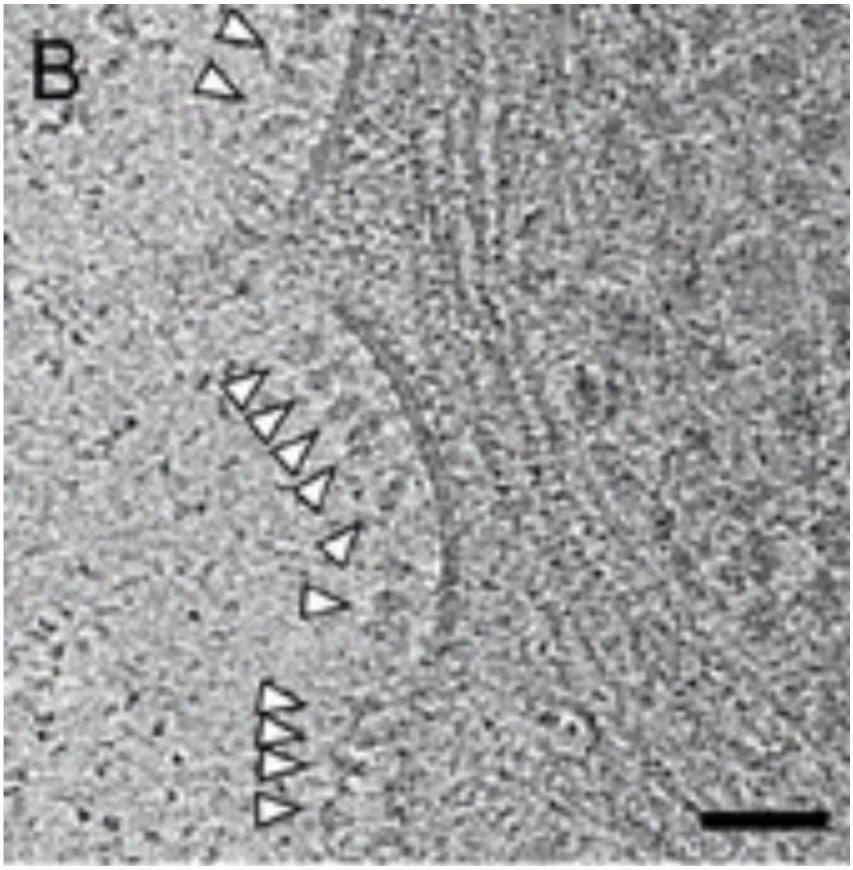
The spike protein **alone** can be studied whilst it **alone** is causing lung injury … does that raise any alarm bells within the scientific community?

A recent paper stated clearly that the risk of clotting from a Covid vaccine is far less than if you contract SARS-CoV-2. The message is that taking risk/reward into account, everyone should be vaccinated.

Well, those pushing that narrative failed to take into account that to make that risk/reward calculation, the risk in the Oxford paper has to be multiplied by the risk of actually being (officially) diagnosed with Covid. Once that is done, the risk is much higher for those vaccinated.

The image below demonstrates how successful the current crop of vaccines are at producing spike proteins. The white arrows point to spike proteins on the cell surface following the Astrazeneca vaccine. Those vaccine

induced spike proteins were claimed to provoke an immune response to protect life — but, based on the literature I have referenced, we should now look at them very differently.



In Conclusion

Simply put, there is overwhelming evidence that the SARS-CoV-2 spike protein (that is also synthetically produced by the Covid vaccines) is a central part of the mechanisms of morbidity and mortality of SARS-CoV-2, and therefore is also a risk of the vaccine. In regard to clotting, that risk is greater if you receive a vaccine.

The data clearly demonstrate that the last thing you would ever want to do is make a vaccine that produces a spike protein. As the literature clearly showed, it would cause significant damage, including brain clots and death. And that literature, for the most part, was available before the release of Covid vaccines to the public.

Dr. Wolfgang Wodarg: Dangerous side effects of genetically induced production of SARS CoV-2 spike proteins

https://www.wodarg.com/english/

Wolfgang Wodarg 15.3.2021

Neither Coronaviruses nor their spikes do enter blood in uncomplicated infections. In more than 90% of all corona-infections immune barriers in the upper respiratory tract or local mucosa immunity will prevent this. This is the result of T-cell driven cross-immunity. (1)

We do not find such an immunity by analyzing antibodies, instead we would have to analyze many T- cell epitopes of corona viruses (2), which is an effort to big to be used for preventive public health reasons.

No matter, which new mutation of a virus will come, the cellular memory of the local immune system is able to recognize tens of different typical epitopes of each respiratory virus species, even then, when some of them have changed by mutations (2).

This seems to be true for all mild respiratory infections and not just for coronaviruses*.

In rare cases of insufficient local immunity, or by medical manipulations (intubation!) viruses happen to enter the blood and become targets of a stronger and more generalized immune defence with humoral and cellular traces (e.g. antibodies) and symptoms like fever or even hampered organ function (less than 1%) (3).

If coronaviruses reach blood, the effect of corona-Spikes within the blood system is well known to be the reason for complicated or deadly Corona infection courses. Some of them are seen as a direct effect in reaction with certain cell receptors, others are reported as secondary effects, happening when infected cells start reproducing new viruses.

All those reactions take place or start within some days or in the first weeks after the infection. Those effects may be the reason for the fact that even some younger patients are dying each year with atypical pneumonia, heart or central nervous complications after some infection with different flu viruses like Influenza A or B, Parainfluenza, human Metapneumovirus, RS-Virus, Coronavirus and many others.

It is well known that also virus-virus synergism as well as superinfections with bacteria or nosocomial infections may play an important role in those rare complications among children and younger adults. Very often there are other pathogenetic factors that lead to complications. All those cases have to be distinguished from elderly victims, where frailty und chronic diseases weaken the resistance against any additional infectious stress.

No matter, where those corona-spikes come from, whether they are part of whole viruses or just spike-proteins, produced by genetically programmed cells, in both cases dangerous reactions may result, if they reach the patient's blood vessels.

Again, a normal acute respiratory infection without fever or severer symptoms (> 99%) does not come along with corona-spike protein reaching the blood and does not initiate risky generalized immune alarms.

However when genetically engineered vectors or particles are injected into the upper arm muscle, natural immune barriers or systems of defence are bypassed.

There are not enough competent immune cells in the tissue of the m. deltoideus. And as soon as some closer cells in the muscle start to produce and present spike protein, there should be a strong and more and more

generalizing local immune reaction with swellings and pain. This fits well with observed side effects of the ongoing experimental use of all genetically modifying injections.

It is unknown where the new self-made spike proteins remain, or whether parts of them could go with the blood. As there are many blood vessels in the muscle, it may happen often and easily, that part of the injected dose reaches the blood already during injection.

If this happens, the complications may be similar to those, coming along with hematogenous sowing during a complicated infection.

In such cases there are **three possible risks of vaccination**, that can have similar serious consequences and even may happen in combination with each other:

1.

after intramuscular injection, it must be expected that at least in some cases the injected genetic information may leave the injection site by mistake or accidentally and more or less enter the bloodstream to be spread throughout the body [1].

In such cases, it must be also expected that the genetic information will be distributed in the bloodstream and taken up by endothelial cells in different parenchymatic organs. Endothelic cells are those cells, with which blood vessel walls are lined. It can be assumed, that such uptake in endothelial cells occurs particularly at sites with slow blood flow. This will presumedly happen, where the contact time is long enough, such as during capillary passage or in the venous system following with low pressure and orthostatic narrow venous network.

When this happens, the injected genetic information will cause those endothelial cells to produce portions of spike proteins and present them on their surfaces to passing blood cells.

Many healthy individuals have CD8 lymphocytes that patrol the blood and recognize such corona spike peptides, which may be due to previous COVID infection but also to cross-reactivity with other coronavirus types [6; 7] [8].

We must assume that these CD8 lymphocytes launch an attack on the corresponding cells upon contact. This can lead to vascular wall damage at countless sites in the body with subsequent triggering of blood clotting by activation of platelets (thrombocytes). This is what happens when the vaccine itself enters the blood.

2.

when such spike proteins, genetically engineered from our cells, enter the blood, they directly bind with the ACE2 receptors of platelets, which also leads to blood clotting and thrombosis [9][10]. This has also been observed with whole coronaviruses entering the blood in rare cases. Thrombocytopenia so developed has also been reported in vaccinated individuals [11][12][13].

3.

In addition: the ability of the SARS-CoV-2 spike proteins to initiate cell fusions is very strong. The resulting giant cells can also lead to vasoobstruction, inflammatory responses, and microthrombosis. (14)

Manifestations of all three risks

On blood tests, it can be seen by a drop in platelet count and the appearance of D-dimers (fibrin degradation products) in the blood. Clinically, there can be innumerable damages as a result of circulatory disorders throughout the body, including the brain, spinal cord and heart. Because of such consumption of clotting

factors and platelets, hemorrhage can also occur in various organs and have fatal consequences, for example, in the brain.

Importantly, for all of the above possibilities that can lead to disseminated intravascular coagulation (DIC), all three vaccines lack evidence that those risks have been excluded by the EMA prior to their approval for use in humans.

References:

(1) Zhou et al. BMC Infectious Diseases 2013, 13:433, http://www.biomedcentral.com/1471-2334/13/433

(2) SARS-CoV-2-derived peptides define heterologous and COVID-19-induced T cell recognition, Nature immunology.

(3) Systemic and mucosal antibody responses specific to SARS-CoV-2 during mild versus severe COVID-19 Cervia, Carlo et al. Journal of Allergy and Clinical Immunology, Volume 147, Issue 2, 545 - 557.e9

(4) Hassett, K. J.; Benenato, K. E.; et al.(2019).Optimization of Lipid Nanoparticles for Intramuscular Administration of mRNA Vaccines, Molecular therapy. Nucleic acids 15 : 1-11.

(5) Chen, Y. Y.; Syed, A. M.; MacMillan, P.; Rocheleau, J. V. and Chan, W. C. W.(2020). Flow rate affects nanoparticle uptake into endothelial cells, Advanced materials 32 : 1906274.

(6) Grifoni, A. et al.(2020). Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals, Cell 181 : 1489-1501.e15.

(7) Nelde, A.; Bilich et al (2020). SARS-CoV-2-derived peptides define heterologous and COVID-19-induced T cell recognition, Nature immunology.

(8) Sekine, T. et al.(2020). Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19, Cell 183 : 158-168.e14.

(9) Zhang, S.; Liu, Y.; Wang, et al.(2020). SARS-CoV-2 binds platelet ACE2 to promote thrombosis in COVID-19, Journal of hematology & oncology 13 : 120.

(10) Lippi, G. et al. 2019 (COVID-19) infections: a meta-analysis, Clin. Chim. Acta 506 : 145-148.

(11) Grady, D. (2021). A Few Covid Vaccine Recipients Developed a Rare Blood Disorder, The New York Times, Feb. 8, 2021.

(12) Geoffrey D. Wool,: The Impact of COVID-19 Disease on Platelets and Coagulation, DOI: 10.1159/000512007.

(13) Giannis D, Ziogas IA, Gianni P. Coagulation disorders in coronavirus infected patients: COVID-19, SARS-CoV-1, MERS-CoV and lessons from the past. J Clin Virol. 2020 Jun; 127: 104362.

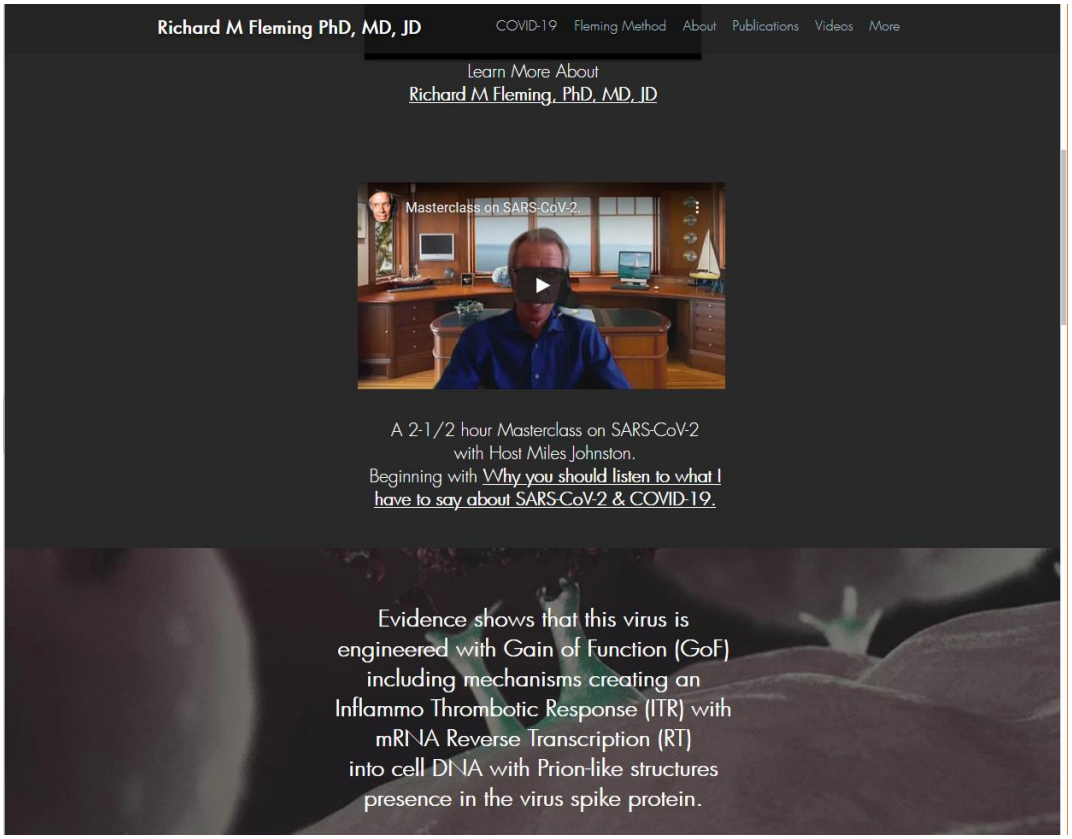
(14) Theuerkauf et al, iScience 24, 102170, March 19, 2021[12]Nickbakhsh, Sema, (2019) Virus-virus interactions impact the population dynamics of influenza and the common cold, www.pnas.org/cgi/doi/10.1073/pnas.1911083116

(15) Virus-virus interactions impact the population dynamics of influenza and the common cold, Sema Nickbakhsh, et al. (2019)MRC-University of Glasgow, Centre for Virus Research

Dr Richard M Fleming: delovanje spike proteina in cepiv na človeka

https://www.flemingmethod.com/

Analiza dr. Fleminga, ki je razvil in raziskal zdravljenje Covid s kombinacijami zdravil, razkriva škodljivost spike proteina in cepiv.



Gain of Function Research

With a paper trail from China's bat caves to North Carolina, to increase infectivity and virulence of virus. Documents tracking the virus back to Wuhan with $3.5 million from U.S. National Institute of Health funding.

"There are viruses that exist in bat species, preprogrammed to jump between species and replicate just fine in humans. We had no access to the viruses in China, all we had was access to the sequence."
min 2:15 - 2:30

Dr. Ralph Baric
Professor of Microbiology and Immunology
University of North Carolina

Reports

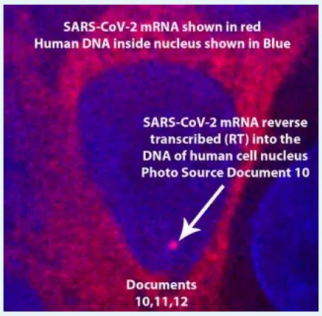
- A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence
- Difference in Receptor Usage between Severe Acute Respiratory Syndrome (SARS) Coronavirus and SARS-Like Coronavirus of Bat Origin
- Dual-Use Gain-of-Function by Viral Serial Passage Mimics Zoonotic Jump

mRNA Transcription Capacity

Evidence shows that SARS-CoV-2 spike protein can Integrate into human DNA.

Image below shows mRNA getting into brain cells

- Using the Reverse Transcriptase (RT) found in human platelets, CD4 (Helper Cells) and other cells carrying Long Interspersed Nuclear Elements (LINE-1); or by the HIV-RT. Research has shown that SARS-CoV-2 mRNA can insert itself into human DNA
- LINE-1 averages 6,000 base pairs (bp) and comprises approximately 17% of human DNA
- 80 -100 of these LINE-1 segments are known to retro transpose leading to insertions, deletions, and rearrangement of genetic material.



Report

- SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome

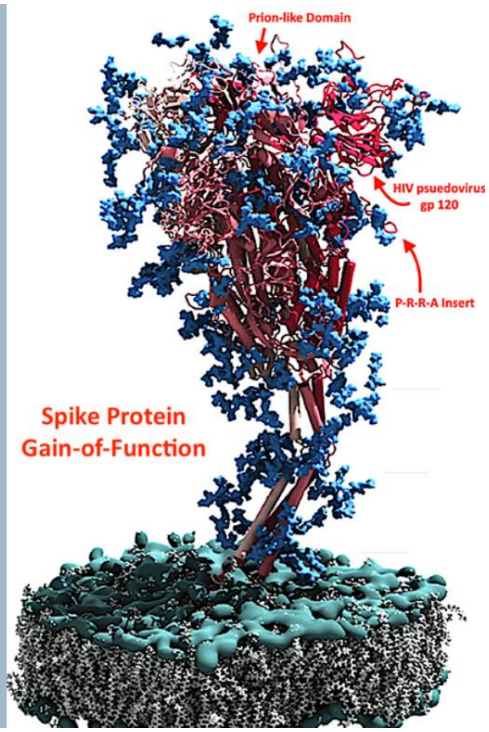
Presence of Prion-like Structure in Spike Protein

Prion-like domains are critical to SARS-CoV-2 virulence. Prions are associated with "Mad Cow Disease" and neuromuscular movement disorders seen in Parkinson's Disease and Alzheimer's.

Creutzfeldt–Jakob disease (CJD), also known as subacute spongiform encephalopathy or neurocognitive disorder due to prion disease, is a fatal degenerative brain disorder.[4][1] Early symptoms include memory problems, behavioral changes, poor coordination, and visual disturbances.[4] Later symptoms include dementia, involuntary movements, blindness, weakness, and coma.[4] About 70% of people die within a year of diagnosis.[4]

Reports

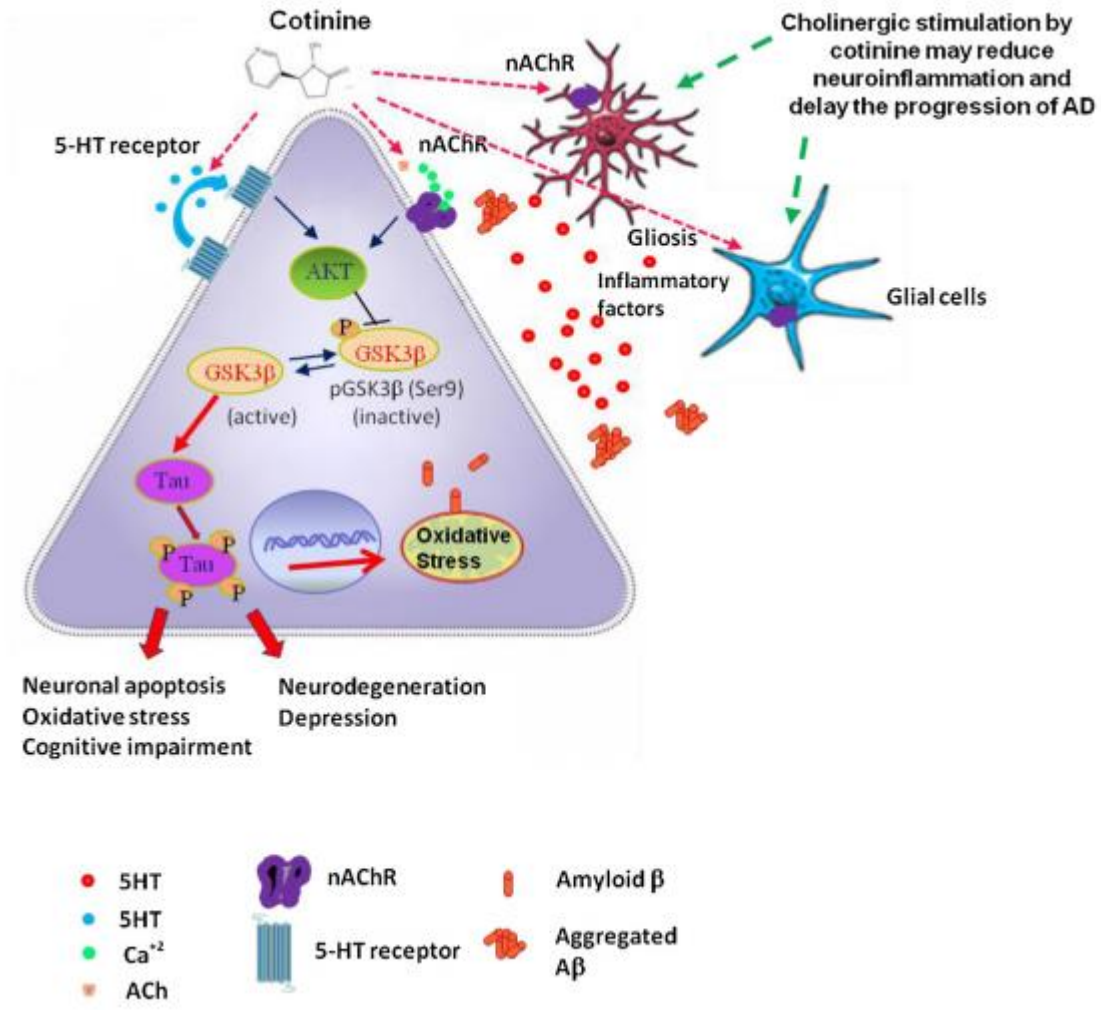
- SARS-CoV-2 prion-like domains in spike proteins enable higher affinity to ACE2
- Somatic APP gene recombination and mutations occur mosaically in normal and Alzheimer's disease neurons



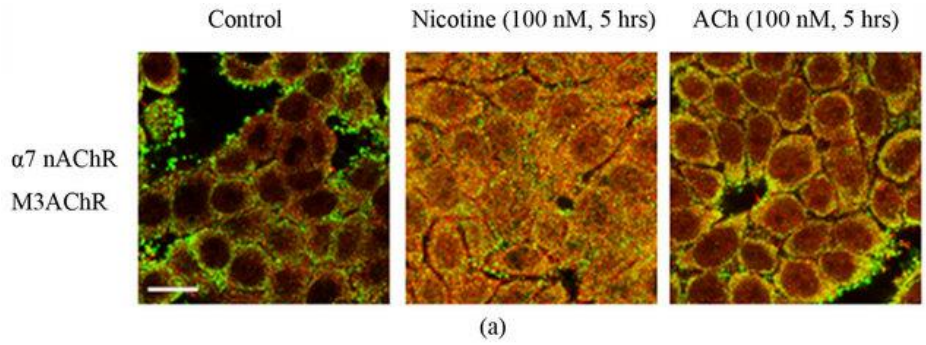
Spike protein SARS virusa je rakotvorno in nevrodegenerativno Bio-orožje

A BIOWEAPON - AN UNPARALLELED DEATH MACHINE: THE SPIKE PROTEIN OF SARS-CoV-2 IS AN ONCOGENIC/NEURODEGENERATIVE VIRAL BIOWEAPON. IT ALSO CAUSES IMMEDIATE ENDOTHELIAL DAMAGE.

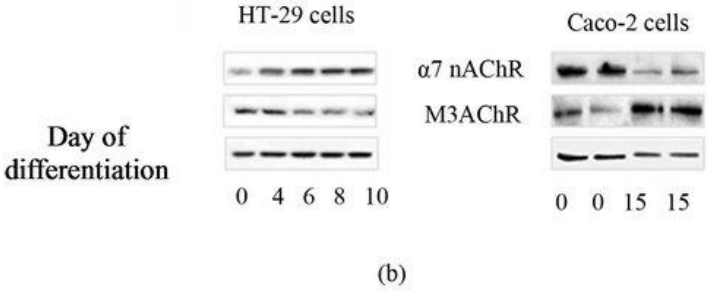
Make no mistake. The respiratory effects of SARS-CoV-2 are a dangerous distraction. At The Center:



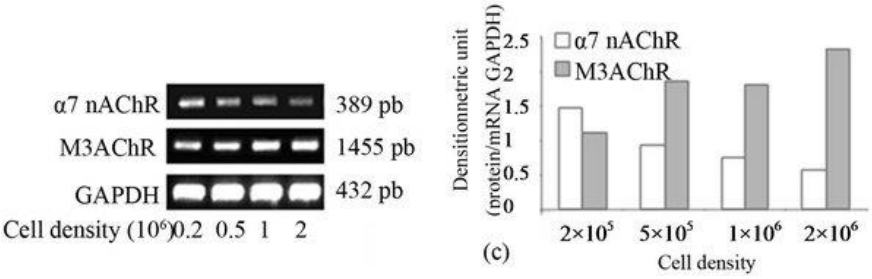
2) Endothelial cells are a nexus of receptors for oncogenesis and neurodegenaration. In addition to having ACE2 receptors, allowing for the invasion of SARS-CoV-2, they also have a7 nAChR receptors. The spike protein antagonizes these receptors and allows for neuroinflammation and neurodegeneration, in addition to interfering with The Cholinergic Anti-inflammatory Pathway. Antagonizing a7 nAChR receptors also DESTABALIZES EPITHELIAL CELL ORGANIZATION. It disrupts epithelium integrity and promotes inflammatory response and tumor development. The spike protein also alters the metabolism of the body. It causes mitochondrial damage which alters cellular metabolism. The body is put into a state of starvation. It is the same state as cancer cachexia (wasting disease).



(a)



(b)



(c)

SARS IS A HIGHLY SPECIALIZED, BOUTIQUE VIRUS

PERFECTLY AND MOST EFFICIENTLY TUNED TO THE EXACT RECEPTORS NEEDED TO PROMOTE CANCER, NEURODEGENERATION AND MULTIPLE SYSTEM ATROPHY (ORGAN FAILURE). We are dealing with a virus that will eliminate a vast majority of mankind. Putting the spike protein in people allows for this without exposing individuals to the N protein, which is much more likely to put you in the ICU with ARDS. THERE IS NO IMMUNITY - ONLY ACCELERATION. Furthermore, a study from Wuhan shows that altering a7 nAChR receptors can have effects on the fetus promoting autoimmune disease.

https://file.scirp.org/Html/11-8901696_35274.htm

https://oncotarget.com/article/21526/text/

http://ijcep.com/files/ijcep0096190.pdf

https://biorxiv.org/content/10.110