COVID-19: The Science We Should Know

Overview

Since the inception of the COVID-19 pandemic in the spring of 2020, the messaging from most governmental authorities and major-media outlets has been largely consistent — COVID-19 poses a grave threat to all of humanity, lockdown policies and mask mandates are necessary to 'stop the spread,' existing diagnostic tests are reliable indicators of infection, no preventatives or treatments exist for COVID-19, the inoculations developed under Operation Warp Speed are 'safe and effective,' and mass inoculation is essential to end the pandemic. Meanwhile, dissenters from this orthodoxy have been routinely vilified and censored, regardless of their qualifications, personal experience, or the substance of their case.

In such a divisive and restrictive environment, acquiring a well-informed understanding of most any COVID-related topic is remarkably challenging. Sensible evaluation of any issue requires familiarity not only with the arguments for prevailing beliefs, but also the evidence presented by knowledgeable skeptics and critics.

This document is intended as a reference resource for anyone curious about the science and data underlying such contrarian positions. Organized by topic, it presents links to primary-source materials, the bulk of which are scientific manuscripts (i.e., scholarly studies, papers, articles, meta-analyses) and related resources. The testimonies of credentialed scientists and medical professionals are also included, while materials based on inexpert opinion have been assiduously avoided.

For ease of use and comprehension, key excerpts accompany most citations, but we strongly encourage you to dig further by following the links and doing your own independent research.

To suggest an addition for this compilation meeting the criteria described above, or to notify us in the event that a cited manuscript has been retracted, please send an e-mail to JurorNumber8@protonmail.com.

This compilation is for informational purposes only, and is not predictive or prescriptive. So please think for yourself, do your own due diligence, and draw your own (well-informed) conclusions.

Peace & good health to you and yours.

Updated **November 17, 2021**.

indicates a cited work to be checked for updates with each release of this document.

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Lockdowns and Mask Mandates

Lockdowns: Ineffectiveness and Harms

Note: The citations below are presented in reverse, chronological order.

[1] ***Longitudinal Trends in Body Mass Index Before and During the COVID-19 Pandemic Among Persons Aged 2–19 Years — United States, 2018–2020***
CDC
Samantha J. Lange, Lyudmyla Kompaniyets, *et al*.
September 17, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7037a3-H.pdf

> "Obesity is a serious health concern in the United States, affecting more than one in six children and putting their long-term health and quality of life at risk. During the COVID-19 pandemic, children and adolescents spent more time than usual away from structured school settings, and families who were already disproportionally affected by obesity risk factors might have had additional disruptions in income, food, and other social determinants of health. As a result, children and adolescents might have experienced circumstances that accelerated weight gain, including increased stress, irregular mealtimes, less access to nutritious foods, increased screen time, and fewer opportunities for physical activity (e.g., no recreational sports)… **Between the prepandemic and pandemic periods, the rate of BMI increase approximately doubled**, from 0.052 (95% confidence interval [CI] = 0.051–0.052 to 0.100 (95% CI = 0.098–0.101) [*emphasis added*]."

[2] ***The Truth About Lockdowns***
Rational Ground
July 6, 2021
https://rationalground.com/the-truth-about-lockdowns/

> A list of links to authoritative studies and articles on the impact of lockdown policies. Categories include people suffering with other diseases, starvation and food insecurity, effects on children, domestic/sexual abuse, economy and poverty, mental health, suicides, and substance abuse.

[3] **ADDED since 10/14/2021**
Editor's Note – Cancer Review Issue
Collateral Global
Jay Bhattacharya
June 1, 2021
https://collateralglobal.org/article/editors-note-4/

> "Lockdown-related diagnosis and treatment delays will result in long-term harms for cancer patients…
>
> To protect our health care systems, the media and some in public health created the impression in many that COVID is more deadly than cancer. This impression, unfortunately, led many cancer patients to skip their life-saving treatments. An American Cancer Society survey in May 2020 of cancer patients reported shocking numbers. Nearly eight out of ten cancer patients

reported delays in care, with almost six out ten skipping doctor visits, one in four skipping imaging, and one in six missing surgery. **These are directly visible harms caused by the lockdown** [*emphasis added*]."

[4] ***The Impact of the COVID-19 Pandemic and Policy Responses on Excess Mortality***
National Bureau of Economic Research
Virat Agrawal, Jonathan H. Cantor, Neeraj Sood, and Christopher M. Whaley
June 2021
https://www.nber.org/system/files/working_papers/w28930/w28930.pdf

"**Abstract**: As a way of slowing COVID-19 transmission, many countries and U.S. states implemented shelter-in-place (SIP) policies. However, the effects of SIP policies on public health are a priori ambiguous as they might have unintended adverse effects on health. The effect of SIP policies on COVID-19 transmission and physical mobility is mixed. To understand the net effects of SIP policies, we measure the change in excess deaths following the implementation of SIP policies in 43 countries and all U.S. states…

Introduction: [W]e fail to find that SIP policies saved lives. To the contrary, we find a positive association between SIP policies and excess deaths. We find that following the implementation of SIP policies, **excess mortality increases** [*emphasis added*]…

If SIP were implemented when excess deaths were rising then the results … would be biased towards finding that SIP policies lead to excess deaths. However, we find the opposite: countries that implemented SIP policies experienced a decline in excess mortality prior to implementation compared to countries that did not implement SIP policies…

[T]he implementation of SIP policies does not appear to have met the aim of reducing excess mortality. There are several potential explanations for this finding. First, it is possible that SIP policies do not slow COVID-19 transmission… Second, it is possible that SIP policies increased deaths of despair due to economic and social isolation effects of SIP policies. Recent estimates in the U.S between March and August 2020 show that drug overdoses, homicides, and unintentional injuries increased in 2020, while suicides declined (Faust et al. 2021). Third, existing studies suggest that SIP policies led to a reduction in non-COVID-19 health care, which might have contributed to an increase in non-COVID-19 deaths."

[5] ***Covid Lockdown Cost/Benefits: A Critical Assessment of the Literature***
Simon Fraser University
Douglas W. Allen
April 2021
https://www.sfu.ca/~allen/LockdownReport.pdf?

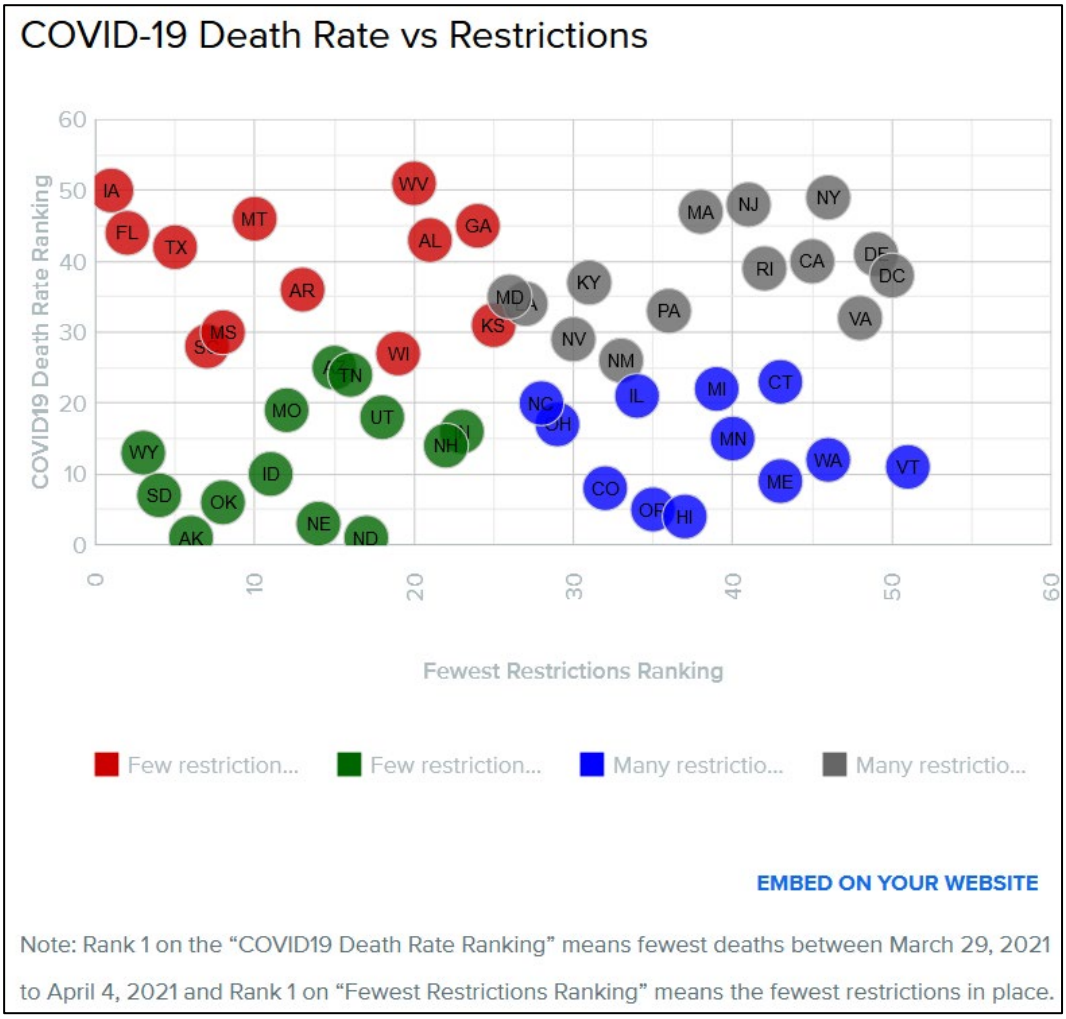
"**Abstract**: An examination of over 80 Covid-19 studies reveals that many relied on assumptions that were false, and which tended to over-estimate the benefits and under-estimate the costs of lockdown. As a result, most of the early cost/benefit studies arrived at conclusions that were refuted later by data, and which rendered their cost/benefit findings incorrect. Research done over the past six months has shown that lockdowns have had, at best, a marginal effect on the number of Covid-19 deaths… The limited effectiveness of lockdowns explains why, after one year, the unconditional cumulative deaths per million, and the pattern of daily deaths per million, is not negatively correlated with the stringency of lockdown across countries."

[6] ***The Backward Art of Slowing the Spread? Congregation Efficiencies during COVID-19***
Casey B. Mulligan
April 2021
https://bfi.uchicago.edu/wp-content/uploads/2021/04/BFI_WP_2021-51-1.pdf

> "Micro evidence contradicts the public-health ideal in which households would be places of solitary confinement and zero transmission. Instead, the evidence suggests that 'households show the highest transmission rates' and that 'households are high-risk settings for the transmission of [COVID-19].'"

[7] ***States with the Fewest Coronavirus Restrictions***
WalletHub
Adam McCann
April 6, 2021
https://wallethub.com/edu/states-coronavirus-restrictions/73818

> "In order to determine the states with the fewest coronavirus restrictions, WalletHub compared the 50 states and the District of Columbia across 13 key metrics. Our data set ranges from whether restaurants are open to whether the state has required face masks in public and workplace temperature screenings. Read on for the state ranking, additional insight from a panel of experts and a full description of our methodology…
>
> **Sources**: Data used to create this ranking were collected from the U.S. Census Bureau, the U.S. Bureau of Labor Statistics, the Kaiser Family Foundation, Ballotpedia, Editorial Projects in Education, Centers for Disease Control and Prevention, National Restaurant Association, Littler Mendelson, Husch Blackwell and Ogletree Deakins."
>
> **US States**



[8] ***Sweden saw lower 2020 death spike than much of Europe – data***
Reuters
Johan Ahlander
March 24, 2021
https://www.reuters.com/article/us-health-coronavirus-europe-mortality-idUSKBN2BG1R9

> "Sweden, which has shunned the strict lockdowns that have choked much of the global economy, emerged from 2020 with a smaller increase in its overall mortality rate than most European countries, an analysis of official data sources showed…
>
> Preliminary data from EU statistics agency Eurostat compiled by Reuters showed Sweden had 7.7% more deaths in 2020 than its average for the preceding four years. Countries that opted for several periods of strict lockdowns, such as Spain and Belgium, had so-called excess mortality of 18.1% and 16.2% respectively…
>
> Sweden's excess mortality also came out at the low end of the spectrum in a separate tally of Eurostat and other data released by the UK's Office for National Statistics last week."

[9] **#The Price of Panic**
Last updated March 21, 2021
A collection of links illustrating the derivative harms incurred by policy responses to the COVID-19 pandemic. Categories include 'Hunger & Poverty,' 'Death from Other Diseases,' 'Harm to Children,' 'Anxiety, Depression & Suicides,' and 'Oppression.'
https://thepriceofpanic.com/

> "The negative effects of lockdown are too often dismissed as small sacrifices, necessary to keep a highly deadly disease from spreading. These sacrifices are, in fact, neither necessary nor small. The disease is a serious threat to a minority of the population that *can* be protected without lockdowns. All too often, when major harms become hard to ignore, they are lamented as damage caused by COVID-19 itself, even though it is our panic-driven measures that are to blame. This is an effort to bring focus to the magnitude of suffering taking place around us because of lockdowns."

[10] ***COVID-19 Lockdown Policies: An Interdisciplinary Review***
University of Greenwich
Oliver Robinson
March 10, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3782395

> "**Abstract**: Lockdown interventions employed in response to the COVID-19 pandemic have been evaluated via research at biomedical, economic, psychological, and ethical levels of analysis. The aim of this article is to integrate these perspectives into an interdisciplinary biopsychosocial review. Biomedical evidence from the early months of the pandemic suggests that lockdowns were associated with a reduced viral reproductive rate, but that less restrictive measures also had a similar effect. Lockdowns are associated with reduced mortality in epidemiological modelling studies but not in studies based on empirical data from the Covid-19 pandemic. Psychological research supports the proposition that lengthy lockdowns may exacerbate stressors such as social isolation and unemployment that have been shown to be strong predictors of falling ill if exposed to a respiratory virus. Studies at the economic level of analysis points to the possibility that deaths associated with economic harms or underfunding of other health issues may outweigh the deaths that lockdowns save, and that the extremely high financial cost of lockdowns may have negative implications for overall population health in terms of diminished resources for treating other conditions."

[11] ***Stay-at-home policy is a case of exception fallacy: an internet-based ecological study***
Nature - Scientific Reports
R.F. Savaris, G. Pumi, J. Dalzochio, and R. Kunst
March 5, 2021
https://www.nature.com/articles/s41598-021-84092-1

> "**Abstract**: A recent mathematical model has suggested that staying at home did not play a dominant role in reducing COVID-19 transmission. The second wave of cases in Europe, in regions that were considered as COVID-19 controlled, may raise some concerns. Our objective was to assess the association between staying at home (%) and the reduction/increase in the number of deaths due to COVID-19 in several regions in the world. In this ecological study, data from www.google.com/covid19/mobility/, ourworldindata.org and covid.saude.gov.br were combined… After preprocessing the data, 87 regions around the world were included, yielding

3741 pairwise comparisons for linear regression analysis. Only 63 (1.6%) comparisons were significant. With our results, we were not able to explain if COVID-19 mortality is reduced by staying at home in ~ 98% of the comparisons after epidemiological weeks 9 to 34.

Discussion: We were not able to explain the variation of deaths/million in different regions in the world by social isolation, herein analyzed as differences in staying at home, compared to baseline… These findings are in accordance with those found by Klein et al… Likewise, Chaudry et al. made a country-level exploratory analysis, using a variety of socioeconomic and health-related characteristics, similar to what we have done here, and reported that **full lockdowns and wide-spread testing were not associated with COVID-19 mortality** per million people [*emphasis added*]."

[12] ***Assessing mandatory stay-at-home and business closure effects on the spread of COVID-19***
European Journal of Clinical Investigation
Eran Bendavid, Christopher Oh, Jay Bhattacharya, and John Ioannidis
January 5, 2021
https://onlinelibrary.wiley.com/doi/10.1111/eci.13484

"**Results**: … **In none of the 8 countries and in none out of the 16 comparisons** (against Sweden or South Korea) were the effects of mrNPIs [*more restrictive nonpharmaceutical interventions*] significantly negative (beneficial) [*emphasis added*]."

"**Discussion**: In the framework of this analysis, there is no evidence that more restrictive non-pharmaceutical interventions ('lockdowns') contributed substantially to bending the curve of new cases in England, France, Germany, Iran, Italy, the Netherlands, Spain, or the United States in early 2020. By comparing the effectiveness of NPIs on case growth rates in countries that implemented more restrictive measures with those that implemented less restrictive measures, the evidence points away from indicating that mrNPIs (major interventions) provided additional meaningful benefit above and beyond lrNPIs (light interventions)…

In summary, we fail to find strong evidence supporting a role for more restrictive NPIs in the control of COVID in early 2020. We do not question the role of all public health interventions, or of coordinated communications about the epidemic, but we fail to find an additional benefit of stay-at-home orders and business closures. The data cannot fully exclude the possibility of some benefits. However, even if they exist, these benefits may not match the numerous harms of these aggressive measures. More targeted public health interventions that more effectively reduce transmissions may be important for future epidemic control without the harms of highly restrictive measures."

[13] ***White Paper: Covid Recovery – A Scientific Approach***
COVID-19 Ireland
December 2020
https://covidrecovery.ie/
Medical Signatories:
https://drive.google.com/file/d/1Mfc85i17Z9d2CyLzlf0bOqin3vbXbQfd/view
About: "Our goal is to bring objectivity and balance to the discussion around management of the COVID19 Pandemic. Our values are based on the time honoured clinical mantra of 'first, do no harm.' We are gravely concerned with the complete absence of reasonable debate on the subject within our media. As clinicians, we see first hand the other side of the 'daily case numbers' update: depression, fear, isolation, unemployment, the destruction of hope etc. We are committed to

proposing reasonable and workable solutions to the problems faced by our society at this time and urge avoidance of the destructive and singular path of cyclical lockdown. Directly below is our white paper, which is a medically composed paper, written and verified by doctors and medical practitioners on the effects of lockdown, and the path out of this pandemic."

> "**Lockdown Interventions – are there convincing real-world benefits for morbidity / mortality?** … We now have the benefit of experience and multiple published analyses reflecting real-world data and outcomes. A recent paper in The Lancet showed no correlation between lockdown measures and mortality outcomes: 'Rapid border closures, full lockdowns, and wide-spread testing were not associated with COVID-19 mortality per million people.' Notably, a large number of published preprint analyses converge on lockdowns having a minimal beneficial effect on mortality outcomes. There is a dearth of published evidence indicating that lockdowns reduce overall mortality; a significant concern in itself, given the enormous negative impacts of lockdown. Sweden is particularly notable as a 'control' country which largely followed the 2019 WHO Pandemic Guidelines, rather than pursuing the very new lockdown approach. With this strategy, they experienced a similar mortality impact to other European countries, when various key factors are accounted for."
>
> "**Lockdown Interventions – what is the evidence for costs far exceeding any benefits?** It is critical that we now apply our understanding of these analyses and ask the question: Do the costs of lockdown outweigh (possibly greatly) - the benefits of lockdown? A recent paper published in the British Medical Journal concluded that lockdown interventions could increase COVID-19 mortality rates over the long term. Another analysis in preprint proposes the same unintended consequences. It is crucial that we consider these latest analyses, and face the possibility that lockdown interventions could result in more COVID-19 deaths than if we simply followed the WHO 2019 pandemic guidelines, as Sweden did."

[14] ***Lockdowns Do Not Control the Coronavirus: The Evidence***
AIER
December 19, 2020
A review of the findings from 35 studies examining the effectiveness and consequences of lockdown policies, with key excerpts and related links.
https://www.aier.org/article/lockdowns-do-not-control-the-coronavirus-the-evidence/

> "The use of universal lockdowns in the event of the appearance of a new pathogen has no precedent. It has been a science experiment in real time, with most of the human population used as lab rats. The costs are legion…
>
> The pro-lockdown evidence is shockingly thin, and based largely on comparing real-world outcomes against dire computer-generated forecasts derived from empirically untested models, and then merely positing that stringencies and 'nonpharmaceutical interventions' account for the difference between the fictionalized vs. the real outcome. The anti-lockdown studies, on the other hand, are evidence-based, robust, and thorough, grappling with the data we have (with all its flaws) and looking at the results in light of controls on the population."

[15] ***Covid-19 Mortality: A Matter of Vulnerability Among Nations Facing Limited Margins of Adaptation***
Frontiers in Public Health
Quentin De Larochelambert, Andy Marc, Juliana Antero, Eric Le Bourg, and Jean-François Toussaint
November 19, 2020
https://www.frontiersin.org/articles/10.3389/fpubh.2020.604339/full

> "**Results**: Higher Covid death rates are observed in the [25/65°] latitude and in the [−35/−125°] longitude ranges. The national criteria most associated with death rate are life expectancy and its slowdown, public health context (metabolic and non-communicable diseases (NCD) burden vs. infectious diseases prevalence), economy (growth national product, financial support), and environment (temperature, ultra-violet index). Stringency of the measures settled to fight pandemia, including lockdown, did not appear to be linked with death rate.
>
> **Conclusion**: Countries that already experienced a stagnation or regression of life expectancy, with high income and NCD rates, had the highest price to pay. This burden was not alleviated by more stringent public decisions. Inherent factors have predetermined the Covid-19 mortality: understanding them may improve prevention strategies by increasing population resilience through better physical fitness and immunity."

[16] ***The Mystery of Taiwan***
AIER
Amelia Janaskie
November 7, 2020
https://www.aier.org/article/the-mystery-of-taiwan/

> "In terms of stringency, Taiwan ranks among the lowest in the world, with fewer controls than Sweden and far lower than the U.S… The government did test at the border and introduce some minor controls but nowhere near that of most counties. In general, Taiwan rejected lockdown in favor of maintaining social and economic functioning.
>
> How did Taiwan fare in terms of cases? Taiwan has seen 573 cases, which is remarkably low for a country with a population of close to 24 million and a population density of 1,739 people per square mile.
>
> The Taiwanese case reveals something extraordinary about pandemic response. As much as public-health authorities imagine that the trajectory of a new virus can be influenced or even controlled by policies and responses, the current and past experiences of coronavirus illustrate a different point. The severity of a new virus might have far more to do with endogenous factors within a population rather than the political response. According to the lockdown narrative, Taiwan did almost everything 'wrong' but generated what might in fact be the best results in terms of public health of any country in the world."

[17] **Interview with Dr. David Nabarro, WHO Special Envoy on COVID-19**
The Spectator
October 9, 2020
https://twitter.com/spectator/status/1314573157827858434

> "We in the World Health Organization do not advocate lockdowns as the primary means of control of this virus… It seems we may well have a doubling of world poverty by next year. We may well have at least a doubling of child malnutrition… This is a terrible, ghastly global catastrophe."

[18] ***The Great Barrington Declaration***
Martin Kulldorff, Sunetra Gupta, Jay Bhattacharya, *et al*.
October 4, 2020
https://gbdeclaration.org/
Signatures: https://gbdeclaration.org/view-signatures/
Signed by 14,879 medical & health scientists and 43,804 medical practitioners, as of September 4, 2021.

> "As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection... Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden."

[19] ***Undoing the untold harms of COVID-19 on young people: a call to action***
University of Exeter
Matthew Owens
September 10, 2020
https://thefatemperor.com/wp-content/uploads/2020/11/PDF-UK-Site-Reachwell.org-Mental-Health-Evidence-Based.com_.pdf

> "Some 80% of the 2000 young people with a history of mental health needs surveyed by the charity Young Minds agreed that the COVID-19 crisis had worsened their mental health[3]…
>
> [T]he risk of mortality is moderated sharply by advancing years such that, compared to young people (0-19), being 80 years old or over increases the odds of death more than 80-fold[5]."
>
> "Although the risk posed by SARS-CoV-2 is very low, there is unfortunately already a wealth of evidence suggesting that the lockdown is causing **untold harms to children and young people** [*emphasis added*]. Compared to other age groups, children's mental health has deteriorated the most during this time[12 13 14], which may also cause long-term damage[15] In addition, reported physical abuse to children rose by half during the lockdown[16] , children's physical conditions have worsened through delayed presentation to services[17] and most pupils are thought by teachers to be behind in their school learning (by an estimated 3 months)[18]."

[20] ***Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020***
Centres for Disease Control and Prevention (CDC)
Mark E. Czeisler, Rashon I. Lane, *et al*.
August 14, 2020
https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm

"**What is added by this report?** During June 24–30, 2020, U.S. adults reported considerably elevated adverse mental health conditions associated with COVID-19. Younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers reported having experienced disproportionately worse mental health outcomes, increased substance use, and elevated suicidal ideation."

"To assess mental health, substance use, and suicidal ideation during the pandemic, representative panel surveys were conducted among adults aged ≥18 years across the United States during June 24–30, 2020. Overall, **40.9% of respondents reported at least one adverse mental or behavioral health condition**, including symptoms of anxiety disorder or depressive disorder (30.9%), symptoms of a trauma- and stressor-related disorder (TSRD) related to the pandemic† (26.3%), and having started or increased substance use to cope with stress or emotions related to COVID-19 (13.3%). The **percentage of respondents who reported having seriously considered suicide in the 30 days before completing the survey (10.7%)** was significantly higher among respondents aged 18–24 years (**25.5%**), minority racial/ethnic groups (Hispanic respondents [**18.6%**], non-Hispanic black [black] respondents [**15.1%**]), self-reported unpaid caregivers for adults (**30.7%**), and essential workers (**21.7%**) [*emphasis added*]…

At least one adverse mental or behavioral health symptom was reported by more than one half of respondents who were aged 18–24 years (74.9%) and 25–44 years (51.9%), of Hispanic ethnicity (52.1%), and who held less than a high school diploma (66.2%), as well as those who were essential workers (54.0%), unpaid caregivers for adults (66.6%), and who reported treatment for diagnosed anxiety (72.7%), depression (68.8%), or PTSD (88.0%) at the time of the survey."

[21] ***"Stay at Home, Protect the National Health Service, Save Lives": A cost benefit analysis of the lockdown in the United Kingdom***
International Journal of Clinical Practice
David K. Miles, Michael Stedman, and Adrian H. Heald
August 13, 2020
https://onlinelibrary.wiley.com/doi/10.1111/ijcp.13674

"**Conclusion**: There is a need to normalise how we view COVID-19 because its costs and risks are comparable to other health problems (such as cancer, heart problems, diabetes) where governments have made resource decisions for decades. Treating possible future COVID-19 deaths as if nothing else matters is going to lead to bad outcomes. Good decision making does not mean paying little attention to the collateral damage that comes from responding to a worst-case COVID-19 scenario.

The lockdown is a public health policy and we have valued its impact using the tools that guide health care decision [*sic*] in the UK public health system. On that basis and taking a wide range of scenarios of costs and benefits of severe restrictions, we find the lockdown has consistently

generated costs that are greater—and often dramatically greater—than possible benefits."

[22] ***A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes***
The Lancet
Rabail Chaudhry, George Dranitsaris, Talha Mubashir, Justyna Bartoszko, and Sheila Riazi
July 21, 2020
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30208-X/fulltext

"**Background**: A country level exploratory analysis was conducted to assess the impact of timing and type of national health policy/actions undertaken towards COVID-19 mortality and related health outcomes.

3.4. Factors affecting COVID-19 critical cases rates and mortality… Lastly, government actions such as border closures, full lockdowns, and a high rate of COVID-19 testing **were not associated with statistically significant reductions in the number of critical cases or overall mortality** [*emphasis added*]."

[23] ***The State of Food Security and Nutrition in the World***
United Nations
July 13, 2020
https://www.who.int/docs/default-source/nutritionlibrary/publications/state-food-security-nutrition-2020-inbrief-en.pdf?sfvrsn=65fbc6ed_4

"A preliminary assessment suggests that the COVID-19 pandemic may add between **83 and 132 million people to the total number of undernourished** in the world in 2020 [*emphasis added*]…

The nutritional status of the most vulnerable population groups is likely to deteriorate further due to the health and socio-economic impacts of COVID-19."

[24] ***Exploring inter-country coronavirus mortality***
PANDA (Pandemics – Data & Analytics)
Trevor Nell, Ian McGorian, and Nick Hudson
July 9, 2020
https://pandata.org/wp-content/uploads/2020/07/Exploring-inter-country-variation.pdf

"**Abstract**. One of the most interesting features of the COVID-19 outbreak is the stark difference between mortality experience in different countries. No simple and plausible explanations that we are aware of have been advanced. Though various hypotheses have been put forward, some more hopeful than others, many display an element of confirmation bias in attempting to locate all differences in non-pharmaceutical intervention approaches.

For each country put forward as an example, usually in some pairwise comparison and with an attendant single cause explanation, there are a host of countries that fail the expectation. We set out to model the disease with every expectation of failure. In choosing variables it was obvious from the outset that there would be contradictory outcomes in the real world. But there were certain variables that appeared to be reliable markers as they had surfaced in much of the media and pre-print papers. These included age, co-morbidity prevalence and the seemingly light population mortality rates in poorer countries than that in richer countries. Even the worst

among developing nations—a clutch of countries in equatorial Latin America—have seen lighter overall population mortality than the developed world. Our aim therefore was not to develop the final answer, rather to seek common cause variables that would go some way to providing an explanation and stimulating discussion. There are some very obvious outliers in this theory, not the least of these being Japan.

We test and find wanting the popular notions that lockdowns with their attendant social distancing and various other NPIs confer protection."

[25] ***Comment on Flaxman et al. (2020): The illusory effects of non-pharmaceutical interventions on COVID-19 in Europe***
Nature
Stefan Homburg and Christof Kuhbandner
June 17, 2020
https://advance.sagepub.com/articles/preprint/Comment_on_Flaxman_et_al_2020_The_illusory_effects_of_non-pharmaceutical_interventions_on_COVID-19_in_Europe/12479987/1

"In a recent article, Flaxman et al. allege that non-pharmaceutical interventions imposed by European countries saved millions of lives. We show that their methods involve circular reasoning. The purported effects are pure artefacts, which contradict the data. Moreover, we demonstrate that the United Kingdom's lockdown was both superfluous and ineffective."

[26] ***Millions in UK miss cancer screenings, tests and treatments due to Covid-19***
The Guardian
Denis Campbell
June 1, 2021
https://web.archive.org/web/20200724212540/https://amp.theguardian.com/society/2020/jun/01/millions-in-uk-miss-cancer-screenings-tests-and-treatments-due-to-covid-19

"Almost 2.5 million Britons have not been screened, tested or treated for cancer because the Covid-19 pandemic has led to 'enormous disruption' of NHS care for the disease, experts have warned.

More than 24,000 cases of cancer have gone undiagnosed as a result of the suspension of normal services while delays in treatment mean some people's disease is now inoperable, Cancer Research UK (CRUK) says."

[27] ***Projected Deaths of Despair from COVID-19***
The Well Being Trust
Stephen Petterson, John M. Westfall, and Benjamin F. Miller
May 8, 2020
http://psych-history.weill.cornell.edu/pdf/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf

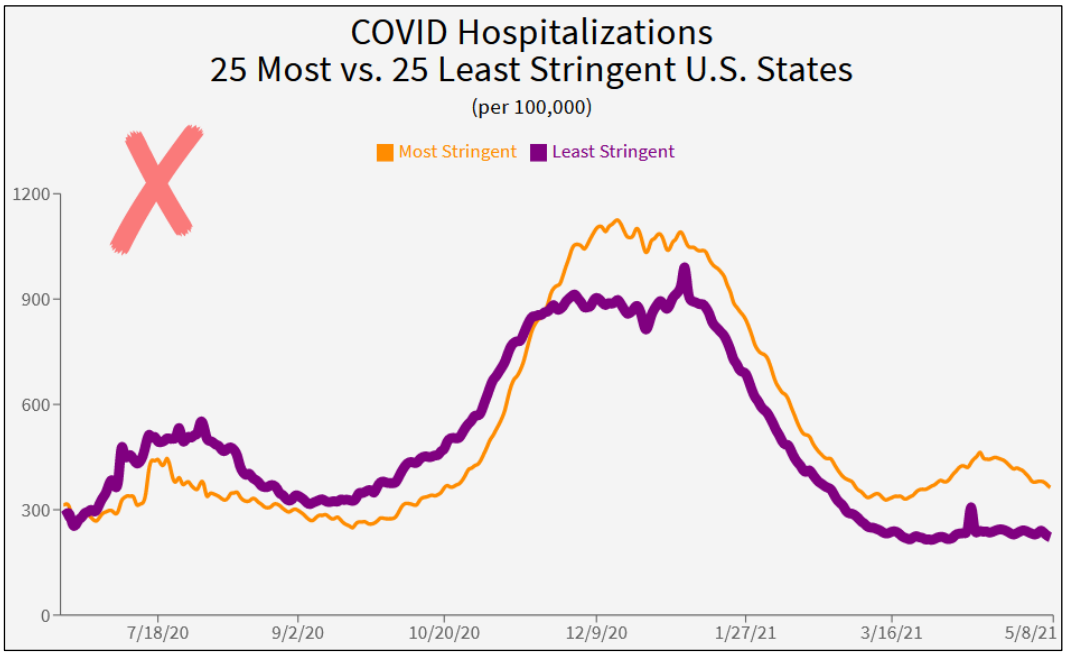
"**Executive Summary**: More Americans could lose their lives to deaths of despair, deaths due to drug, alcohol, and suicide, if we do not do something immediately. Deaths of despair have been on the rise for the last decade, and in the context of COVID-19, deaths of despair should be seen as the epidemic within the pandemic. The goal of this report is to predict what deaths of despair we might see based on three assumptions during COVID-19: economic recovery, relationship between deaths of despair and unemployment, and geography. Across nine different scenarios, additional deaths of despair range from 27,644 (quick recovery, smallest

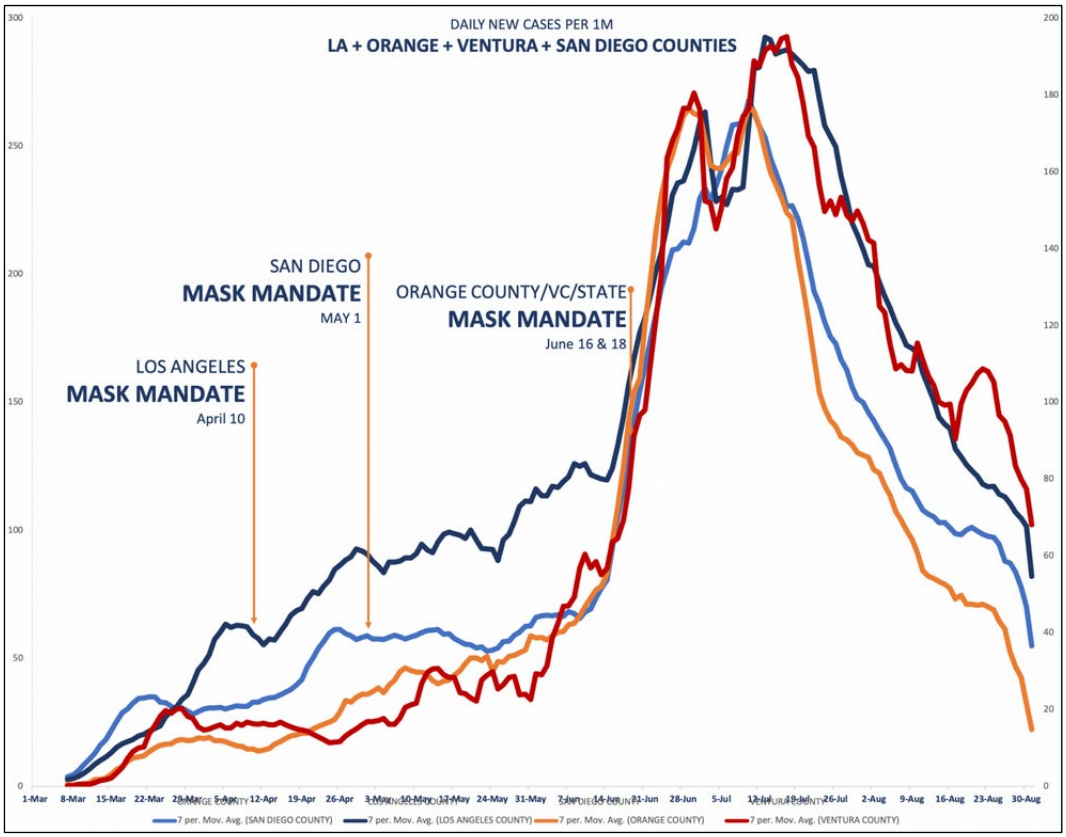
impact of unemployment on deaths of despair) to 154,037 (slow recovery, greatest impact of unemployment on deaths of despair), with somewhere in the middle being around 68,000."

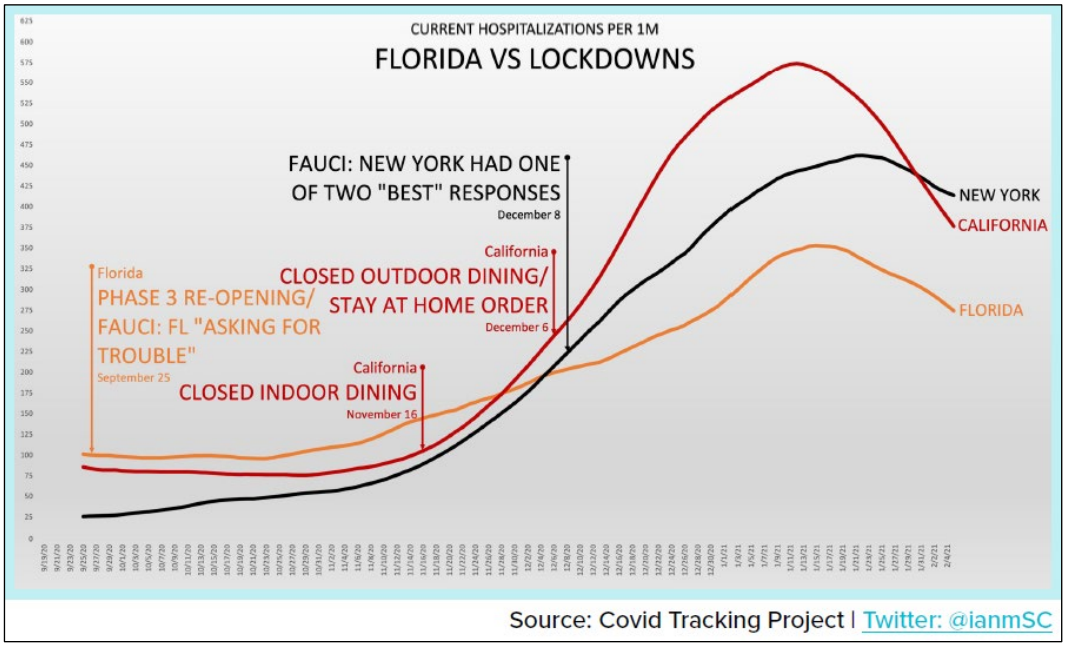
Mask Mandates: Ineffectiveness and Harms

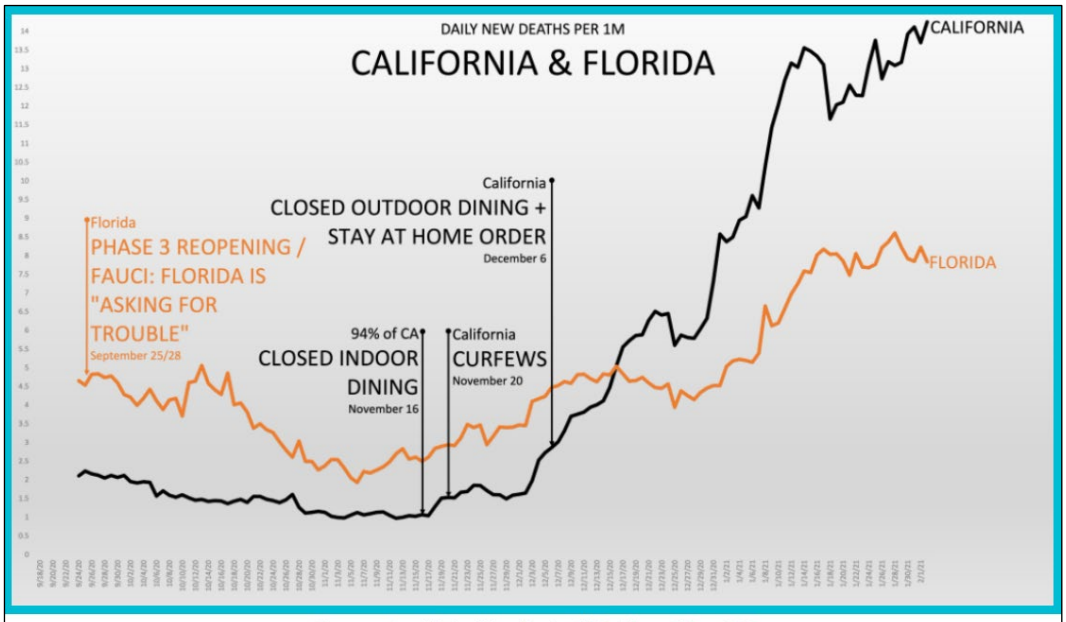
[28] **Mask charts**
A collection of charts from a wide range of jurisdictions demonstrating the lack of correlation (and, thus, causation) between governmental imposition of mask mandates and case, hospitalization, and death rates. (Source data: The COVID Tracking Project and Our World in Data)
https://rationalground.com/mask-charts/
https://rationalground.com/more-mask-charts/
https://twitter.com/yinonw/status/1321177359601393664
https://tomwoods.com/covid/
COVID-Charts Quiz: https://www.covidchartsquiz.com/

Mask-chart Examples:

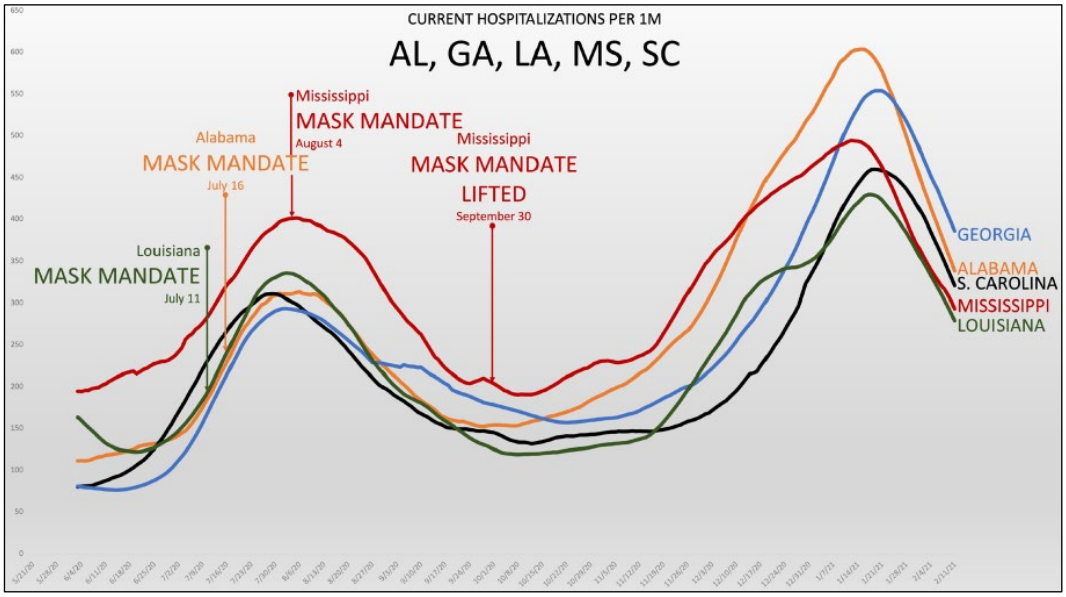


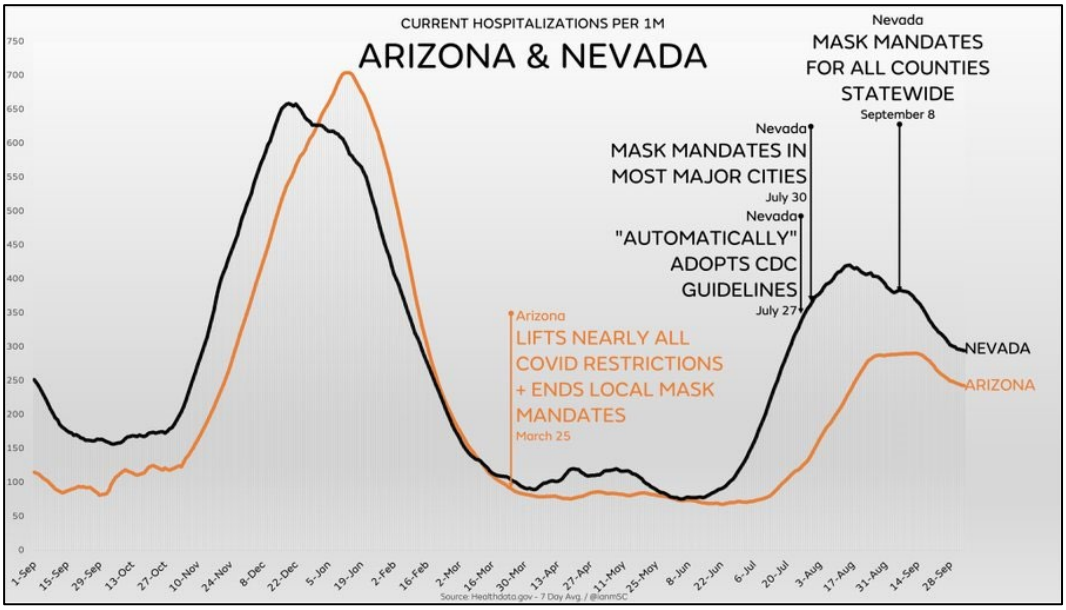

DAILY NEW CASES PER 1M
LA + ORANGE + VENTURA + SAN DIEGO COUNTIES
SAN DIEGO
MASK MANDATE
MAY 1
ORANGE COUNTY/VC/STATE
MASK MANDATE
June 16 & 18
LOS ANGELES
MASK MANDATE
April 10
7 per. Mov. Avg. (SAN DIEGO COUNTY)
7 per. Mov. Avg. (LOS ANGELES COUNTY)
7 per. Mov. Avg. (ORANGE COUNTY)
7 per. Mov. Avg. (VENTURA COUNTY)

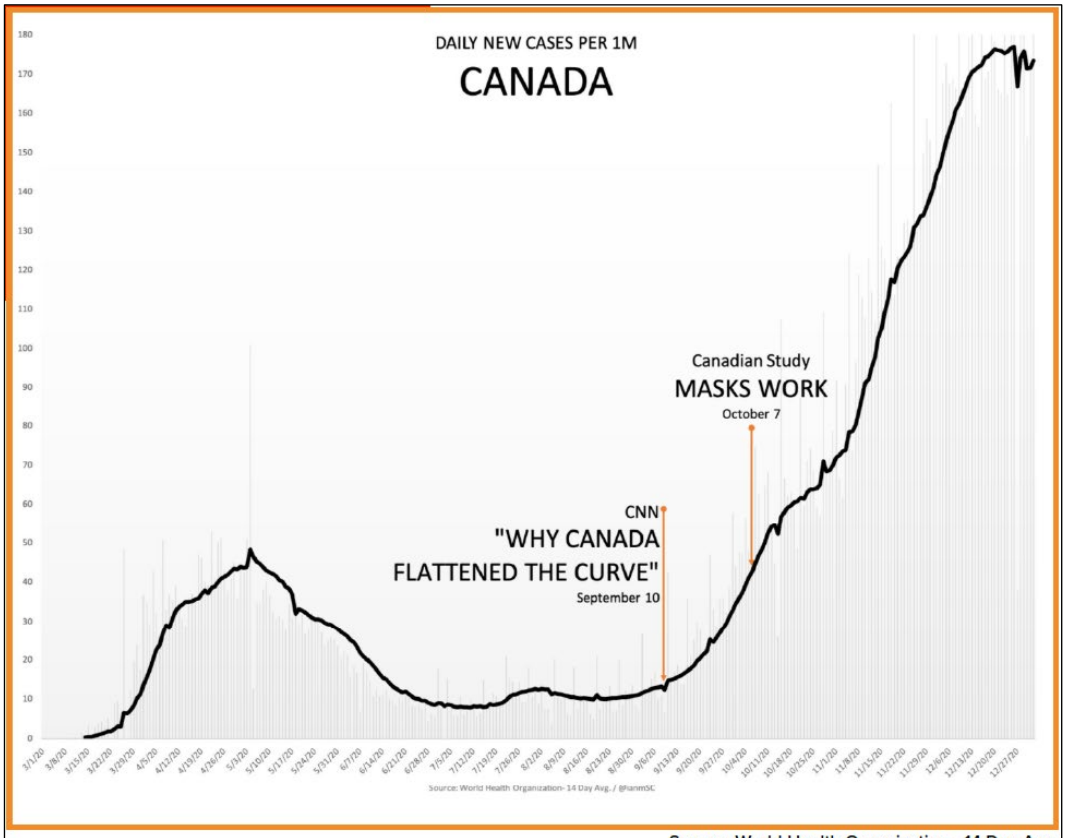

CURRENT HOSPITALIZATIONS PER 1M
FLORIDA VS LOCKDOWNS
FAUCI: NEW YORK HAD ONE OF TWO "BEST" RESPONSES
December 8
California
CLOSED OUTDOOR DINING/ STAY AT HOME ORDER
December 6
Florida
PHASE 3 RE-OPENING/ FAUCI: FL "ASKING FOR TROUBLE"
September 25
California
CLOSED INDOOR DINING
November 16
NEW YORK
CALIFORNIA
FLORIDA
Source: Covid Tracking Project | Twitter: @ianmSC



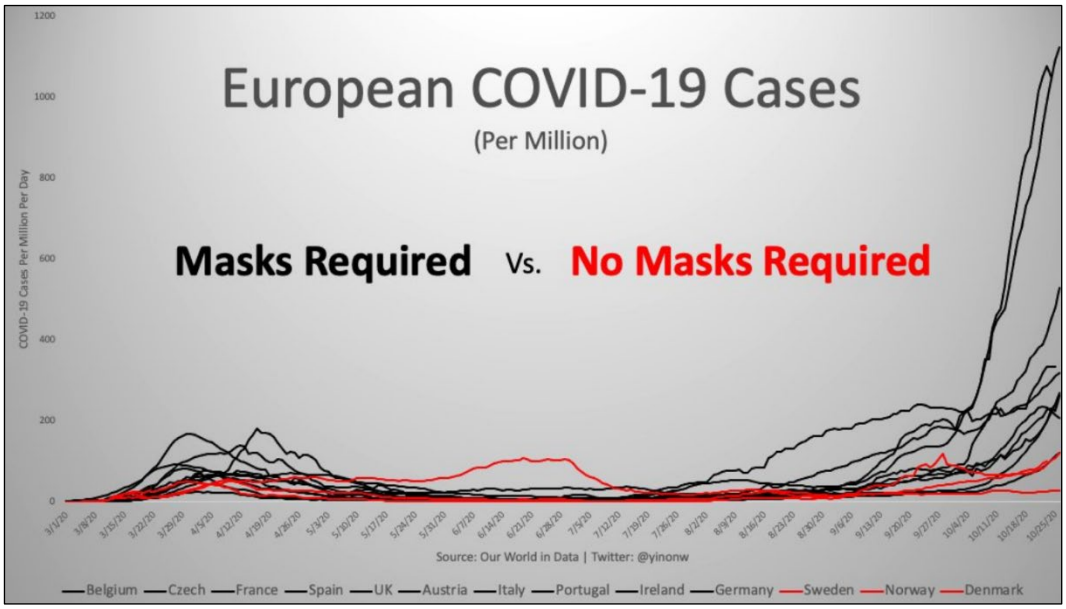
Source: Covid Tracking Project | Twitter: @ianmSC

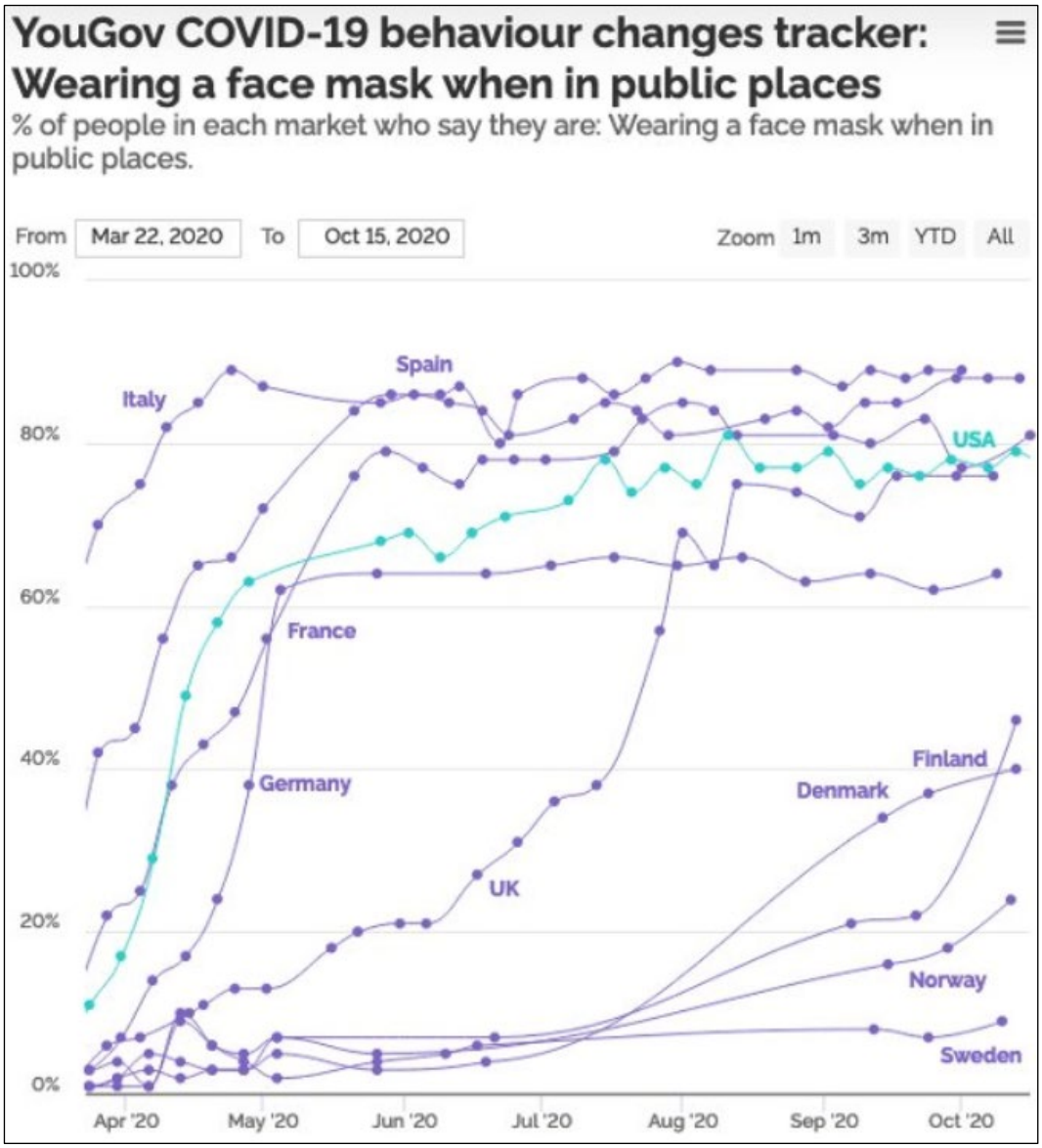


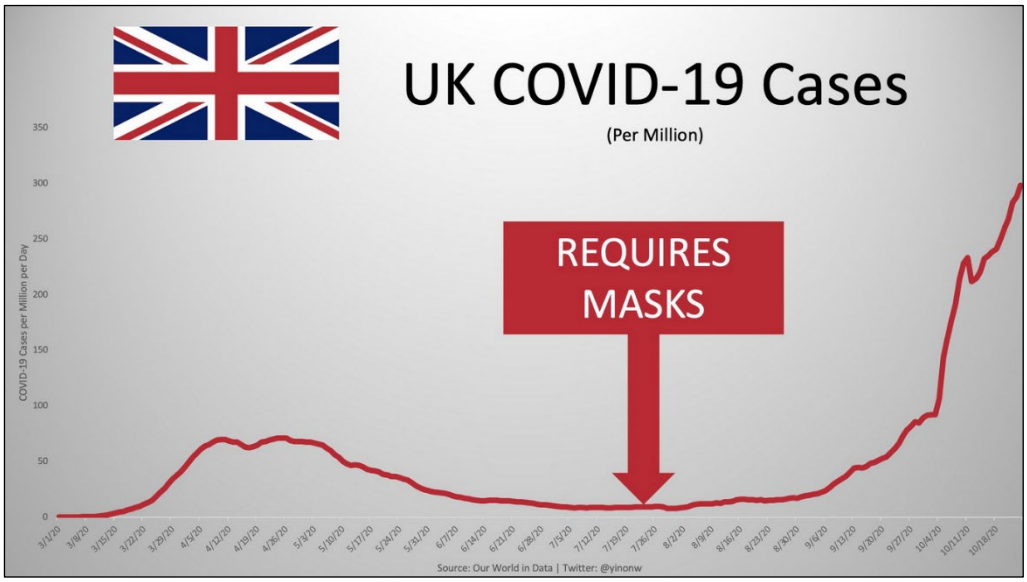




Source: World Health Organization - 14 Day Avg.
3/1/2020 - 12/27/2020


European COVID-19 Cases
(Per Million)
Masks Required Vs. No Masks Required
COVID-19 Cases Per Million Per Day
1200
1000
800
600
400
200
0
Source: Our World in Data | Twitter: @yinonw
Belgium Czech France Spain UK Austria Italy Portugal Ireland Germany Sweden Norway Denmark


YouGov COVID-19 behaviour changes tracker:
Wearing a face mask when in public places
% of people in each market who say they are: Wearing a face mask when in public places.
From Mar 22, 2020 To Oct 15, 2020
Zoom 1m 3m YTD All
100%
80%
60%
40%
20%
0%
Italy
Spain
USA
France
Germany
UK
Finland
Denmark
Norway
Sweden
Apr '20
May '20
Jun '20
Jul '20
Aug '20
Sep '20
Oct '20

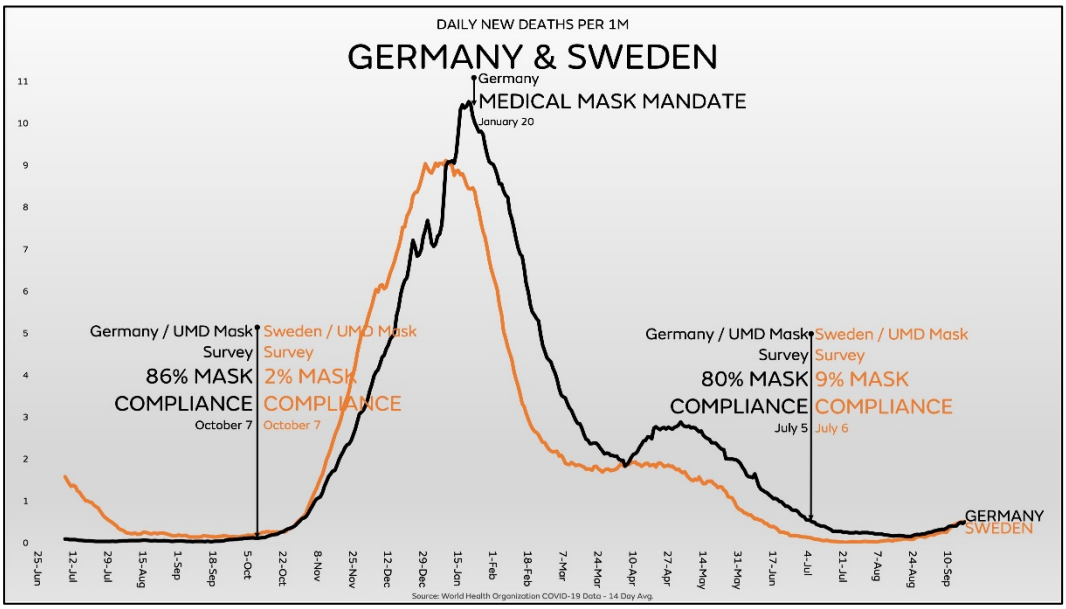

UK COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

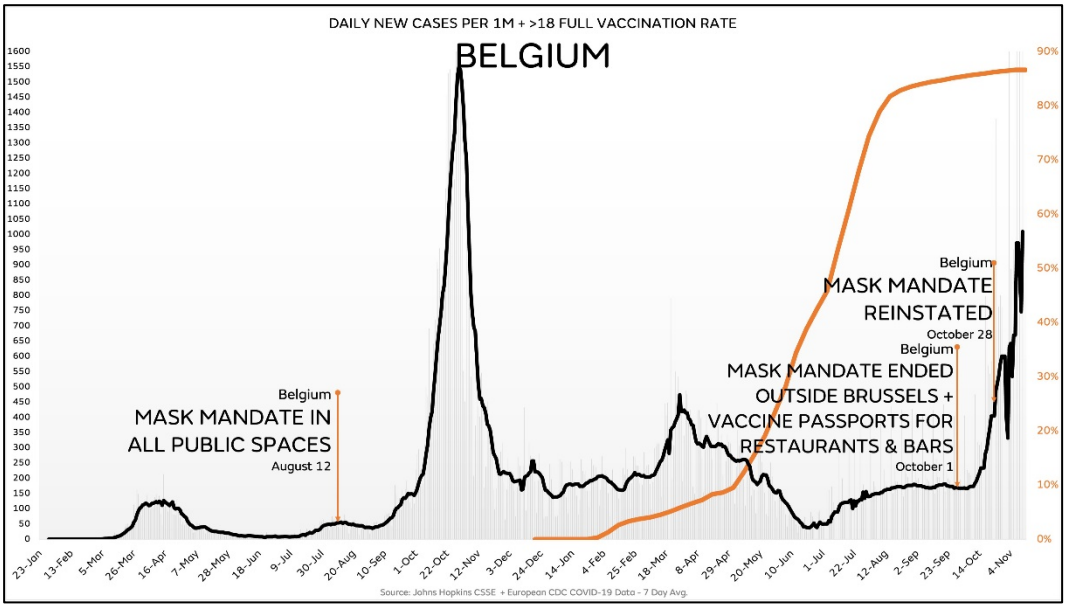

Italy COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

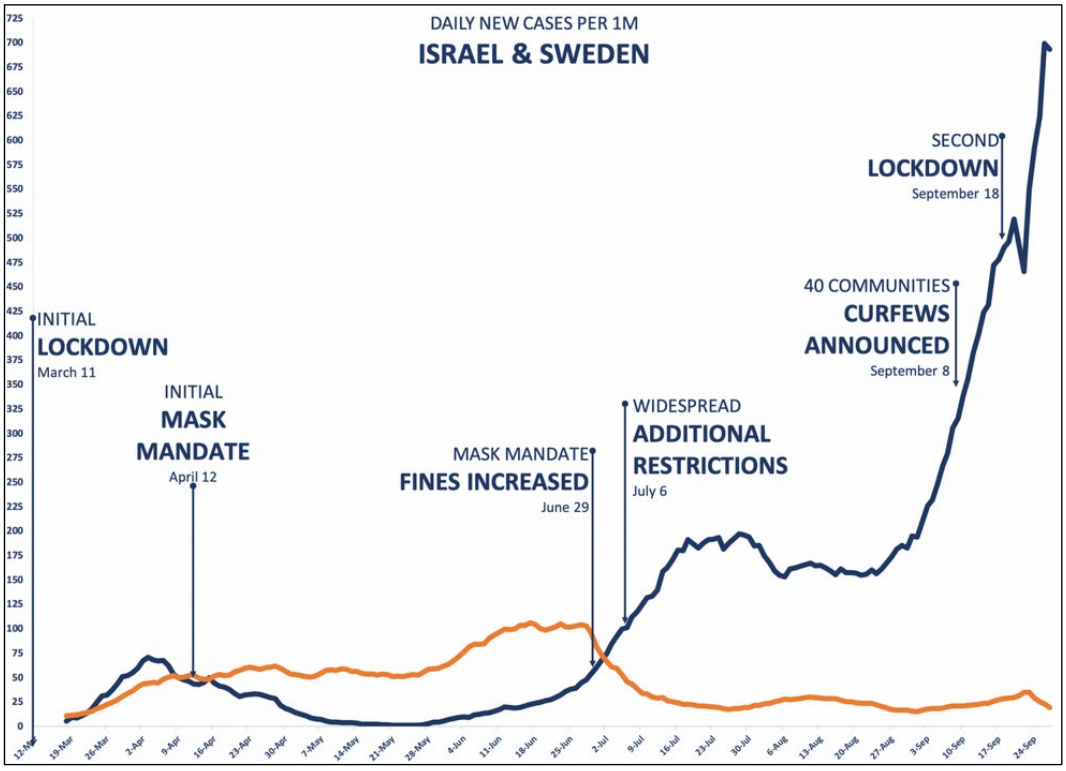

Spain COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

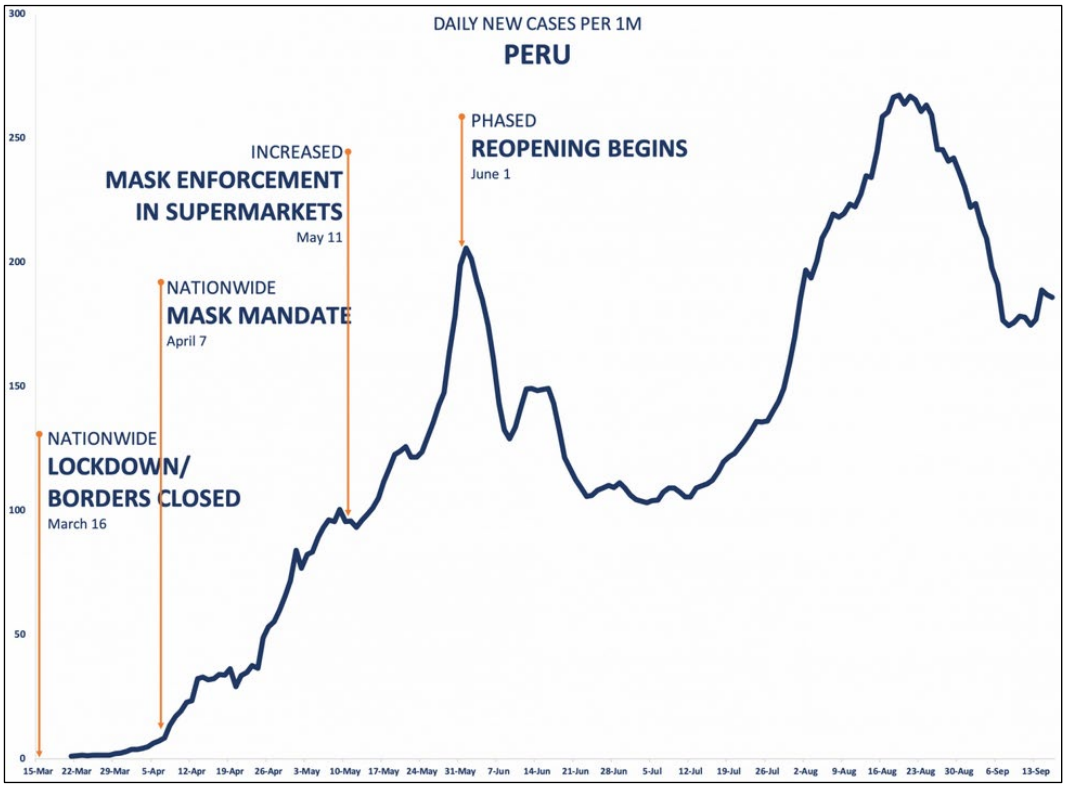

France COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

Source: Our World in Data | Twitter: @yinonw




DAILY NEW CASES PER 1M + >18 FULL VACCINATION RATE
BELGIUM
Belgium
MASK MANDATE IN
ALL PUBLIC SPACES
August 12
Belgium
MASK MANDATE ENDED
OUTSIDE BRUSSELS +
VACCINE PASSPORTS FOR
RESTAURANTS & BARS
October 1
Belgium
MASK MANDATE
REINSTATED
October 28
Source: Johns Hopkins CSSE + European CDC COVID-19 Data - 7 Day Avg.


DAILY NEW CASES PER 1M
ISRAEL & SWEDEN
INITIAL
LOCKDOWN
March 11
INITIAL
MASK
MANDATE
April 12
MASK MANDATE
FINES INCREASED
June 29
WIDESPREAD
ADDITIONAL
RESTRICTIONS
July 6
40 COMMUNITIES
CURFEWS
ANNOUNCED
September 8
SECOND
LOCKDOWN
September 18



Source: World Health Organization - 7 Day Avg. | Twitter: @ianmSC

Note: The citations below are presented in reverse, chronological order.

[29] **ADDED since 10/14/2021**
Plastic waste release caused by COVID-19 and its fate in the global ocean
PNAS (Nanking University)
Yiming Peng, Peipei Wu, Amina T. Schartup, and Yanxu Zhang
November 8, 2021
https://www.pnas.org/content/118/47/e2111530118

> "**Abstract**: The COVID-19 pandemic has led to an increased demand for single-use plastics that intensifies pressure on an already out-of-control global plastic waste problem. While it is suspected to be large, the magnitude and fate of this pandemic-associated mismanaged plastic waste are unknown. Here, we use our MITgcm ocean plastic model to quantify the impact of the pandemic on plastic discharge. We show that 8.4 ± 1.4 million tons of pandemic-associated plastic waste have been generated from 193 countries as of August 23, 2021, with 25.9 ± 3.8 thousand tons released into the global ocean representing 1.5 ± 0.2% of the global total riverine plastic discharge."

[30] **ADDED since 10/14/2021**
Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review
Cato Institute
Ian T. Liu, Vinay Prasad, and Jonathan J. Darrow
November 8, 2021
https://www.cato.org/sites/cato.org/files/2021-11/working-paper-64.pdf

> "**Abstract**: The use of cloth facemasks in community settings has become an accepted public policy response to decrease disease transmission during the COVID-19 pandemic. Yet evidence of facemask efficacy is based primarily on observational studies that are subject to confounding and on mechanistic studies that rely on surrogate endpoints (such as droplet dispersion) as proxies for disease transmission. The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with **fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit** in the intent-to-treat populations [*emphasis added*]. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle. Although weak evidence should not preclude precautionary actions in the face of unprecedented events such as the COVID-19 pandemic, ethical principles require that the strength of the evidence and best estimates of amount of benefit be truthfully communicated to the public."

[31] **#*Are Face Masks Effective? The Evidence.***
Swiss Policy Research
Published July 2020, updated September 2021
A review of existing studies examining the effectiveness of face masks, the development of COVID-19 cases after mask mandates, and the health risks associated with face masks.
https://swprs.org/face-masks-evidence/

"**Conclusion**: Face masks in the general population might be effective, at least in some circumstances, but there is currently little to no evidence supporting this proposition. If the coronavirus is indeed transmitted via indoor aerosols, face masks are unlikely to be protective. Health authorities should therefore not assume or suggest that face masks will reduce the rate or risk of infection."

[32] ***Mask mandate and use efficacy for COVID-19 containment in US States***
medRxiv
Damian D. Guerra and Daniel J. Guerra
August 7, 2021
https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v1.full

"**Discussion**: Our main finding is that mask mandates and use are not associated with lower SARS-CoV-2 spread among US states. 80% of US states mandated masks during the COVID-19 pandemic. Mandates induced greater mask compliance but did not predict lower growth rates when community spread was low (minima) or high (maxima)…

In summary, mask mandates and use were poor predictors of COVID-19 spread in US states. Case growth was independent of mandates at low and high rates of community spread, and **mask use did not predict case growth** during the Summer or Fall-Winter waves [*emphasis added*]."

[33] ***47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects***
July 23, 2021
https://www.lifesitenews.com/news/47-studies-confirm-inefectiveness-of-masks-for-covid-and-32-more-confirm-their-negative-health-effects/

[34] ***Covid: Disposable masks pose pollutants risk, study finds***
BBC News
May 4, 2021
https://www.bbc.com/news/uk-wales-56972074

"The Swansea University team found heavy metals and plastic fibres were released when throw-away masks were submerged in water…

Back in November last year, the researchers were only originally interested in the plastic waste impact on our environment. But as they tested more and more masks, they uncovered more chemicals…

The team found traces of lead, antimony and cadmium - all heavy metals which can be toxic in low doses…

He [*Dr Geraint Sullivan*] said the heavy metals found were also 'bio-accumulative', which means they are not removed from aquatic systems and they build up over time.

Every mask tested leached chemicals when submerged."

[35] **Video (3m): *Do Masks Work? Viral immunologist Dr. Byram Bridle performs a simple experiment to see*.**
April 24, 2021
https://www.youtube.com/watch?v=tIaul0U83d0

> "As a scientist, I'm going to present the facts and let people draw their own conclusions… With a lot of respiratory pathogens, they get transmitted through large water droplets, especially when we cough and sneeze. Now the primary mode of transmission of SARS-CoV-2 is through aerosols.
>
> There are three sizes of water droplets that can come out of your lungs. Large droplets … that are over 60 microns. They have this trajectory under gravity where they quickly fall to the ground. Then there's small water droplets that are between 10 and 60 microns in diameter. And then there's what we call 'droplet nuclei,' which are smaller than 10 microns. So when we talk about aerosols, we're talking about these droplet nuclei and small droplets.
>
> If you want to visualize it, when you go out in cold air in the middle of winter when you can see your breath, that's the aerosols. That's the aerosol condensing in the air. And it doesn't just drop to the ground…
>
> Scientific studies before this pandemic have shown that low-cost masks — so we're talking about surgical masks and the cloth masks we're wearing … have pore sizes that range between 80 and 500 microns in size. The diameter of the virus is 1 micron. The largest possible small droplet for an aerosol is 62 microns in diameter. So let's put that in perspective. The smallest pore size is 80, so that means the largest droplet with the virus can pass right through."

[36] ***Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?***
International Journal of Environmental Research and Public Health
Kai Kisielinski, Paul Gibon, *et al*.
April 20, 2021
https://www.mdpi.com/1660-4601/18/8/4344/htm

> "**Abstract**: … We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O2 drop (67%), N95 mask and CO2 rise (82%), N95 mask and O2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields."

[37] **The 'Danish Study': *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers. A Randomized Controlled Trial*.**
Annals of Internal Medicine
Henning Bundgaard, Johan Skov Bundgaard, *et al*.
March 2021
https://www.acpjournals.org/doi/10.7326/M20-6817

"**Results**: A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%)... Although the difference observed was not statistically significant, the 95% CIs are compatible with a 46% reduction to a 23% increase in infection."

Discussion: "Our results suggest that the recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, the incidence of SARS-CoV-2 infection in mask wearers in a setting where social distancing and other public health measures were in effect…"

[38] ***Review of scientific reports of harms caused by face masks, up to February 2021***
Denis Rancourt
February 22, 2021
https://denisrancourt.ca/entries.php?id=15&name=2021_02_22_review_of_scientific_reports_of_harms_caused_by_face_masks_up_to_february_2021

"[H]arms from prolonged masking are increasingly being documented in many scientific studies, especially in the areas of healthcare workers, school children, newborn infants, and bacterial infections in the general population, as described below."

[39] ***Masking: A Careful Review of the Evidence***
AIER
Paul E. Alexander
February 11, 2021
An analysis of the scientific literature on the effectiveness of face masks and related policies/issues.
https://www.aier.org/article/masking-a-careful-review-of-the-evidence/

"**Predominant finding?** The predominant conclusion is that face masks have a very important role in places such as hospitals, but there exists very little evidence of widespread benefit for members of the public (adults or children), as well as evidence that masking is truly an ineffectual way to manage pandemic-related spread of viral disease…"

"Our view is that masks as they are worn now, and the masks that are in use, offer zero protection… We state emphatically that public health policy, or any policy for that matter, must be undergirded by sound data and evidence. As we have said, the reality is that widespread use of masks is not supported by science and in fact just the opposite."

"**Conclusion**: In sum, when we look at the science, there is emerging and troubling evidence of harms from mask use in the absence of any benefits."

[40] ***Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study***
The Lancet – Infectious Diseases
Michael Marks, Pere Millat-Martinez, *et al*.
February 2, 2021
https://www.thelancet.com/journals/laninf/issue/vol21no5/PIIS1473-3099(21)X0005-9

"[W]e did not note any association between mask use and risk either in our unadjusted analysis (table 3) or in a multivariable model excluding type of exposure."

[41] ***"Exercise with facemask; Are we handling a devil's sword?" – A physiological hypothesis***

Medical Hypotheses
Baskaran Chandrasekaran and Shifra Fernandes
November 2020
https://www.sciencedirect.com/science/article/abs/pii/S0306987720317126?via%3Dihub

"**Abstract**: Though WHO supports facemasks only for Covid-19 patients, healthy 'social exercisers' too exercise strenuously with customized facemasks or N95 which hypothesized to pose more significant health risks and tax various physiological systems especially pulmonary, circulatory and immune systems. Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus."

[42] ***Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial***
PLOS One
Mohammad Alfelali, Elizabeth A. Haworth, *et al*.
October 13, 2020
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0240287

"**Background**: In this large-scale cluster-randomized controlled trial (cRCT) we sought to assess the effectiveness of facemasks against viral respiratory infections.

Method and results: … By intention-to-treat analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections… nor against clinical respiratory infection."

[43] **ADDED since 10/14/2021**
An Evidence Based Scientific Analysis of Why Masks are Ineffective, Unnecessary, and Harmful
Jim Meehan
October 10, 2020
https://ratical.org/PandemicParallaxView/mp3s/An-Evidence-Based-Scientific-Analysis-of-Why-Masks-are-Ineffective-Unnecessary-and-Harmful-10-12-2020.pdf

Pages 27-39: *Masks are Harmful: 17 Ways That Masks Can Cause Harm* (includes embedded links to primary sources):

1. Medical masks adversely affect respiratory physiology and function
2. Medical masks lower oxygen levels in the blood
3. Medical masks raise carbon dioxide levels in the blood…
4. SARS CoV-2 is armed with a "furin cleavage site" that makes it more pathogenic
5. Medical masks trap exhaled viral (and other) pathogens in the mouth/mask interspace, increase viral/infectious load, and increase the severity of disease

6. SARS CoV-2 Becomes More Dangerous When Blood Oxygen Levels Decline
7. The furin cleavage site of SARS CoV-2 increases cellular invasion, especially during hypoxia (low blood oxygen levels)
8. Cloth masks may increase the risk of contracting Covid-19 and other respiratory infections
9. Wearing a face mask may give a false sense of security
10. Masks compromise communications and reduce social distancing
11. Untrained and inappropriate management of face masks
12. Masks Worn Imperfectly Are Dangerous
13. Masks collect and colonize viruses, bacteria, and mold
14. Wearing a face mask makes the exhaled air (respiratory plumes) go into the eyes
15. Contact tracing studies show that asymptomatic carrier transmission is very rare
16. Face masks and stay at home orders prevent the development of herd immunity
17. Face masks are dangerous and contraindicated for a large number of people with pre-existing medical conditions and disabilities

[44] ***Medical Doctor Warns that "Bacterial Pneumonias Are on the Rise" from Mask Wearing***
Global Research
John C.A. Manley
October 6, 2020
https://www.globalresearch.ca/medical-doctor-warns-bacterial-pneumonias-rise-mask-wearing

> "Dr. James Meehan, MD [warned] that mask wearing has 'well-known risks that have been well-studied and they're not being discussed in the risk analysis.'
>
> 'I'm seeing patients that have facial rashes, fungal infections, bacterial infections. Reports coming from my colleagues, all over the world, are suggesting that the bacterial pneumonias are on the rise.
>
> 'Why might that be? Because untrained members of the public are wearing medical masks, repeatedly… in a non-sterile fashion… They're becoming contaminated. They're pulling them off of their car seat, off the rearview mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time.'"

[45] ***Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media***
September 20, 2020
https://www.aier.org/article/open-letter-from-medical-doctors-and-health-professionals-to-all-belgian-authorities-and-all-belgian-media/
Signatories: https://docs4opendebate.be/en/signatories/

> "[T]he following letter has made an impact on public health authorities not only in Belgium but around the world… So far it has been signed by 394 medical doctors, 1,340 medically trained health professionals, and 8,897 citizens."
>
> Letter excerpts:
>
> "Oral masks belong in contexts where contacts with proven at-risk groups or people with upper respiratory complaints take place, and in a medical context/hospital-retirement home setting. They reduce the risk of droplet infection by sneezing or coughing. Oral masks in healthy individuals are ineffective against the spread of viral infections.
>
> Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. **Some experts even warn of an increased transmission of the virus** in case of inappropriate use of the mask [*emphasis added*].
>
> Our Labour Code (Codex 6) refers to a CO2 content (ventilation in workplaces) of 900 ppm, maximum 1200 ppm in special circumstances. After wearing a mask for one minute, this toxic limit is considerably exceeded to values that are three to four times higher than these maximum values. Anyone who wears a mask is therefore in an extreme poorly ventilated room."

[46] ***Psychosocial, biological, and immunological risks for children and pupils make long-term wearing of mouth masks difficult to maintain***
British Medical Journal – Rapid Response
Carla Peeters, Wim Vanden Berghe, and Mattias Desmet
August 19, 2020
https://www.bmj.com/content/370/bmj.m3021/rr-6

> "This rapid response considers **the negative effects at the immunological and psychological level of mandating facemasks for children** and adolescents and maintains that they outweigh the possible gains [*emphasis added*]…
>
> 2. Facemasks at school: a slippery slope from virus protection to mental breakdown? … At the outset of the pandemic, WHO experts advised that use of facemasks is not recommended as potential benefits are rather limited and there is a **potential risk of self-contamination if used improperly** [*emphasis added*]. Moreover the WHO stated in their report of June 5 'At present, there is no direct evidence (from studies on Covid19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including Covid19. Contamination of the upper respiratory tract by viruses and bacteria on the outside of medical face masks has been detected in several hospitals. Another research shows that a moist mask is a breeding ground for (antibiotic

resistant) bacteria and fungi, which can undermine mucosal viral immunity…

Several studies show that long-term exposure to socio-psychological stress leaves neuro-epigenetic scars that are difficult to cure in young people and often escalate into mental behavioural problems and a weakened immune system. A recent study by the CDC concludes that in young adults (18-24 years), the level of anxiety and **depression has increased by 63%** since the corona crisis. A quarter of them think about suicide [*emphasis added*]. As a result, the use of antidepressants has increased by 25%. Several researchers have shown a relationship between the increase in stress experiences and the risk of upper respiratory tract infections and mortality."

[47] ***Increased plastic pollution due to COVID-19 pandemic: Challenges and recommendations***
Chemical Engineering Journal
Joana C. Prata, Ana L.P. Silva, *et al*.
August 17, 2020
https://www.sciencedirect.com/science/article/abs/pii/S1385894720328114

"**Abstract**: Plastics have become a severe transboundary threat to natural ecosystems and human health, with studies predicting a twofold increase in the number of plastic debris (including micro and nano-sized plastics) by 2030. However, such predictions will likely be aggravated by the excessive use and consumption of single-use plastics (including personal protective equipment such as masks and gloves) due to COVID-19 pandemic. This review aimed to provide a comprehensive overview on the effects of COVID-19 on macroplastic pollution and its potential implications on the environment and human health considering short- and long-term scenarios…"

[48] ***COVID-19 Pandemic Repercussions on the Use and Management of Plastics***
Environmental Science & Technology
Joana C. Prata, Ana L.P. Silva, *et al*.
June 12, 2020
https://pubs.acs.org/doi/full/10.1021/acs.est.0c02178

"**Abstract**: Mismanagement of personal protective equipment (PPE) during the COVID-19 pandemic, with a monthly estimated use of 129 billion face masks and 65 billion gloves globally, is resulting in widespread environmental contamination. This poses a risk to public health as **waste is a vector for SARS-CoV-2 virus** [*emphasis added*]..."

[49] ***Advice on the use of masks in the context of COVID-19***
World Health Organization
June 5, 2020
https://apps.who.int/iris/bitstream/handle/10665/332293/WHO-2019-nCov-IPC_Masks-2020.4-eng.pdf?sequence=1&isAllowed=y

"At present, there is no direct evidence (from studies on COVID-19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including COVID-19…

[T]he widespread use of masks by healthy people in the community setting is **not yet supported by high quality or direct scientific evidence** and **there are potential benefits and harms to consider** [*emphasis added*]…"

Potential harms/disadvantages

The likely disadvantages of the use of mask by healthy people in the general public include:

- potential increased risk of self-contamination due to the manipulation of a face mask and subsequently touching eyes with contaminated hands;
- potential self-contamination that can occur if non-medical masks are not changed when wet or soiled. This can create favourable conditions for microorganism to amplify;
- potential headache and/or breathing difficulties, depending on type of mask used;
- potential development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours; …
- waste management issues; improper mask disposal leading to increased litter in public places, risk of contamination to street cleaners and environment hazard; …

[50] ***Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures***
CDC Emerging Infectious Diseases
Jingyi Xiao, Eunice Y.C. Shiu, *et al*.
May 2020
https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article

"**Face Masks**: … In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks…

Disposable medical masks (also known as surgical masks) are loose-fitting devices that were designed to be worn by medical personnel to protect accidental contamination of patient wounds, and to protect the wearer against splashes or sprays of bodily fluids. There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found **no significant effect of face masks on transmission of laboratory-confirmed influenza** [*emphasis added*]."

[51] ***Covid-19: important potential side effects of wearing face masks that we should bear in mind***
British Medical Journal – Rapid Response
Antonio Lassarino, A. Steptoe, M. Harner, and S. Michie
April 9, 2020
https://www.bmj.com/content/369/bmj.m1435/rr-40

"Most scientific articles and guidelines in the context of the covid-19 pandemic highlight two potential side effects of wearing surgical face masks in the public, but we believe that there are other ones that are worth considering before any global public health policy is implemented involving billions of people.

The two potential side effects that have already been acknowledged are: …

(1) Wearing a face mask may give a false sense of security and make people adopt a reduction in compliance with other infection control measures, including social distancing and hands washing.

(2) Inappropriate use of face mask: people must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose them correctly and adopt other management measures, **otherwise their risks and those of others may increase** [*emphasis added*].

Other potential side effects that we must consider are: …

(4) Wearing a face mask makes the exhaled air go into the eyes. This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself.

(5) Face masks make breathing more difficult. For people with COPD, face masks are in fact intolerable to wear as they worsen their breathlessness. Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those two phenomena increase breathing frequency and deepness, and hence they increase the amount of inhaled and exhaled air. This may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs.

(5B) The effects described at point 5 are amplified **if face masks are heavily contaminated** [*emphasis added*].

(6) The innate immunity's efficacy is highly dependent on the viral load. If face masks determine a humid habitat where the SARS-CoV-2 can remain active due to the water vapour continuously provided by breathing and captured by the mask fabric, they determine an increase in viral load and therefore they can cause a **defeat of the innate immunity** and **an increase in infections** [*emphasis added*].

It is necessary to quantify the complex interactions that may well be operating between positive and negative effects of wearing surgical masks at population level. It is not time to act without evidence."

[52] ***Masks Don't Work: A review of science relevant to COVID-19 social policy***
D.G. Rancourt
April 2020
https://www.rcreader.com/sites/default/files/Denis%20G.%20Rancourt%20PhD%20April%202020%20%22Masks%20Don%27t%20Work%3A%20A%20review%20of%20science%20relevant%20to%20COVID-19%20social%20policy%22.pdf

"**Unknown Aspects of Mask Wearing**: Many potential harms may arise from broad public policies to wear masks, and the following unanswered questions arise:

- Do used and loaded masks become sources of enhanced transmission, for the wearer and others?
- Do masks become collectors and retainers of pathogens that the mask wearer would

otherwise avoid when breathing without a mask?

- Are large droplets captured by a mask atomized or aerolized into breathable components? Can virions escape an evaporating droplet stuck to a mask fiber?
- What are the dangers of bacterial growth on a used and loaded mask?
- How do pathogen-laden droplets interact with environmental dust and aerosols captured on the mask?
- What are long-term health effects on HCW, such as headaches, arising from impeded breathing?
- Are there negative social consequences to a masked society?
- Are there negative psychological consequences to wearing a mask, as a fear-based behavioural modification?
- What are the environmental consequences of mask manufacturing and disposal?
- Do the masks shed fibres or substances that are harmful when inhaled?"

[53] ***Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis***
Journal of Evidence-Based Medicine
Youlin Long, Tengyue Hu, *et al*.
March 13, 2020
https://onlinelibrary.wiley.com/doi/10.1111/jebm.12381

"**Objective**: Previous meta-analyses concluded that there was insufficient evidence to determine the effect of N95 respirators. We aimed to assess the effectiveness of N95 respirators versus surgical masks for prevention of influenza by collecting randomized controlled trials (RCTs)…

Results: A total of six RCTs involving 9 171 participants were included. There were no statistically significant differences in preventing laboratory-confirmed influenza (RR = 1.09, 95% CI 0.92-1.28, P > .05), laboratory-confirmed respiratory viral infections (RR = 0.89, 95% CI 0.70-1.11), laboratory-confirmed respiratory infection (RR = 0.74, 95% CI 0.42-1.29) and influenzalike illness (RR = 0.61, 95% CI 0.33-1.14) using N95 respirators and surgical masks. Meta-analysis indicated a protective effect of N95 respirators against laboratory-confirmed bacterial colonization (RR = 0.58, 95% CI 0.43-0.78).

Conclusion: The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and nonhigh-risk medical staff those are not in close contact with influenza patients or suspected patients."

[54] ***Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers***
BioMed Central Infectious Diseases
Abrar Ahmad Chughtai, Sacha Stelzer-Braid, *et al*.
June 3, 2019
https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-019-4109-x

"**Discussion**: To our knowledge this is the first study examining the presence of respiratory viruses on the outer surface of used medical masks…

In this study, the risk of mask contamination was associated with duration of masks use and number of patients seen. Currently there is no standard duration for the time period that facemasks and respirators can safely be used. Theoretically, there may be a risk of infection in wearer if contaminated masks are used for prolonged time. Currently there are no data around risk associated with reuse and extended used of masks and other PPE."

[55] ***Effect of a surgical mask on six minute walking distance***
Revue des Maladies Respiratoires
E. Person, C. Lemercier, *et al*.
March 2018
https://pubmed.ncbi.nlm.nih.gov/29395560/

"**Aim of the study**: To evaluate the effect of wearing a surgical mask during 6MWT in healthy subjects.

Results: Distance was not modified by the mask (P=0.99). Dyspnea [*shortness of breath or breathlessness*] variation was significantly higher with surgical mask (+5.6 vs. +4.6; P<0.001) and the difference was clinically relevant. No difference was found for the variation of other parameters.

Conclusion: Wearing a surgical mask modifies significantly and clinically dyspnea without influencing walked distance."

[56] ***A cluster randomised trial of cloth masks compared with medical masks in healthcare workers***
British Medical Journal
C. Raina MacIntyre, Holly Seale, *et al*.
March 26, 2015
https://bmjopen.bmj.com/content/5/4/e006577

"**Objective**: The aim of this study was to compare the efficacy of cloth masks to medical masks in hospital healthcare workers (HCWs). The null hypothesis is that there is no difference between medical masks and cloth masks.

Main outcome measure: Clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed respiratory virus infection.

Results: The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95%

CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%.

Conclusions: This study is the first RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated."

Bioethics, Human Rights, and Informed Consent

International Law

[57] ***White Paper: Civil Liberties surrounding Medical Experimentation***
America's Frontline Doctors
https://americasfrontlinedoctors.org/wp-content/uploads/2021/06/NEW-Civil-Liberties-Human-Rights-Issues-Surrounding-the-COVID-19-Vaccine-Candidates7.36.22-PM-min.pdf

> "For many decades it has been illegal and unethical to mandate or coerce any medical treatment. Virtually all countries, NGOs, organizations, policy leaders, and physicians adhere to this principle, including the USA, the European Union, United Nations and the World Health Organization. Quite simply, by international law, no person can ever be coerced to take an experimental treatment. Unfortunately, AFLDS is aware of many people who have already been fired for refusing to take what is currently an experimental medication. This paper addresses this issue."

Note: The citations below are presented in chronological order.

[58] ***The Nuremberg Code***
August 1947
http://www.cirp.org/library/ethics/nuremberg/

[59] ***International Covenant on Civil and Political Rights***
December 16, 1966
https://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx

> "**Article 7**. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."

[60] ***Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction***
Bureau of International Security and Nonproliferation
March 26, 1975
https://2009-2017.state.gov/t/isn/4718.htm

> "Have agreed as follows:
>
> **Article I**
>
> Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
>
> (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
>
> (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."

[61] ***Universal Declaration on Bioethics and Human Rights***
October 19, 2005
http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

"Article 3 – Human dignity and human rights:

1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the sole interest of science or society."

"**Article 4 – Benefit and harm**: In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized."

"**Article 6 – Consent**

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent."

US Law

[62] ***21 U.S. Code § 360bbb–3 - Authorization for medical products for use in emergencies***
https://www.law.cornell.edu/uscode/text/21/360bbb-3

"(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed … (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

[63] **Electronic Code of Federal Regulations: *45 CFR § 46.116 - General requirements for informed consent.***
https://www.law.cornell.edu/cfr/text/45/46.116

"**(a) General**. General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section…

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence…

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) Basic elements of informed consent. … [I]n seeking informed consent the following information shall be provided to each subject or the legally authorized representative:..

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject."

Professional Medical Codes

Note: The citations below are presented in chronological order.

[64] ***World Medical Association Declaration of Geneva***
Adopted September 1948 and last amended October 2017
https://www.wma.net/policies-post/wma-declaration-of-geneva/

"**The Physician's Pledge**

As a member of the medical profession:

I solemnly pledge to dedicate my life to the service of humanity;

The health and well-being of my patient will be my first consideration;

I will respect the autonomy and dignity of my patient;

I will maintain the utmost respect for human life; …

I will not use my medical knowledge to violate human rights and civil liberties, even under threat"

[65] ***Declaration of Helsinki***
World Medical Association
June 1964
https://apps.who.int/iris/bitstream/handle/10665/268312/PMC2566407.pdf?sequence=1&isAllowed=y

"**B. Basic principles for all medical research** …

20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship."

[66] ***Physicians Declaration – Global COVID Summit, Rome, Italy***
International Alliance of Physicians and Medical Scientists
September 2021
https://doctorsandscientistsdeclaration.org/

"**Update**: As of 1pm ET on 10/8 over 11,400 doctors & scientists have signed the Rome Declaration.

We the physicians of the world, united and loyal to the Hippocratic Oath, recognizing the profession of medicine as we know it is at a crossroad, are compelled to declare the following; …

WHEREAS, there is an unprecedented assault on our ability to care for our patients;

WHEREAS, public policy makers have chosen to force a 'one size fits all' treatment strategy, resulting in needless illness and death, rather than upholding fundamental concepts of the individualized, personalized approach to patient care which is proven to be safe and more effective; …

WHEREAS, physicians are increasingly being discouraged from engaging in open professional discourse and the exchange of ideas about new and emerging diseases, not only endangering the essence of the medical profession, but more importantly, more tragically, the lives of our patients;

WHEREAS, thousands of physicians are being prevented from providing treatment to their patients, as a result of barriers put up by pharmacies, hospitals, and public health agencies, rendering the vast majority of healthcare providers helpless to protect their patients in the face of disease. Physicians are now advising their patients to simply go home (allowing the virus to replicate) and return when their disease worsens, resulting in hundreds of thousands of unnecessary patient deaths, due to failure-to-treat;

WHEREAS, this is not medicine. This is not care. These policies may actually constitute crimes against humanity.

NOW THEREFORE, IT IS:

RESOLVED, that the physician-patient relationship must be restored. The very heart of medicine is this relationship, which allows physicians to best understand their patients and their illnesses, to formulate treatments that give the best chance for success, while the patient is an active participant in their care.

RESOLVED, that the political intrusion into the practice of medicine and the physician/patient relationship must end. Physicians, and all health care providers, must be free to practice the art and science of medicine without fear of retribution, censorship, slander, or disciplinary action… More than ever, the right and ability to exchange objective scientific findings, which further our understanding of disease, must be protected.

RESOLVED, that physicians must defend their right to prescribe treatment, observing the tenet FIRST, DO NO HARM. Physicians shall not be restricted from prescribing safe and effective treatments. These restrictions continue to cause unnecessary sickness and death. The rights of patients, after being fully informed about the risks and benefits of each option, must be restored to receive those treatments…

RESOLVED, that we invite the scientists of the world, who are skilled in biomedical research and uphold the highest ethical and moral standards, to insist on their ability to conduct and publish objective, empirical research without fear of reprisal upon their careers, reputations and livelihoods…

IN WITNESS WHEREOF, the undersigned has signed this Declaration as of the date first written."

COVID-19 Statistics

Infection Fatality Rate (IFR) for COVID-19

Note: The citations below are presented in reverse, chronological order.

[67] ***#Studies on COVID-19 Lethality***
Swiss Policy Research
Updated September 2021
https://swprs.org/studies-on-covid-19-lethality/

> **Note**: For a list of IFRs by country, see the Table under '1. Antibody studies.'
>
> "For comparison, the IFR of seasonal influenza, against which prior immunity and vaccines exist, is about 0.05% to 0.1%; the IFR of epidemic and medium pandemic influenza, such as in 1936, 1951, 1957 and 1968, is about 0.3%; the IFR of the 1918 pandemic influenza was about 2%."

[68] ***Reconciling estimates of global spread and infection fatality rates of COVID-19: An overview of systematic evaluations***
European Journal of Clinical Investigation
John P A Ioannidis
March 26, 2021
https://onlinelibrary.wiley.com/doi/10.1111/eci.13554

> "**Conclusions**: … Acknowledging residual uncertainties, the available evidence suggests average global IFR of **~0.15%** and ~1.5-2.0 billion infections by February 2021 with substantial differences in IFR and in infection spread across continents, countries and locations."

[69] ***Infection fatality rate of COVID-19 inferred from seroprevalence data***
World Health Organization
John P A Ioannidis
October 14, 2020
https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

> "**Results**: … Across 51 locations, the median COVID-19 infection fatality rate was 0.27% (corrected **0.23%**)"

[70] ***Global perspective of COVID-19 epidemiology for a full-cycle pandemic***
European Journal of Clinical Investigation
John P A Ioannidis
October 7, 2020
https://onlinelibrary.wiley.com/doi/10.1111/eci.13423

> "**Abstract**: … Global infection fatality rate is **0.15-0.20%** (0.03-0.04% in those <70 years), with large variability across locations with different age-structure, institutionalization rates, socioeconomic inequalities, population-level clinical risk profile, public health measures, and health care."

[71] ***Estimating the infection fatality ratio in England***
Centre for Evidence-Based Medicine
Daniel Howdon, Jason Oke, and Carl Heneghan
August 21, 2020
https://www.cebm.net/covid-19/estimating-the-infection-fatality-ratio-in-england/

> "**Summary**: This article presents data from two models estimating daily infections in England, deriving recent IFRs estimates of **0.30%** using the MRC unit's data and **0.49%** using ONS data."

[72] ***Serology-informed estimates of SARS-CoV-2 infection fatality risk in Geneva, Switzerland***
The Lancet
Javier Perez-Saez, Stephen A. Lauer, *et al*.
July 14, 2020
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30584-3/fulltext

> "After accounting for demography and age-specific seroprevalence, we estimated a population-wide IFR of 0·64% [***0-0.64%***]"

At-risk Demographics for COVID-19

Demographic: Existing Conditions

[73] ***#Weekly Updates by Select Demographic and Geographic Characteristics - Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)***
Centers for Disease Control and Prevention
Excerpted text as of October 3, 2021
https://www.cdc.gov/nchs/nvss/vsrr/COVID_weekly/index.htm#Comorbidities

> "**Comorbidities and other conditions**. Table 3 shows the types of health conditions and contributing causes mentioned in conjunction with deaths involving coronavirus disease 2019 (COVID-19). The number of deaths that mention one or more of the conditions indicated is shown for all deaths involving COVID-19 and by age groups. For over **5% of these deaths**, COVID-19 was the only cause mentioned on the death certificate. For deaths with conditions or causes in addition to COVID-19, on average, there were **4.0 additional conditions** or causes per death [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[74] ***Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021***
CDC Preventing Chronic Disease
Lyudmyla Kompaniyets, Audrey F. Pennington, *et al*.
July 2021
https://www.cdc.gov/pcd/issues/2021/pdf/21_0123.pdf

> "**Results**: Among 4,899,447 hospitalized adults… 540,667 (11.0%) were patients with COVID-19, of whom 94.9% had at least 1 underlying medical condition. Essential hypertension (50.4%), disorders of lipid metabolism (49.4%), and obesity (33.0%) were the most common. **The strongest risk factors for death were obesity** (adjusted risk ratio [aRR] = 1.30; 95% CI, 1.27–

1.33), **anxiety and fear-related disorders** (aRR = 1.28; 95% CI, 1.25–1.31), **and diabetes with complication** (aRR = 1.26; 95% CI, 1.24–1.28), **as well as the total number of conditions** [*emphasis added*]."

[75] ***Deaths involving COVID-19, England and Wales***
UK Office for National Statistics
June 2020 edition
Note: This is the last dataset produced in this series.
https://www.ons.gov.uk/file?uri=%2fpeoplepopulationandcommunity%2fbirthsdeathsandmarriages%2fdeaths%2fdatasets%2fdeathsinvolvingcovid19englandandwales%2fjune2020/referencetables.xlsx

"These data tables contain detailed analysis of all deaths that occurred in England and Wales between 1 March and 30 June 2020, registered up to 4 July 2020, where the coronavirus (COVID-19) was involved. There are breakdowns by age and sex and the causes of death mentioned on the death certificate."

Note: As indicated by the death certificates for this period, **91.3%** [(47,809 – 4,169) / 47,809] **of all COVID-related fatalities had one or more pre-existing conditions** [*emphasis added*], as calculated from the figures below.

Table 6b: Number of deaths involving COVID-19 by main pre-existing condition, sex and age, England, deaths occurring between March and June 2020

4,169 deaths with "No pre-existing conditions" – Sum of:

- 95 deaths, Age 0-44
- 89 deaths, Age 45-49
- 111 deaths, Age 50-54
- 209 deaths, Age 55-59
- 215 deaths, Age 60-64
- 278 deaths, Age 65-69
- 370 deaths, Age 70-74
- 485 deaths, Age 75-79
- 654 deaths, Age 80-84
- 753 deaths, Age 85-89
- 910 deaths, Age 90+

47,809 "All deaths involving COVID-19" – Sum of:

- 517 deaths, Age 0-44
- 441 deaths, Age 45-49
- 803 deaths, Age 50-54

- 1,375 deaths, Age 55-59
- 1,970 deaths, Age 60-64
- 2,629 deaths, Age 65-69
- 4,368 deaths, Age 70-74
- 6,351 deaths, Age 75-79
- 9,137 deaths, Age 80-84
- 9.808 deaths, Age 85-89
- 10,410 deaths, Age 90+

[76] ***Nearly 90% of People Hospitalized for COVID-19 Have Underlying Conditions, Says CDC***
Health magazine
Amber Brenza
April 9, 2020
https://www.health.com/condition/infectious-diseases/coronavirus/covid-19-hospitalization

> "In a new study published for the CDC's Morbidity and Mortality Weekly Report, researchers found that the majority of those hospitalized due to COVID-19 have preexisting conditions—about 90% of patients with available data had one or more underlying conditions. The most common, per the CDC, include hypertension (49.7%), obesity (48.3%), chronic lung disease (34.6%), diabetes mellitus (28.3%), and cardiovascular disease (27.8%)."

Demographic: Age

[77] ***#COVID-19 confirmed deaths in England report***
Public Health England
Updated September 8, 2021
https://www.gov.uk/government/publications/covid-19-reported-sars-cov-2-deaths-in-england/covid-19-confirmed-deaths-in-england-report

Table 2. Number of deaths and mortality rate (per 100,000 population) in laboratory-confirmed cases of COVID-19, by age group†**

Age group	Deaths (week 27 onwards*)	Mortality rate** (95% CI) (week 27 onwards*)	Deaths (January 2021)	Mortality rate** (95% CI) (January 2021)
<5	<10	0.3 (0.1-0.6)	<10	0.7 (0.1-2.6)
5-9	<10	0.1 (0.0-0.4)	<10	0.3 (0.0-1.9)
10-19	18	0.5 (0.3-0.7)	<10	0.9 (0.3-2.1)
20-29	89	2.1 (1.7-2.5)	39	6.3 (4.5-8.6)
30-39	331	7.4 (6.6-8.3)	185	28.9 (24.9-33.4)
40-49	962	22.8 (21.4-24.3)	507	83.7 (76.6-91.3)
50-59	2,955	65.9 (63.5-68.3)	1,574	244.6 (232.6-256.9)
60-69	6,746	192.9 (188.4-197.6)	3,354	668.4 (645.9-691.4)
70-79	15,473	553.9 (545.3-562.7)	7,231	1,803.8 (1,762.5-1,845.9)
80+	39,897	2,376.4 (2,353.2-2,399.9)	18,931	7,856.9 (7,745.4-7,969.6)

*Data is presented from 29 June 2020 to 31 January 2021.

[78] ***#Studies on Covid-19 Lethality - Median age of Covid-19 deaths per country***
Swiss Policy Research
Published May 2020, updated September 2021
https://swprs.org/studies-on-covid-19-lethality/#age

Half of all deaths were below, half were above the median age.

Country	Median age	Source
Australia	82 years	DOH
Austria	82 years	EMS
Belgium	86 years	IBS
Brazil	70 years	MDX
Canada	86 years	HCSC
England	82 years	NHS
France	84 years	SPF
Germany	83 years	RKI
Italy	82 years	ISS
South Africa	62 years	SAC
Spain	82 years	MDS
Sweden	84 years	FOHM
Switzerland	86 years	BAG
USA	78 years	CDC

Note: The citations below are presented in reverse, chronological order.

[79] **ADDED since 10/14/2021**
Physicians Declaration II
International Alliance of Physicians and Medical Scientists (Global Covid Summit)
October 29, 2021
https://doctorsandscientistsdeclaration.org/

For excerpts, see [368].

[80] ***Why are we vaccinating children against COVID-19?***
Toxicology Reports
Ronald N. Kostoff, Daniela Calina, *et al*.
October 7, 2021
https://www.sciencedirect.com/science/article/pii/S221475002100161X

"**Abstract**: This article examines issues related to COVID-19 inoculations for children. The bulk of the official COVID-19-attributed deaths per capita occur in the elderly with high comorbidities, and the COVID-19 attributed deaths per capita are negligible in children. The bulk of the normalized post-inoculation deaths also occur in the elderly with high comorbidities, while the normalized post-inoculation deaths are small, but not negligible, in children. Clinical trials for these inoculations were very short-term (a few months), had samples not representative of the total population, and for adolescents/children, had poor predictive power because of their small size. Further, the clinical trials did not address changes in biomarkers that could serve as early warning indicators of elevated predisposition to serious diseases. Most importantly, the clinical trials did not address long-term effects that, if serious, would be borne by children/adolescents for potentially decades…

Discussion: … [W]here is the data justifying inoculation for children, much less most people under forty? It's not found on Fig. 1, where the most vulnerable are almost exclusively the elderly with many comorbidities…

What is the rush for a group at essentially zero risks? Given that the inoculations were tested only for a few months, only very short-term adverse effects could be obtained. It is questionable how well even these short-term effects obtained from the clinical trials reflect the short-term effects from the initial mass inoculation results reported in VAERS.

Fig. 1, Fig. 2 reflect only these very short-term results. A number of researchers have suggested the possibility of severe longer-term autoimmune, Antibody-Dependent Enhancement, neurological, and other potentially serious effects, with **lag periods ranging from months to years**. If such effects do turn out to be real, the children are the ones who will have to bear the brunt of the suffering [*emphasis added*]."

[81] **ADDED since 10/14/2021**

The Flimsy Evidence Behind the CDC's Push to Vaccinate Children

Wall Street Journal

Marty Makary, Johns Hopkins University School of Medicine

July 19, 2021

https://web.archive.org/web/20210801202627/https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868

"A tremendous number of government and private policies affecting kids are based on one number: 335. That is how many children under 18 have died with a Covid diagnosis code in their record, according to the Centers for Disease Control and Prevention. Yet the CDC, which has 21,000 employees, hasn't researched each death to find out whether Covid caused it or if it involved a pre-existing medical condition.

Without these data, the CDC Advisory Committee on Immunization Practices decided in May that the benefits of two-dose vaccination outweigh the risks for all kids 12 to 15. I've written hundreds of peer-reviewed medical studies, and I can think of no journal editor who would accept the claim that 335 deaths resulted from a virus **without data to indicate if the virus was incidental or causal**, and without an analysis of relevant risk factors such as obesity [*emphasis added*].

My research team at Johns Hopkins worked with the nonprofit FAIR Health to analyze approximately 48,000 children under 18 diagnosed with Covid in health-insurance data from

April to August 2020. Our report found a **mortality rate of zero** among children without a pre-existing medical condition such as leukemia [*emphasis added*]. If that trend holds, it has significant implications for healthy kids and whether they need two vaccine doses."

[82] **ADDED since 10/14/2021**
Deaths from COVID 'incredibly rare' among children
Nature
Heidi Ledford
July 15, 2021
https://www.nature.com/articles/d41586-021-01897-w

"A comprehensive analysis of hospital admissions and reported deaths across England suggests that COVID-19 carries a lower risk of dying or requiring intensive care among children and young people than was previously thought.

In a series of preprints published on medRxiv, a team of researchers picked through all hospital admissions and deaths reported for people younger than 18 in England. The studies found that COVID-19 caused 25 deaths in that age group between March 2020 and February 2021.

About half of those deaths were in individuals with an underlying complex disability with high health-care needs, such as tube feeding or assistance with breathing."

[83] ***Children and young people remain at low risk of COVID-19 mortality***
The Lancet – Child & Adolescent Health
Sunil S Bhopal, Jayshree Bagaria, Bayanne Olabi, and Raj Bhopal
March 10, 2021
https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(21)00066-3/fulltext

"In the USA, UK, Italy, Germany, Spain, France, and South Korea, deaths from COVID-19 in children remained rare up to February, 2021, at 0·17 per 100 000 population…"

[84] ***Statistics of the COVID-19 pandemic in the United States***
Wikipedia
February 17, 2021
https://en.wikipedia.org/wiki/Statistics_of_the_COVID-19_pandemic_in_the_United_States#Deaths_by_age
Note: In 2020 and early 2021, the CDC Web site presented data on the Infection Fatality Rates (IFR) by Age Group for COVID-19, and IFR is the best measurement to assess the risk of death for each age cohort. Although the CDC no longer appears to provide this information, the table below may serve as a proxy.

Provisional COVID-19 deaths in the United States by age as of February 17, 2021

Age group	Death count	% of deaths	Rate per 100,000
All ages	**460,234**	**100%**	**140.2**
Under 1y	45	<0.1%	1.2
1-4y	23	<0.1%	0.1
5-14y	72	<0.1%	0.2
15-24y	648	0.2%	1.5
25-34y	2,922	0.7%	6.4
35-44y	7,711	2%	18.5
45-54y	21,251	5%	60.0
55-64y	54,134	12%	127.5
65-74y	99,019	21%	314.5
75-84y	128,192	27%	802.7
85y and over	146,217	32%	2,213.7

[85] **ADDED since 10/14/2021**
Covid-19 in schoolchildren: A comparison between Finland and Sweden
Public Health Agency of Sweden
July 7, 2020
https://www.folkhalsomyndigheten.se/contentassets/c1b78bffbfde4a7899eb0d8ffdb57b09/covid-19-school-aged-children.pdf

> "**Summary**: This report is a comparison between Finland and Sweden, two in many ways similar countries who applied different measures regarding schools during the covid-19 pandemic. There is no difference in the overall incidence of the laboratory confirmed covid-19 cases in the age group 1-19 years in the two countries… Severe covid-19 disease as measured in ICU admittance is very rare in both countries in this age group and **no deaths were reported** [*emphasis added*]…
>
> In conclusion, closure or not of schools had no measurable direct impact on the number of laboratory confirmed cases in school-aged children in Finland or Sweden. The negative effects of closing schools must be weighed against the positive indirect effects it might have on the mitigation of the covid-19 pandemic."

[86] ***Characteristics and Outcomes of Children With Coronavirus Disease 2019 (COVID-19) Infection Admitted to US and Canadian Pediatric Intensive Care Units***
JAMA Pediatrics
Lara S. Shekerdemian, Nabihah R. Mahmood, *et al*.
May 11, 2020
https://jamanetwork.com/journals/jamapediatrics/fullarticle/2766037

"[U]p to this time of the pandemic in North America, children continue to face a far greater risk of critical illness from influenza than from COVID-19, pointing to the imperative for ongoing preventive pediatric health maintenance during this time."

Demographic: Body Mass / Obesity

[87] **ADDED since 10/14/2021**
Impact of obesity on intensive care outcomes in patients with COVID-19 in Sweden—A cohort study
PLOS ONE (University of Gothenburg, Sweden)
Lovisa Sjögren, Erik Stenberg, *et al*.
October 13, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0257891

"**Background**: Previous studies have shown that a high body mass index (BMI) is a risk factor for severe COVID-19. The aim of the present study was to assess whether a high BMI affects the risk of death or prolonged length of stay (LOS) in patients with COVID-19 during intensive care in Sweden.

Methods and findings: In this observational, register-based study, we included patients with COVID-19 from the Swedish Intensive Care Registry admitted to intensive care units (ICUs) in Sweden… We found a significant association between BMI and the risk of the composite outcome death or LOS ≥14 days in survivors (OR per standard deviation [SD] increase 1.30, 95%CI 1.16–1.44, adjusted for sex, age and comorbidities), and this association remained after further adjustment for severity of illness (simplified acute physiology score; SAPS3) at ICU admission (OR 1.30 per SD, 95%CI 1.17–1.45). Individuals with a BMI ≥ 35 kg/m2 had a doubled risk of the composite outcome. A high BMI was also associated with death during intensive care and a prolonged LOS in survivors assessed as separate outcomes…

Conclusions: In this large cohort of Swedish ICU patients with COVID-19, a high BMI was associated with increasing risk of death and prolonged length of stay in the ICU…

Discussion: Previous studies, both observational and studies using the Mendelian randomization approach, have consistently found higher susceptibility and severity of the COVID-19 disease course in individuals with obesity. A UK study including almost 7 million individuals concluded increased risk of hospitalization and death due to COVID-19 in individuals with obesity… Another study that included over 17 million adults observed increased risk of COVID-19 related death with increasing obesity… Furthermore, one previous Swedish study found an increased risk of severe COVID-19 in patients with obesity with the most pronounced excess risk in individuals younger than 56 years of age… In the present study, using up-to-date BMI data, we found that a high BMI was associated with increased risk of death and prolonged intensive care in patients with severe COVID-19 after adjustment of age, sex and comorbidities..."

[88] ***Body Mass Index and Risk for COVID-19–Related Hospitalization, Intensive Care Unit Admission, Invasive Mechanical Ventilation, and Death — United States, March–December 2020***
CDC Morbidity and Mortality Weekly Report
Lyudmyla Kompaniyets, Alyson B. Goodman, *et al*.
March 8, 2021

https://www.cdc.gov/mmwr/volumes/70/wr/mm7010e4.htm?s_cid=mm7010e4_w

"**What is added by this report?** Among 148,494 U.S. adults with COVID-19, a nonlinear relationship was found between body mass index (BMI) and COVID-19 severity, with lowest risks at BMIs near the threshold between healthy weight and overweight in most instances, then increasing with higher BMI. Overweight and obesity were risk factors for invasive mechanical ventilation. Obesity was a risk factor for hospitalization and death, particularly among adults aged <65 years…

A J-shaped (nonlinear) relationship was observed between continuous BMI and risk for three outcomes. Risk for hospitalization, ICU admission, and death were lowest at BMIs of 24.2 kg/m2, 25.9 kg/m2, and 23.7 kg/m2, respectively, and then **increased sharply with higher BMIs** [*emphasis added*] (Figure 2)… Estimated risks for hospitalization and death were consistently higher for older age groups; however, within each age group, risk increased with higher BMIs.

Discussion: … The findings in this report are similar to those from previous studies that indicate an increased risk for severe COVID-19–associated illness among persons with excess weight and provide additional information about a dose-response relationship between higher BMI and risk for hospitalization, ICU admission, invasive mechanical ventilation, and death."

COVID-19 Risk Calculators

[89] **QCovid algorithm**
Oxford University
https://qcovid.org/Home/AcademicLicence?licencedUrl=%2FCalculation

"PLEASE NOTE: This implementation of the QCovid risk calculator is NOT intended for use supporting or informing clinical decision-making."

[90] **COVID-19 Mortality Risk Calculator**
Johns Hopkins & University of Maryland
https://covid19risktools.com:8443/riskcalculator

"The tool provides an assessment of individualized risks for mortality from COVID-19 using the best publicly available information on risks associated with various predisposing factors. The tool is meant for individuals who are currently not infected and not vaccinated and it does not account for all risk-factors that might increase an individual's chance of infection and/or health complications after infection."

COVID-19 Cases, Hospitalizations, and Deaths

[91] **Our World in Data**
Useful site for international comparisons of COVID-19 deaths and hospitalizations. Includes tools for the creation of custom charts.
COVID-19 Deaths: https://ourworldindata.org/covid-deaths
COVID-19 Hospitalizations: https://ourworldindata.org/covid-hospitalizations

[92] ***#Estimated COVID-19 Burden***
Centers for Disease Control and Prevention (CDC)
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

Note: As of October 9, 2020, here are the CDC estimates for the period February 2020 to May 2021:

- 120.2 million estimated total infections
- 6.2 million estimated hospitalizations
- 767,000 estimated total deaths

"**Why CDC Estimates COVID-19 Infections, Illnesses, Hospitalizations, and Deaths**: The cumulative burden of COVID-19 is an estimate of the number of people who may have been infected, sick, hospitalized, or died as a result of a COVID-19 infection in the United States… COVID-19 infections, symptomatic illnesses, hospitalizations, and deaths might be underdetected and go unreported for a variety of reasons.

- Some people infected with SARS-CoV-2 never show symptoms (asymptomatic infection), so their infection will likely go undetected.
- Case reports sent to CDC are often missing patient information, like age or hospitalization status, or are delayed.

Because current surveillance systems do not capture all cases or deaths of COVID-19 occurring in the United States, CDC provides these estimates to better reflect the larger burden of COVID-19. CDC uses these types of estimates to inform policy decisions and public messages."

[93] ***COVID-19 Vaccine Breakthrough Case Investigation and Reporting***
Centers for Disease Control and Prevention (CDC)
Page last reviewed September 29, 2021
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

"**Defining a vaccine breakthrough infection**: For the purpose of this surveillance, a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person **≥14 days after they have completed all recommended doses** of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine [*emphasis added*]."

Note: So by definition, anyone getting a one-shot COVID-19 'vaccination series' cannot be counted as a breakthrough case until 14 days after their inoculation. Similarly, people getting a two-shot 'vaccination series' cannot be counted as a breakthrough case until 14 days after their second inoculation. Thus, in a system that 1) adheres to this CDC definition, and 2) categorizes COVID-19 cases in a binary scheme (e.g., 'vaccinated' vs. 'unvaccinated'), inoculation recipients testing positive at the 13-day mark or earlier are counted as **not** vaccinated. For an example, see '**King County, WA: *COVID-19 Outcomes by Vaccination Status***' below.

[94] **King County, WA: *COVID-19 Outcomes by Vaccination Status***
King County government
As of October 3, 2021
https://kingcounty.gov/depts/health/covid-19/data/vaccination-outcomes.aspx

Note: To view the following definitions, click **Open data notes**.

'"**Fully vaccinated individuals**: individuals who received their last recommended dose of a COVID-19 vaccine and have had at least 14 days to establish protection. Fully vaccinated cases includes [*sic*] only individuals who have tested positive for COVID-19 (either a PCR test or an antigen test) at least 14 days **after** they completed their vaccination series.

Not fully vaccinated individuals: individuals who have not received any vaccine doses, individuals who have started their vaccine series, and individuals who have completed their vaccination series within the past 14 days. Residents not currently eligible (under the age of 12 years old) are considered 'not fully vaccinated.'"

Note: The citations below are presented in reverse, chronological order.

[95] ***Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States***
European Journal of Epidemiology
S.V. Subramanian and Akhil Kumar
September 30, 2021
https://link.springer.com/article/10.1007/s10654-021-00808-7

"**Findings**: At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 1). In fact, the trend line suggests a marginally positive association such that **countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people** [*emphasis added*]. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days. The lack of a meaningful association between percentage population fully vaccinated and new COVID-19 cases is further exemplified, for instance, by comparison of Iceland and Portugal. Both countries have over 75% of their population fully vaccinated and have more COVID-19 cases per 1 million people than countries such as Vietnam and South Africa that have around 10% of their population fully vaccinated.

Across the US counties too, the median new COVID-19 cases per 100,000 people in the last 7 days is largely similar across the categories of percent population fully vaccinated (Fig. 2). Notably there is also substantial county variation in new COVID-19 cases within categories of percentage population fully vaccinated. There also appears to be no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated (Fig. 3).

Of the top 5 counties that have the highest percentage of population fully vaccinated (99.9–84.3%), the US Centers for Disease Control and Prevention (CDC) identifies 4 of them as "High" Transmission counties. Chattahoochee (Georgia), McKinley (New Mexico), and Arecibo (Puerto Rico) counties have above 90% of their population fully vaccinated with all three being classified as "High" transmission. Conversely, of the 57 counties that have been classified as "low" transmission counties by the CDC, 26.3% have percentage of population fully vaccinated below 20%...

Interpretation: … [I]n a report released from the Ministry of Health in Israel, the **effectiveness of 2 doses of the BNT162b2 (Pfizer-BioNTech) vaccine against preventing COVID-19 infection was reported to be 39%**, substantially lower than the trial efficacy of 96% [*emphasis added*]. It is also emerging that immunity derived from the Pfizer-BioNTech vaccine may not be as strong as immunity acquired through recovery from the COVID-19 virus. A substantial decline in immunity from mRNA vaccines 6-months post immunization has also been reported. Even though vaccinations offers protection to individuals against severe hospitalization and death, the CDC reported an increase from 0.01 to 9% and 0 to 15.1% (between January to May 2021) in the rates of hospitalizations and deaths, respectively, amongst the fully vaccinated "

[96] ***Our Most Reliable Pandemic Number Is Losing Meaning - A new study suggests that almost half of those hospitalized with COVID-19 have mild or asymptomatic cases***
The Atlantic
David Zweig
September 13, 2021
https://www.theatlantic.com/health/archive/2021/09/covid-hospitalization-numbers-can-be-misleading/620062/

"[T]he overall tallies of COVID hospitalizations, made available on various state and federal dashboards and widely reported on by the media, do not differentiate based on severity of illness… How many patients fall into each category has been a topic of much speculation. In August, researchers from Harvard Medical School, Tufts Medical Center, and the Veterans Affairs Healthcare System decided to find out...

The authors of the paper … analyzed the electronic records for nearly 50,000 COVID hospital admissions at the more than 100 VA hospitals across the country…

The study found that from March 2020 through early January 2021—before vaccination was widespread, and before the Delta variant had arrived—the proportion of patients with mild or asymptomatic disease was 36 percent. From mid-January through the end of June 2021, however, that number rose to 48 percent. In other words, the study suggests that roughly **half of all the hospitalized patients showing up on COVID-data dashboards in 2021 may have been admitted for another reason entirely, or had only a mild presentation of disease** [*emphasis added*]."

[97] ***Fractured record keeping leaves Philly hospitals unsure which patients are vaccinated***
Philadelphia Inquirer
Jason Laughlin
August 31, 2021
https://www.inquirer.com/health/coronavirus/vaccine-records-philadelphia-covid-pennsylvania-data-20210831.html

"A patchwork of vaccination record keeping has left hospitals with no easy way to be precise about which of their patients have received inoculations against COVID-19…

'This is what everybody's craving for,' said John Zurlo, division director of infectious disease at Thomas Jefferson University. 'You'd hope we can get really accurate information about that and right now we really don't get accurate information.'…

[T]he lack of reliable vaccine records, Zurlo said, complicates efforts to precisely understand vaccine effectiveness and determine how many local hospitalizations and deaths are resulting from COVID-19 breakthrough infections."

[98] ***"For COVID" or "With COVID": Classification of SARS-CoV-2 Hospitalizations in Children***
Hospital Pediatrics
Lauren E. Kushner, Alan R. Schroeder, Joseph Kim and Roshni Mathew
August 1, 2021
https://hosppeds.aappublications.org/content/11/8/e151

"**Discussion**: Our findings reveal that most children hospitalized with SARS-CoV-2 have asymptomatic or mild or moderate disease, and nearly one-half of these hospitalizations were not caused by infection from the virus itself."

[99] ***Adjudicating Reasons for Hospitalization Reveals That Severe Illness From COVID-19 in Children Is Rare***
Hospital Pediatrics
Amy Beck and Monica Gandhi
July 12, 2021
https://hosppeds.aappublications.org/content/early/2021/07/12/hpeds.2021-006084

"In this issue of Hospital Pediatrics, Kushner et al conducted an extensive chart review of 117 pediatric hospitalizations with a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) polymerase chain reaction (PCR) test from May 10, 2020, to February 10, 2021 [and]…

Webb et al reviewed the charts of 146 children hospitalized with a positive SARS-CoV-2 PCR test result at another large children's hospital in California from May 1, 2020, to September 30, 2020…

Notably, the percentage of hospitalized children with an incidental finding of a positive SARS-CoV-2 PCR test result was remarkably similar between the two studies (45% Kushner et al; 40% Webb et al). In addition, the percentage of children deemed with severe or critical COVID-19 in the Kushner et al study was close to the percentage of children deemed significantly symptomatic in the study by Webb et al (17% vs 14%). Taken together, these studies underscore the importance of clearly distinguishing between children hospitalized with SARS-CoV-2 found on universal testing versus those hospitalized for COVID-19. **Both studies reveal that reported hospitalization rates greatly overestimate the true burden of COVID-19 in children** [*emphasis added*]."

[100] ***What to do to get your Covid vaccination added to your medical record***
CNN
Megan Marples
April 26, 2021

https://www.cnn.com/2021/04/26/health/coronavirus-vaccine-official-medical-record-wellness/index.html

"Getting vaccinated against Covid-19 and receiving a vaccination card has become a rite of passage for many Americans who have endured the pandemic for the last year.

Securing a vaccination card, however, doesn't necessarily mean your Covid-19 vaccine status is in your medical records.

Many got the vaccines at drive-in events, sports stadiums and other mass vaccination locations in their communities. If you are among the countless people who didn't get the doses at a primary care doctor's office, **there may not be any record of the vaccination on file with your doctor** [*emphasis added*]."

[101] ***Current Hospital Capacity Estimates – Snapshot***
Centers for Disease Control & Prevention
July 14, 2020
https://www.cdc.gov/nhsn/covid19/report-patient-impact.html

Note: In the Table copied below, the CDC estimates that **8% of all inpatient hospital-bed occupants** in the US were COVID-19 patients for the period **April 1, 2020, to July 13, 2020**.

Downloadable Dataset

The following downloadable file contains national and state estimates from the NHSN COVID-19 Module. This file will not be updated after July 14, 2020 and includes data from April 1 to July 14.

Download national and state estimates NHSN COVID-19 Module data [CSV – 600 KB]

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National Estimates

Estimates for July 13	Number (95% CI)	Percentage (95% CI)
Inpatient Beds Occupied (all Patients)	504,432 (479,075 - 529,789)	63% (62% - 64%)
Inpatient Beds Occupied (COVID-19 Patients)	64,496 (61,047 - 67,946)	8% (8% - 9%)
ICU Beds Occupied (all Patients)	75,257 (70,290 - 80,225)	61% (59% - 62%)

Updated: 07/14/2020

Statistical methods: Statistical methods were used to generate estimates of patient impact and hospital capacity measures that are representative at the national level. The estimates are based on data submitted by acute care hospitals to the NHSN COVID-19 Module. The statistical methods include weighting (to account for non-response) and multiple imputation (to account for missing data). The estimates (number and percentage) are shown along with 95% confidence intervals that reflect the statistical error that is primarily due to non-response.

Data source: Centers for Disease Control and Prevention, National Healthcare Safety Network
For more information: https://www.cdc.gov/nhsn/covid19/index.html

[102] **Video (:45s): Remarks by Ngozi O. Ezike, Director**
Illinois Department of Public Health press conference

May 25, 2020
https://odysee.com/@LockdownSkepticism:f/Department-of-Public-Health-Director:d

> **Ezike**: "I just want to be clear in terms of the definition of 'people dying of COVID.' The case definition is very simplistic. It means, at the time of death, it was a COVID positive diagnosis. That means that if you were in hospice and had already been given a few weeks to live, and then you were also found to have COVID, that would be counted as a COVID death. It means, technically even if you died of a clear alternate cause, but you had COVID at the same time, **it's still listed as a COVID death** [*emphasis added*]. Everyone who is listed as a COVID death, doesn't mean that was the cause of the death, but they had COVID at the time of death. I hope that's helpful."

[103] **Interview with Dr. Scott Jensen**
Fox News
April 8, 2020
https://odysee.com/@barrythetruth:2/Dr--Scott-Jensen-With-Laura-Ingraham---The-Ridiculous-CDC-Guidlines:4

> "Right now Medicare is determining that if you have a COVID-19 admission to the hospital, you'll get paid $13,000. If that COVID-19 patient goes on a ventilator, you get $39,000, three times as much. Nobody can tell me after 35 years in the world of medicine that sometimes those kinds of things impact on what we do."

[104] ***Some doctors moving away from ventilators for virus patients***
AP News
Mike Stobbe
April 8, 2020
https://apnews.com/article/health-us-news-ap-top-news-international-news-virus-outbreak-8ccd325c2be9bf454c2128dcb7bd616d

> "As health officials around the world push to get more ventilators to treat coronavirus patients, some doctors are moving away from using the breathing machines when they can.
>
> The reason: Some hospitals have reported unusually high death rates for coronavirus patients on ventilators, and some doctors worry that the machines could be harming certain patients…
>
> Generally speaking, 40% to 50% of patients with severe respiratory distress die while on ventilators, experts say. But **80% or more of coronavirus patients placed on the machines in New York City have died**, state and city officials say [*emphasis added*].
>
> Higher-than-normal death rates also have been reported elsewhere in the U.S., said Dr. Albert Rizzo, the American Lung Association's chief medical officer.
>
> Similar reports have emerged from China and the United Kingdom. One U.K. report put the figure at 66%. A very small study in Wuhan, the Chinese city where the disease first emerged, said 86% died."

[105] **Remarks by Deborah Birx, US Coronavirus Response Coordinator**
White House press conference
April 8, 2020
https://www.youtube.com/watch?v=blZpgra3XbU

> "If someone dies with COVID-19, **we are counting that as a COVID-19 death** [*emphasis added*]."

[106] ***Why have so many coronavirus patients died in Italy?***
The Telegraph
Sarah Newey
March 23, 2020
https://www.telegraph.co.uk/global-health/science-and-disease/have-many-coronavirus-patients-died-italy/

> "According to Prof Walter Ricciardi, scientific adviser to Italy's minister of health, the country's mortality rate is far higher due to demographics – the nation has the second oldest population worldwide – and the manner in which hospitals record deaths…
>
> But Prof Ricciardi added that Italy's death rate may also appear high because of how doctors record fatalities.
>
> 'The way in which we code deaths in our country is very generous in the sense that all the people who die in hospitals with the coronavirus are deemed to be dying of the coronavirus.
>
> 'On re-evaluation by the National Institute of Health, **only 12 per cent of death certificates have shown a direct causality from coronavirus**, while 88 per cent of patients who have died have at least one pre-morbidity – many had two or three [*emphasis added*],' he says."

Polymerase Chain Reaction (PCR) Testing

PCR Cycle Thresholds and 'Case' Totals

[107] ***White Paper: Covid Recovery – A Scientific Approach***
COVID-19 Ireland
December 2020
https://covidrecovery.ie/
Medical Signatories:
https://drive.google.com/file/d/1Mfc85i17Z9d2CyLzlf0bOqin3vbXbQfd/view

> "**Is PCR an appropriate tool to inform policy?** We are concerned about the implementation of PCR as the standard test for SARS-CoV-2. PCR has standard false-positive rates of 1 - 3%33 and up to 4% in the UK. Suggesting that every positive PCR result constitutes an infectious "case", is not accurate… This clearly misrepresents the real-world situation, and has undue influence on important policy interventions. In addition, PCR cannot distinguish **infectious live virus from residual dead virus** or viral fragments from previous infection [*emphasis added*]. Therefore many 'cases' have no real meaning in terms of medical status or transmission potential – further misleading clinicians and policymakers alike.
>
> The PCR test functions by amplification of tiny fragments of virus – 'magnifying" them in a series of cycles. The number of cycles required to identify viral genetic material – the cycle threshold (Ct), correlates inversely with the amount of viral genetic material actually present in the original specimen. If there is little virus present, (probably not enough to be infectious) and the test has a high cycle threshold (cycle thresholds are set by the individual test kit manufacturers), it will probably identify harmless viral fragments and the test will be deemed 'positive'. In Ireland, Ct value cut-offs of 35-45 are the norm. **High Ct values (over 35 or even 30) suggest a non- infectious patient** [*emphasis added*], often due to low viral load (or the test identifying dead viral genetic material from a previous infection, or often from contamination in the test process). In contrast, low Ct values are more likely to indicate a high viral load, and therefore an infectious patient…"
>
> "**Problems and inconsistencies with PCR testing have been documented extensively**: non standardised specimen collection techniques; no gold standard test yet identified; different tests used in different labs; no standardised acceptable Ct values; inconsistent quality assurance programs; false positives; identification of irrelevant dead viral genetic material which can persist for months after infection; potential contamination of specimens, to name a few. Poorly designed PCR testing regimes can drive cases in infectious disease outbreaks and several reports exist of 'pseudo' epidemics caused by over sensitive or poorly regulated PCR testing regimes. Patients with Ct values of >35 are extremely unlikely to be infectious unless they have been tested in the early stages of infection."

[108] ***COVID-19 Real-Time PCR Kit Instructions For Use***
World Health Organization
https://www.who.int/diagnostics_laboratory/eual/eul_0535_196_00_covid19_real_time_pcr_kit_ifu.pdf

"**9.2 Interpretation of Results**… The Ct [cycle threshold] value of any fluorescent detection channel for a positive control should be no higher than 34"

[109] **Video (4m): Commentary by Kary Mullis, inventor of the polymerase chain reaction (PCR) technique and Nobel Prize winner**
Date unknown
https://www.bitchute.com/video/DNylgfqjBEpl/
https://www.bitchute.com/video/wOSeTz57xrCF/

Audience question: "How do they misuse PCR to estimate all these supposed free, viral RNAs that may or may not be there?"

Mullis: "… I don't think you can misuse PCR… With PCR, if you do it well, you can find almost anything in anybody. It starts making you believe in the sort of Buddhist notion that everything is contained in everything else. Because if you can amplify one single molecule up to something that you can really measure, which PCR can do, there are just very few molecules that you don't have at least one single one of in your body…

It [*PCR*] tells you something about nature and what's there. It allows you to take a very miniscule amount of anything and make it measurable…

PCR is just a process that's used to make a whole lot of something out of something. **It doesn't tell you that you're sick**, and it doesn't tell you that the thing you ended up with was going to hurt you, or anything like that [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[110] ***CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel***
Centers for Disease Control & Prevention
Effective July 21, 2021
https://www.fda.gov/media/134922/download

"Interpretation of Results and Reporting… 2019-nCoV Markers (N1 and N2)… When all controls exhibit the expected performance, a specimen is considered positive for 2019-nCoV if all 2019-nCoV marker (N1, N2) cycle threshold growth curves **cross the threshold line within 40.00 cycles** (< 40.00 Ct) [*emphasis added*]. The RNase P may or may not be positive as described above, but the 2019-nCoV result is still valid."

[111] **Letter: *Duration of Culturable SARS-CoV-2 in Hospitalized Patients with Covid-19***
New England Journal of Medicine
Min-Chul Kim, Chunguang Cui, *et al*.
February 18, 2021
https://www.nejm.org/doi/full/10.1056/NEJMc2027040

"The data reported here represent all the patients with Covid-19, as confirmed by positive real-time reverse transcriptase–polymerase chain reaction (RT-PCR) testing, who were hospitalized at Chung-Ang University Hospital in Seoul, South Korea, between February and June 2020."

"Viral culture was positive only in samples with a cycle-threshold value of **28.4 or less** [*emphasis added*]. The incidence of culture positivity decreased with an increasing time from symptom onset and with an increasing cycle-threshold value."

[112] ***Op-Ed: Why PCR Cycle Threshold Is Useful in Coronavirus Testing***
Medpage Today
Robert Hagen
January 4, 2021
https://www.medpagetoday.com/infectiousdisease/covid19/90508

> "So how does a qualitative RT-PCR test work? Basically, the manufacturer sets the test to turn off the cycling or amplification process when a certain number is hit. For a qualitative test set at 40, after 40 amplification cycles, if any viral material is detected, it turns off and is reported as positive. If none is detected, it would be reported as negative. If the number of amplification cycles was really 15 or 25, it would still run until it gets to 40 and be reported as positive.
>
> With these type of tests, it's critical to use an agreed-upon cycle threshold value such as 33 (CDC) or 35 (Dr. Fauci) rather than setting it at a potentially misleading 40 or 45. **Many of the current tests in use are preset by the manufacturer to these higher numbers** [*emphasis added*].
>
> The World Health Organization issued a notice last week telling the labs 'the cut-off should be manually adjusted to ensure that specimens with high Ct values are not incorrectly assigned SARS-CoV-2 detected due to background noise.' Could this be a reason why many people test positive but remain asymptomatic? In that same memo, WHO said all labs should report the cycle threshold value to treating physicians…"
>
> "Above that level [*Ct value of 35*], Fauci has said the test is just finding destroyed nucleotides, not virus capable of replicating."

[113] ***Viral cultures for COVID-19 infectious potential assessment – a systematic review***
Clinical Infectious Diseases
T. Jefferson, E.A. Spencer, J. Brassey, and C. Heneghan
December 3, 2020
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217

> "**Results**: We included 29 studies reporting attempts at culturing, or observing tissue infection by, SARS-CoV-2 in sputum, nasopharyngeal or oropharyngeal, urine, stool, blood and environmental specimens… The data suggest a relationship between the time from onset of symptom to the timing of the specimen test, cycle threshold (Ct) and symptom severity. Twelve studies reported that Ct values were significantly lower and log copies higher in specimens producing live virus culture. Two studies reported the odds of live virus culture reduced by approximately 33% for every one unit increase in Ct."
>
> "**Conclusion**: Complete live viruses are necessary for transmission, not the fragments identified by PCR. Prospective routine testing of reference and culture specimens and their relationship to symptoms, signs and patient co-factors should be used to define the reliability of PCR for assessing infectious potential. Those with high cycle threshold are unlikely to have infectious potential."

[114] ***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***.
Corman-Drosten Review Report
Pieter Borger, Bobby Rajesh Malhotra, *et al*.
November 27, 2020
https://cormandrostenreview.com/report/

> "**Abstract**: In the publication entitled "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR" (Eurosurveillance 25(8) 2020) the authors present a diagnostic workflow and RT-qPCR protocol for detection and diagnostics of 2019-nCoV (now known as SARS-CoV-2), which they claim to be validated, as well as being a robust diagnostic methodology for use in public-health laboratory settings.
>
> In light of all the consequences resulting from this very publication for societies worldwide, a group of independent researchers performed a point-by-point review of the aforesaid publication in which 1) all components of the presented test design were cross checked, 2) the RT-qPCR protocol-recommendations were assessed w.r.t. good laboratory practice, and 3) parameters examined against relevant scientific literature covering the field.
>
> The published RT-qPCR protocol for detection and diagnostics of 2019-nCoV and the manuscript suffer from numerous technical and scientific errors, including insufficient primer design, a problematic and insufficient RT-qPCR protocol, and the absence of an accurate test validation. Neither the presented test nor the manuscript itself fulfils the requirements for an acceptable scientific publication. Further, serious conflicts of interest of the authors are not mentioned. Finally, the very short timescale between submission and acceptance of the publication (24 hours) signifies that a systematic peer review process was either not performed here, or of problematic poor quality. We provide compelling evidence of several scientific inadequacies, errors and flaws.
>
> Considering the scientific and methodological blemishes presented here, we are confident that the editorial board of Eurosurveillance has no other choice but to retract the publication.
>
> What is important when designing an RT-PCR Test and the quantitative RT-qPCR test described in the Corman-Drosten publication? …
>
> **Concise Review Report**: There are **ten fatal problems with the Corman-Drosten paper** which we will outline and explain in greater detail in the following sections [*emphasis added*]…
>
> 3. The number of amplification cycles (less than 35; preferably 25-30 cycles);
>
> In case of virus detection, >35 cycles only detects signals which do not correlate with infectious virus as determined by isolation in cell culture [reviewed in 2]; if someone is tested by PCR as positive when a threshold of 35 cycles or higher is used (**as is the case in most laboratories in Europe & the US**), the probability that said person is actually infected is less than 3% [*emphasis added*], the probability that said result is a false positive is 97%…
>
> The maximum reasonably reliable Ct value is 30 cycles. Above a Ct of 35 cycles, rapidly increasing numbers of false positives must be expected. PCR data evaluated as positive after a Ct value of 35 cycles are completely unreliable… Further, scientific studies show that only non-infectious (dead) viruses are detected with Ct values of 35."

[115] ***Cell-based Culture Informs Infectivity and Safe De-Isolation Assessments in Patients with***

Coronavirus Disease 2019
Clinical Infectious Diseases
Kerri Basile, Kenneth McPhie, *et al*.
October 24, 2020
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1579/5937368

"**Background**: The detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA by reverse-transcription polymerase chain reaction (PCR) does not necessarily indicate shedding of infective virions. There are limited data on the correlation between the isolation of SARS-CoV-2, which likely indicates infectivity, and PCR."

"**Methods**: … No clinical samples with PCR Ct values >32 resulted in positive viral cultures."

"**Results**: The highest Ct for the N gene target in any clinical sample where SARS-COV-2 was successfully cultured was 32. Based on this result and the Ct cutoff value of 37 determined by PCR of TCID dilutions and incorporating a 1-log margin of error, we were confident that any clinical sample with a Ct of ≥37 was not indicative of viable virus."

[116] ***One number could help reveal how infectious a COVID-19 patient is. Should test results include it?***
Science magazine
Robert F. Service
September 29, 2020
https://www.science.org/news/2020/09/one-number-could-help-reveal-how-infectious-covid-19-patient-should-test-results

"Standard tests identify SARS-CoV-2 infections by isolating and amplifying viral RNA using a procedure known as the polymerase chain reaction (PCR), which relies on multiple cycles of amplification to produce a detectable amount of RNA. The CT value is the number of cycles necessary to spot the virus; PCR machines stop running at that point. If a positive signal isn't seen after **37 to 40 cycles**, the test is negative [*emphasis added*]. But samples that turn out positive can start out with vastly different amounts of virus, for which the CT value provides an inverse measure. A test that registers a positive result after 12 rounds, for a CT value of 12, starts out with more than 10 million times as much viral genetic material as a sample with a CT value of 35."

"In a study published this week in Clinical Infectious Diseases, researchers led by Bernard La Scola, an infectious diseases expert at IHU-Méditerranée Infection, examined 3790 positive samples with known CT values to see whether they harbored viable virus, indicating the patients were likely infectious. La Scola and his colleagues found that 70% of samples with CT values of 25 or below could be cultured, compared with less than 3% of the cases with CT values above 35."

[117] **Correspondence: *Correlation Between 3790 Quantitative Polymerase Chain Reaction–Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates***
Clinical Infectious Diseases
Rita Jaafar, Sara Aherfi, *et al*.
September 28, 2020
https://academic.oup.com/cid/article/72/11/e921/5912603

> "The outbreak of the coronavirus disease 2019 (COVID-19) pandemic due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared a pandemic on 12 March 2020 by the World Health Organization. A major issue related to the outbreak has been to correlate viral RNA load obtained after reverse-transcription polymerase chain reaction (RT-PCR) and expressed as the cycle threshold (Ct) with contagiousness and therefore duration of eviction from contacts and discharge from specialized infectious disease wards. Several recent publications, based on more than 100 studies, have attempted to propose a cutoff Ct value and duration of eviction, with a consensus at approximately Ct >30 and at least 10 days, respectively. However, in an article published in Clinical Infectious Diseases, Bullard et al reported that patients could not be contagious with Ct >25 as the virus is not detected in culture above this value."
>
> "Since the beginning of the epidemic, we have performed in our institute 250,566 SARS-CoV-2 RT-PCR for 179,151 patients, of which 13,161 (7.3%) tested positive... It can be observed that **at Ct=25, up to 70% of patients remain positive in culture and that at Ct=30 this value drops to 20%**. At Ct=35, the value we used to report a positive result for PCR, < 3% of cultures are positive [*emphasis added*]."

[118] ***Your Coronavirus Test Is Positive. Maybe It Shouldn't Be***.
New York Times
Apoorva Mandavilli
Updated September 17, 2020
https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html

> "**Most [PCR] tests set the limit at 40 [cycles]. A few at 37**. This means that you are positive for the coronavirus if the test process required up to 40 cycles, or 37, to detect the virus [*emphasis added*].
>
> Tests with thresholds so high may detect not just live virus but also genetic fragments, leftovers from infection that pose no particular risk — akin to finding a hair in a room long after a person has left, Dr. Mina said.
>
> Any test with a cycle threshold above 35 is too sensitive, agreed Juliet Morrison, a virologist at the University of California, Riverside. 'I'm shocked that people would think that 40 could represent a positive,' she said.
>
> A more reasonable cutoff would be 30 to 35, she added. Dr. Mina said he would set the figure at 30, or even less. Those changes would mean the amount of genetic material in a patient's sample would have to be 100-fold to 1,000-fold that of the current standard for the test to return a positive result — at least, one worth acting on."

[119] **Video: *Interview with Dr. Anthony Fauci***
This Week in Virology
July 16, 2020
https://www.youtube.com/watch?v=a_Vy6fgaBPE&t=241s

> **Fauci (starting at 4:01)**: "What is now sort of evolving into a bit of a standard is that if you get a cycle threshold of 35 or more, that the chances of it being replication competent [*i.e., accurate*] are **miniscule**… It's very frustrating for the patients, as well as the physicians. Somebody comes in and they repeat their PCR and it's like 37 cycle threshold, but you almost can never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, ya gotta say, you know, it's just **dead nucleotides**, period [*emphasis added*]."

[120] ***Guidance and Standard Operating Procedure COVID-19 Virus Testing in NHS Laboratories***
National Health Service (England)
June 2020
https://www.rcpath.org/uploads/assets/90111431-8aca-4614-b06633d07e2a3dd9/Guidance-and-SOP-COVID-19-Testing-NHS-Laboratories.pdf

> "**5.0 Testing Standard Operating Procedure**… Where Ct values are below an agreed value (based on analysis of Proficiency Testing performance and other local testing data) with satisfactory quality control parameters including internal control performance, the result is considered valid and should be telephoned and a report issued as a final result. Any such positive result will be recorded as 'confirmed' for Public Health reporting purposes and will be notifiable under recent legislation.
>
> Results where:
>
> - the **Ct value is => 40** [*emphasis added*], AND/OR
> - there is an abnormal assay curve, AND/OR
> - the clinical context makes the positive result highly unexpected
>
> should be considered interim or held until reviewed by a laboratory clinician."

[121] ***Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples***
Clinical Infectious Diseases
Jared Bullard, Kerry Dust, *et al*.
May 22, 2020
https://academic.oup.com/cid/article/71/10/2663/5842165

> "**Background**: Reverse-transcription polymerase chain reaction (RT-PCR) has become the primary method to diagnose viral diseases, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). RT-PCR detects RNA, not infectious virus; thus, its ability to determine duration of infectivity of patients is limited. Infectivity is a critical determinant in informing public health guidelines/interventions. Our goal was to determine the relationship between E gene SARS-CoV-2 RT-PCR cycle threshold (Ct) values from respiratory samples, symptom onset to test (STT), and infectivity in cell culture."

"**Conclusions**: SARS-CoV-2 Vero cell infectivity was only observed for RT-PCR Ct < 24 and STT < 8 days. Infectivity of patients with Ct > 24 and duration of symptoms > 8 days may be low. This information can inform public health policy and guide clinical, infection control, and occupational health decisions. Further studies of larger size are needed."

[122] ***Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards***
European Journal of Clinical Microbiology & Infectious Diseases
Bernard la Scola, Marion Le Bideau, *et al*.
April 27, 2020
https://link.springer.com/article/10.1007%2Fs10096-020-03913-9

"**Abstract**: In a preliminary clinical study, we observed that the combination of hydroxychloroquine and azithromycin was effective against SARS-CoV-2 by shortening the duration of viral load in Covid-19 patients. It is of paramount importance to define when a treated patient can be considered as no longer contagious. Correlation between successful isolation of virus in cell culture and Ct value of quantitative RT-PCR targeting E gene suggests that patients with Ct above 33–34 using our RT-PCR system are not contagious and thus can be discharged from hospital care or strict confinement for non-hospitalized patients."

"**Introduction**: … We observed a significant relationship between Ct value and culture positivity rate (Fig. 1). Samples with Ct values of 13–17 all led to positive culture. **Culture positivity rate then decreased progressively according to Ct values to reach 12% at 33 Ct**. No culture was obtained from samples with Ct > 34 [*emphasis added*]."

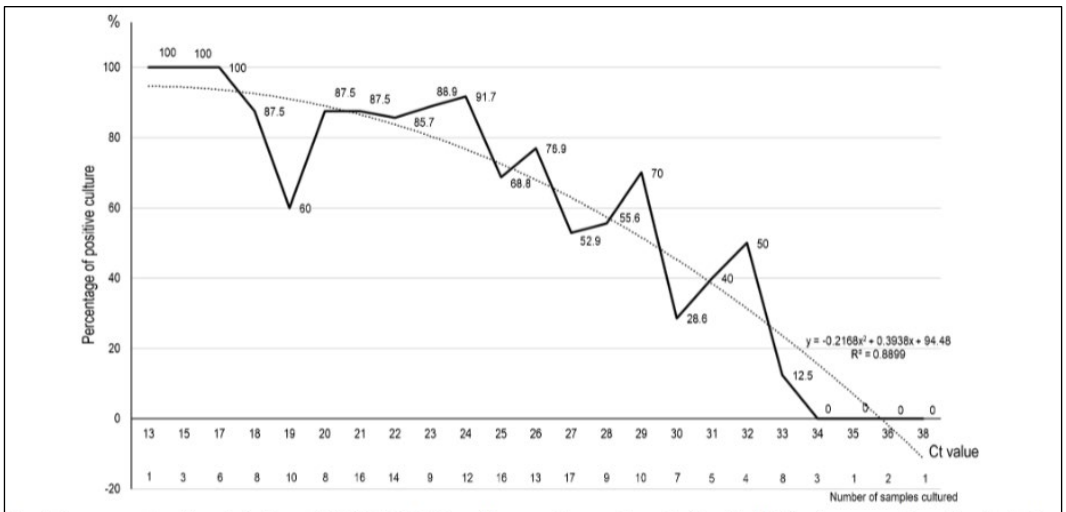


Fig. 1 Percentage of positive viral culture of SARS-CoV-2 PCR-positive nasopharyngeal samples from Covid-19 patients, according to Ct value (plain line). The dashed curve indicates the polynomial regression curve

[123] ***Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19***
Journal of Medical Virology
Yafang Li, Lin Yao, *et al*.
March 26, 2020
https://onlinelibrary.wiley.com/doi/10.1002/jmv.25786

> "**Abstract**: In this study, we collected a total of 610 hospitalized patients from Wuhan between February 2, 2020, and February 17, 2020. We reported a potentially high false negative rate of real-time reverse-transcriptase polymerase chain reaction (RT-PCR) testing for SARS-CoV-2 in the 610 hospitalized patients clinically diagnosed with COVID-19 during the 2019 outbreak. We also found that the RT-PCR results from several tests at different points were variable from the same patients during the course of diagnosis and treatment of these patients…"

Isolation of COVID-19

[124] **ADDED since 10/14/2021**
CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
Centers for Disease Control and Prevention (CDC)
Effective July 21, 2021
https://www.fda.gov/media/134922/download

> "The analytical sensitivity of the rRT-PCR assays contained in the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel were determined in Limit of Detection studies. Since **no quantified virus isolates of the 2019-nCoV were available for CDC use at the time the test was developed** and this study conducted, assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/µL) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to **mimic clinical specimen** *[emphasis added]*."

COVID-19 Vaccines, Manufacturers, and the FDA

FDA Approval of Pfizer-BioNTech COVID-19 BNT162b2 Vaccine

Note: The citations below are presented in reverse, chronological order.

[125] **Package insert for Comirnaty and Pfizer-BioNTech COVID-19 Vaccine**
Food and Drug Administration (FDA)
Revised August 2021.
https://www.fda.gov/media/151707/download

"**8 Use in Specific Populations**

8.1 Pregnancy: … Available data on COMIRNATY administered to pregnant women are **insufficient to inform vaccine-associated risks** in pregnancy [*emphasis added*]…

8.2 Lactation: It is not known whether COMIRNATY is excreted in human milk. Data are not available to assess the effects of COMIRNATY on the breastfed infant or on milk production/excretion….

13 Nonclinical Toxicology

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility: COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility."

[126] ***Does the FDA think these data justify the first full approval of a covid-19 vaccine?***
British Medical Journal
Peter Doshi
August 23, 2021
https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/

"Approval imminent without data transparency, or even an advisory committee meeting?

Last December, with limited data, the FDA granted Pfizer's vaccine an EUA, enabling access to all Americans who wanted one. It sent a clear message that the FDA could both address the enormous demand for vaccines without compromising on the science. A 'full approval' could remain a high bar.

But here we are, with FDA reportedly on the verge of granting a marketing license 13 months into the still ongoing, two year pivotal trial, with **no reported data past 13 March 2021, unclear efficacy after six months due to unblinding, evidence of waning protection irrespective of the Delta variant,** and **limited reporting of safety data** [*emphasis added*]…

Prior to the preprint, my view, along with a group of around 30 clinicians, scientists, and patient advocates, was that there were simply too many open questions about all covid-19 vaccines to support approving any this year. The preprint has, unfortunately, addressed very few of those open questions, and has raised some new ones.

I reiterate our call: 'slow down and get the science right—there is no legitimate reason to hurry

to grant a license to a coronavirus vaccine.'

FDA should be demanding that the companies complete the two year follow-up, as originally planned (even without a placebo group, much can still be learned about safety). They should demand adequate, controlled studies using patient outcomes in the now substantial population of people who have recovered from covid. And regulators should bolster public trust by helping ensure that everyone can access the underlying data."

[127] **Approval letter: *Biologics License Application (BLA) Approval for BioNTech (Pfizer) Manufacturing GmbH***
US Food & Drug Administration
Mary A. Malarkey and Marion F. Gruber
August 23, 2021
https://www.fda.gov/media/151710/download

"**Pediatric Requirements**: … We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed…

Label your annual report as an 'Annual Status Report of Postmarketing Study Requirement/Commitments' and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.
Final Protocol Submission: October 7, 2020
Study Completion: **May 31, 2023**
Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.
Final Protocol Submission: February 8, 2021
Study Completion: **November 30, 2023**
Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.
Final Protocol Submission: January 31, 2022
Study Completion: **July 31, 2024**
Final Report Submission: October 31, 2024…

Postmarketing Commitments to Reporting Requirements under Section 506B: We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled 'Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.'

Final Protocol Submission: July 1, 2021
Study Completion: **June 30, 2025**
Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.
Final Protocol Submission: September 30, 2021
Study Completion: **November 30, 2023**
Final Report Submission: May 31, 2024"

[128] **News release: *FDA Approves First COVID-19 Vaccine***
Food and Drug Administration
August 23 2021
https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

"**Ongoing Safety Monitoring**: The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy."

Emergency Use Authorization (EUA)

Note: The citations below are presented in reverse, chronological order.

[129] ***Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus***
Food and Drug Administration (FDA)
Revised August 12, 2021
https://www.cvlga.org/wp-content/uploads/EUA-27034_FS-for-Recipients-and-Caregivers_myocarditis-pericarditis_Final_6.25.2021-1.pdf

"The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19…

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)? The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA… The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives."

[130] ***FDA Briefing Document - Moderna COVID-19 Vaccine***
Food and Drug Administration (FDA)
December 17, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_2b26a980a8d44de89cd21c42af406565.pdf

"**1. Executive Summary**: …).). The proposed use under an EUA is for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older …

2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product: … In the event an EUA is issued for this product, it would still be considered unapproved and it would be under further investigation…

2.6 Safety and Effectiveness Information Needed to Support an EUA

Effectiveness data: Issuance of an EUA requires a determination that the known and potential benefits of the vaccine outweigh the known and potential risks. For a preventive COVID-19 vaccine to be potentially administered to millions of individuals, including healthy individuals, data adequate to inform an assessment of the vaccine's benefits and risks and support issuance of an EUA would include **meeting the prespecified success criteria for the study's primary efficacy endpoint** [*emphasis added*].

5.2 Study mRNA-1273-P301

5.2.1 Design …

Primary Efficacy Endpoint: The primary efficacy endpoint was efficacy of the vaccine to prevent protocol-defined COVID-19 occurring at least 14 days after the second dose in participants with negative SARS-CoV-2 status at baseline…

5.2.6 Safety: … The safety analyses presented in this review are largely derived from the November 11, 2020 dataset that was the basis for the November 30, 2020 EUA request. **FDA has not independently verified the complete safety dataset and analyses** from the cutoff date of November 25, 2020 [*emphasis added*].

Pregnancies: Study participants of childbearing potential were screened for pregnancy prior to each vaccination, with a positive test resulting in exclusion or discontinuation from study vaccination… Pregnancy outcomes are otherwise unknown at this time.

6. Sponsor's Plans for Continuing Blinded, Placebo-Controlled Follow-Up: … ModernaTX is evaluating the opportunity to amend the protocol to proactively reconsent participants who received placebo to be offered mRNA-1273 vaccination and to remain in the trial, enabling ModernaTX to continue to collect the relevant safety and effectiveness data over the entire two years of follow-up while increasing the likelihood of retaining participants on trial. [***Question:*** *Administering the Moderna product to the placebo group would corrupt the study. How many participants in this group have now been inoculated?*]

8. Benefit/Risk Assessment in the Context of Proposed Indication and Use Under EUA

8.2 Unknown Benefits/Data Gaps

Duration of Protection: As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months…

Effectiveness in certain populations at high-risk of severe COVID-19: Although the proportion of participants at high risk of severe COVID-19 is adequate for the overall evaluation of safety in the available follow-up period, the subsets of certain groups such as immunocompromised individuals (e.g., those with HIV/AIDS) are too small to evaluate efficacy outcomes.

Effectiveness in individuals previously infected with SARS-CoV-2: … [T]he study was not designed to assess the benefit in individuals with prior SARS-CoV-2 infection.

Vaccine effectiveness against mortality: A larger number of individuals at high risk of COVID-19 and higher attack rates **would be needed to confirm efficacy** of the vaccine against mortality [*emphasis added*].

Vaccine effectiveness against transmission of SARS-CoV-2: Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination… Additional evaluations including data from clinical trials and from vaccine use post-authorization **will be needed to assess the effect** of the vaccine in preventing virus shedding and transmission [*emphasis added*], in particular in individuals with asymptomatic infection.

8.4 Unknown Risks/Data Gaps

Safety in certain subpopulations: There are **currently insufficient data to make conclusions about the safety of the vaccine** in subpopulations such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals [*emphasis added*].

10. Appendix A. Phase 1 and 2 Studies

Study Design: Study mRNA-1273-P201 is an ongoing phase 2a, randomized, observer-blind, placebo-controlled, dose-confirmation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1273 in healthy adults 18 years and older."

[131] ***FDA Briefing Document - Pfizer-BioNTech COVID-19 Vaccine***
Food and Drug Administration (FDA)
December 10, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_1136b2851e6e48b1886457ab98b4feef.pdf

"**1. Executive Summary**: … The proposed use under an EUA is 'for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.' …

2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product: … In the event an EUA is issued for this product, it would still be considered unapproved and it would be under further investigation…

Pregnancies: Female study participants of childbearing potential were screened for pregnancy prior to each vaccination, with a positive test resulting in exclusion or discontinuation from study vaccination… Pregnancy outcomes are otherwise unknown at this time.

Duration of Protection: As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months…

Vaccine effectiveness against mortality: A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality.

Vaccine effectiveness against transmission of SARS-CoV-2: Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination… Additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection.

Safety in certain subpopulations: There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals.

Vaccine-enhanced disease. Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure."

[132] ***Emergency Use Authorization for Vaccines to Prevent COVID-19 - Guidance for Industry***
Food and Drug Administration (FDA)
October 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_c7b1f58e161f41f3833918dc5d4091ba.pdf

"III. Criteria and Considerations for the Issuance of an EUA for a COVID-19 Vaccine… Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)) (Ref. 3): …

- **There is no adequate, approved, and available alternative** to the product for diagnosing, preventing, or treating the disease or condition [*emphasis added*]."

COVID-19 Vaccine Trials

Trial Durations and Completion Dates

[133] **Pfizer clinical trial**: ***Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study***
https://clinicaltrials.gov/ct2/show/NCT04848584

"Estimated Study Completion Date: **July 30, 2023**"

[134] **Moderna clinical trial:** ***A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19***
https://www.clinicaltrials.gov/ct2/show/NCT04470427

"Estimated Study Completion Date: **October 27, 2022**"

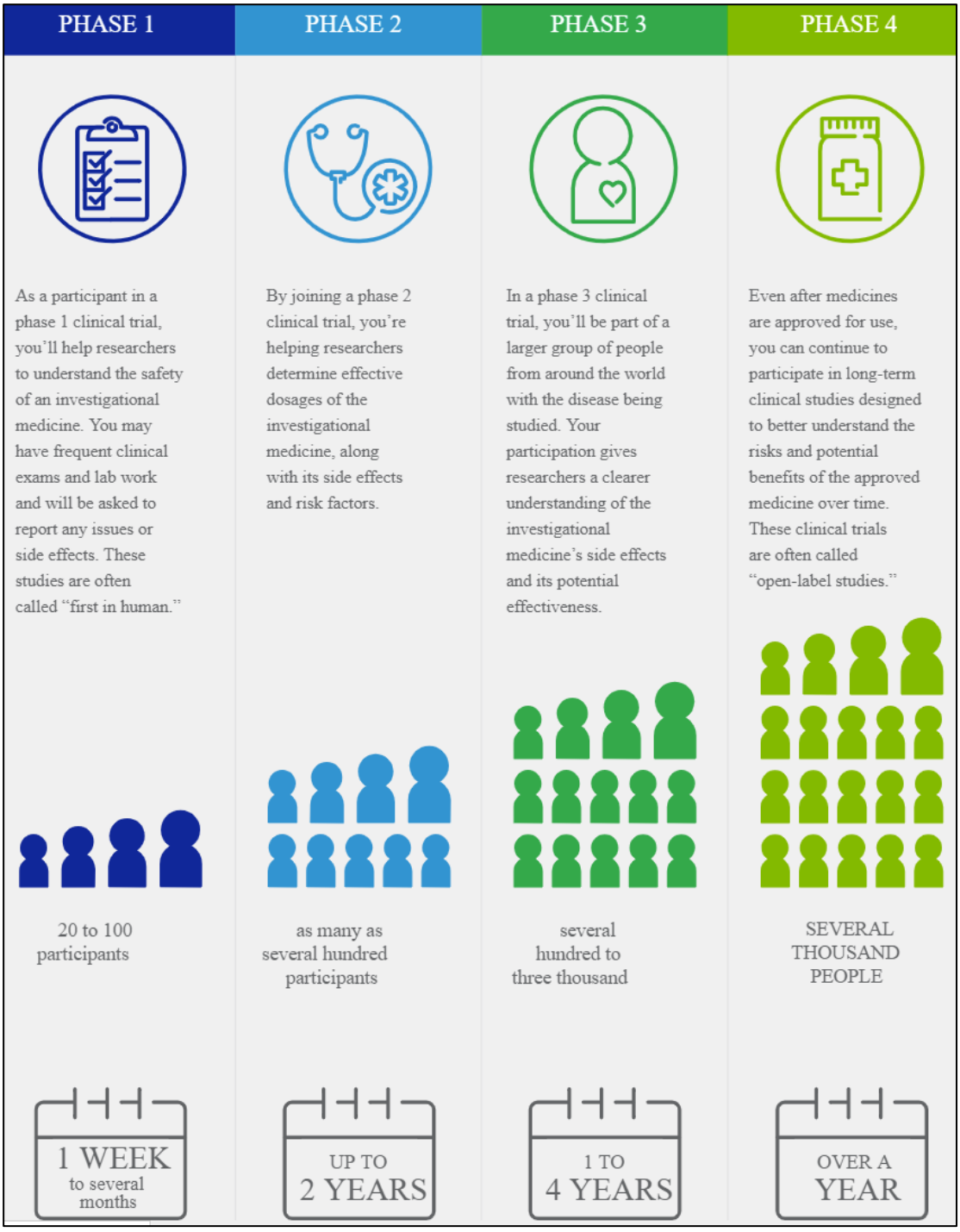
[135] **Johnson & Johnson clinical trial:** ***A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants***
https://clinicaltrials.gov/ct2/show/NCT04505722

"Estimated Study Completion Date: **January 2, 2023**"

[136] **Astrazeneca clinical trial:** ***Phase III Double-blind, Placebo-controlled Study of AZD1222 for the Prevention of COVID-19 in Adults***
https://web.archive.org/web/20201128213442/https://clinicaltrials.gov/ct2/show/results/NCT04516746

"Estimated Study Completion Date: **October 25, 2022**"

[137] ***The Four Phases of Clinical Trials***
Pfizer, Inc.
https://www.pfizer.com/science/clinical-trials/guide-to-clinical-trials/phases


PHASE 1
PHASE 2
PHASE 3
PHASE 4
As a participant in a phase 1 clinical trial, you'll help researchers to understand the safety of an investigational medicine. You may have frequent clinical exams and lab work and will be asked to report any issues or side effects. These studies are often called "first in human."
By joining a phase 2 clinical trial, you're helping researchers determine effective dosages of the investigational medicine, along with its side effects and risk factors.
In a phase 3 clinical trial, you'll be part of a larger group of people from around the world with the disease being studied. Your participation gives researchers a clearer understanding of the investigational medicine's side effects and its potential effectiveness.
Even after medicines are approved for use, you can continue to participate in long-term clinical studies designed to better understand the risks and potential benefits of the approved medicine over time. These clinical trials are often called "open-label studies."
20 to 100 participants
as many as several hundred participants
several hundred to three thousand
SEVERAL THOUSAND PEOPLE
1 WEEK to several months
UP TO 2 YEARS
1 TO 4 YEARS
OVER A YEAR

Trial Endpoints

Note: Efficacy against SARS-CoV-2 transmission/infection and COVID-19 mortality were not endpoints (i.e., tested outcomes) stipulated by the Pfizer or Moderna trial papers.

[138] **Pfizer trial paper: *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine***
Pfizer, Inc.
Fernando P. Polack, Stephen J. Thomas, *et al*.
https://sci-hub.st/10.1056/NEJMoa2034577

> "The first primary end point was the efficacy of BNT162b2 against confirmed Covid-19 with onset at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose; the second primary end point was efficacy in participants with and participants without evidence of prior infection…
>
> Major secondary end points included the efficacy of BNT162b2 against severe Covid-19."

[139] **Moderna trial paper: *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine***
Moderna, Inc.
Lindsey R. Baden, Hana M. El Sahly, *et al*.
https://www.nejm.org/doi/full/10.1056/NEJMoa2035389

> "The primary end point was the efficacy of the mRNA-1273 vaccine in preventing a first occurrence of symptomatic Covid-19 with onset at least 14 days after the second injection in the per-protocol population, among participants who were seronegative at baseline…
>
> A secondary end point was the efficacy of mRNA-1273 in the prevention of severe Covid-19… Additional secondary end points included the efficacy of the vaccine at preventing Covid-19 after a single dose or at preventing Covid-19 according to a secondary (CDC), less restrictive case definition…"

[140] ***Will covid-19 vaccines save lives? Current trials aren't designed to tell us***
British Medical Journal
Peter Doshi
October 21, 2020
https://www.bmj.com/content/371/bmj.m4037

> "**None of the trials** currently under way **are designed to detect a reduction in any serious outcome** such as hospital admissions, use of intensive care, or deaths. Nor are the vaccines being studied to determine whether they can interrupt transmission of the virus [*emphasis added*]…
>
> In all the ongoing phase III trials for which details have been released, laboratory confirmed infections even with only mild symptoms qualify as meeting the primary endpoint definition."

[141] **ADDED since 10/14/2021**
News release: *FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine*
US Food & Drug Administration
December 18, 2020
https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid

> "At this time, data are not available to determine how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person** [*emphasis added*]."

Trial Critiques and Whistleblowers

Note: The citations below are presented in reverse, chronological order.

[142] **ADDED since 10/14/2021**
Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial
British Medical Journal
Paul D. Thacker
November 2, 2021
https://www.bmj.com/content/375/bmj.n2635

> "Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight…
>
> A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that **the company falsified data, unblinded patients, employed inadequately trained vaccinators,** and **was slow to follow up on adverse events** reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding [*emphasis added*]. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio recordings, and emails…
>
> **Poor laboratory management …**
>
> In a recording of a meeting in late September 2020 between Jackson and two directors a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control. 'In my mind, it's something new every day,' a Ventavia executive says. 'We know that it's significant.' …
>
> **A history of lax oversight**
>
> When it comes to the FDA and clinical trials, Elizabeth Woeckner, president of Citizens for Responsible Care and Research Incorporated (CIRCARE), says the agency's oversight capacity is severely under-resourced. If the FDA receives a complaint about a clinical trial, she says the agency rarely has the staff available to show up and inspect. And sometimes oversight

occurs too late…

'There's just a complete lack of oversight of contract research organisations and independent clinical research facilities,' says Jill Fisher, professor of social medicine at the University of North Carolina School of Medicine and author of *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials*…

Other employee's accounts

In recent months Jackson has reconnected with several former Ventavia employees who all left or were fired from the company. One of them was one of the officials who had taken part in the late September meeting. In a text message sent in June the former official apologised, saying that 'everything that you complained about was spot on.'

Two former Ventavia employees spoke to *The BMJ* anonymously for fear of reprisal and loss of job prospects in the tightly knit research community. Both confirmed broad aspects of Jackson's complaint."

[143] **ADDED since 10/14/2021**

Video (6m): Statement by Peter Doshi
US Congressional roundtable – Discussion on COVID-19 vaccines
Peter Doshi, Senior Editor at the British Medical Journal
November 2, 2021
https://www.bitchute.com/video/OvM5meOXk9o/

"Clinical trials have shown that the vaccines authorized for use in the US are highly effective against COVID-19 infection, severe illness, and death."
- Walensky, Walke, Fauci, February 2021

Doshi: "'When that statement by prominent public health officials was penned, there had been just one death – one death – across the 70,000 Pfizer and Moderna trial participants. Today, we have more data and you can see that there were similar numbers of deaths in the vaccine and placebo groups [*15 and 14 deaths, respectively*]. The trials did not show a reduction in death. Even for COVID deaths, the evidence is flimsy, with just 2 deaths in the placebo group and one in the vaccine group…

My point is that **those who claimed the trials showed the vaccines were highly effective in saving lives were wrong**. The trials did not demonstrate this [*emphasis added*]."

[144] **ADDED since 10/14/2021**

Video (5m): Statement by Dr. Robert Kaplan
US Congressional roundtable – Discussion on COVID-19 vaccines
Dr. Robert Kaplan, Distinguished Research Professor Emeritus of Health Policy and Management (UCLA)
November 2, 2021
https://odysee.com/@walt3k:4/Roundtable-expert-panel-on-mandates-Johnson:4

Kaplan (starting at 1:07:45): "I do have concerns about research integrity and the process used to authorize, approve, and mandate vaccines during this emergency. Let me outline some of my concerns...

(L)eading authorities have reported that the vaccines dramatically reduce deaths from COVID-

19. Yet, inspection of the data from the Moderna and Pfizer clinical trials show that **death rates are identical** among those randomly assigned to the vaccines or to placebos [*emphasis added*]…

My second concern is that serious scholars have not been able to examine the raw data that justify the FDA and CDC decisions. The evidence we have comes primarily from highly curated, industry-controlled press releases, and press releases do not provide the detail that we, as scientists, need to offer objective evaluations.

More disturbing is that the **vaccine manufacturers are not honoring requests to provide raw data**. Pfizer, for example, will not make data publically available until 2025 [*emphasis added*]. This is really an unacceptable delay for a product that would be used by billions of people worldwide.

Over the last 80 years, the FDA has evolved standards that require multiple studies and longer term follow-up.

My third concern is that the rapid development and deployment of vaccines to hundreds of millions of people required that some of the usual safeguards needed to be relaxed. Vaccines were authorized on the basis of a single trial with relatively short follow-up, in contrast to the typical standard of multiple trials with sufficient time to evaluate durability and harms…

In contrast to usual FDA applications, the vaccine studies have not made much of the information public. Among 72 studies on the Pfizer vaccine that are registered in ClinicalTrials.gov, **only one is shown to have been completed**, and **zero studies have reported their results publically** [*emphasis added*].

My final concern is that legitimate, scientific challenges have been set aside as 'misinformation'…

So what needs to be done? First, we need more transparency. We should insist on independent data analysis by investigators who are not employed by the vaccine manufacturers…

In summary, we are making big decisions on the basis of limited, highly selected evidence, a compromised scientific process may lead to poor decisions and it may set a bad precedent. So please remember that if it is in the public interest, in this case affecting hundreds of millions of people, it should be in the public domain."

[145] **ADDED since 10/14/2021**
Video (6m): Statement by Dr. Aditi Bhargava
US Congressional roundtable – Discussion on COVID-19 vaccines
Dr. Aditi Bhargava, Professor with the Center for Reproductive Sciences and Dept. of Obstetrics and Gynecology (University of California, San Francisco)
November 2, 2021
https://odysee.com/@Anon:96/aditibhargava:f

Bhargava: "My name is Aditi Bhargava and I'm a professor at UCSF and a microbiologist with 33 years of research experience. These are my scientific views…

It should not have taken the Massachusetts breakthrough infections this summer to discover that fully vaccinated people are just as vulnerable to being infected and transmit SARS-CoV-2 as the unvaccinated. Had the trials been stringent, had the phase II and III [trials] stuck to the

protocols of follow-up, had the regulators enforced manufacturers to study prevention of infection in their clinical trials, **this fiasco could have been avoided** [*emphasis added*].

Instead, manufacturers configured these trials to study the prevention of mild symptoms and used pre-clinical models, such as the rhesus monkeys, in whom the virus does not cause disease. If all we can do is prevent symptoms and severe disease [*then*] we should be talking about drugs to treat COVID, not vaccines and mandates.

We lost the opportunity of discovering these major shortcomings by torpedoing the clinical trials. **The placebo groups were eliminated just two months after the second dose**. Instead, we are learning through trial and error on hundreds of millions of people [*emphasis added*]. And, we insist on eliminating a very important control group by these vaccine mandates. There is no scientific study or experimental design in which we can learn anything of value without a control group. Certainly not about safety and efficacy.

Persistent high levels of antibodies often indicate […] to the body's immune system. That is the basis of autoimmune disease. Hence boosters' long-term adverse events should be taken seriously. The notion that we are in an emergency nearly two years after the pandemic [began] and that should justify cutting corners or taking short-cuts is simply wrong. Trust in scientific methods is at stake.

Media reports often state that [the] science is clear. But scientific publications do not think that the science is clear. And as you've heard from various testimonies – real people suffered adverse events and perhaps **life-long disabilities** due to sloppy trials [*emphasis added*].

I will conclude by asking you. If the vaccines don't prevent infection and transmission, surely mandating person A to protect person B is pointless? But if the vaccines are effective – in preventing infection and transmission [and] decreasing symptoms, hospitalisations rates and death – then what do the vaccinated fear?"

[146] **Video (65m): Dr. Peter McCullough presentation at 78th Annual Meeting of Association of American Physicians and Surgeons (AAPS)**
AAPS
October 2, 2021
https://odysee.com/@alpha:8/Dr-McCullough-78th-AAPS:d

8:10 mark: "**Clinical Concerns** [*of COVID-19 inoculations*]

- mRNA or adenoviral DNA induce production of the Spike protein
    - Cell, tissue, organ endothelial damage
    - Spike protein circulation (body fluids, donated blood)
- No genotoxicity, teratogenicity, or oncogenicity studies
- Concerning ovarian biodistribution study (Pfizer, Japan)
- Concerning reduced fertility study (Moderna, EMA)
- No EAC [*external advisory committees*], DSMB [*Data and Safety Monitoring Board*], Human Ethics Committee

- No restriction of properly excluded groups from RCTs [random controlled trials]
    - Pregnant women, women of childbearing potential
    - COVID survivors, previously immune
- No effort to restrict vaccination according to risk for COVID-19 hospitalization or death
- No attempts to present or mitigate risks for public"

[147] ***The Pfizer mRNA vaccine: pharmacokinetics and toxicity***
Doctors for COVID Ethics
Michael Palmer, MD and Sucharit Bhakdi, MD
July 23, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/07/Pfizer-pharmacokinetics-and-toxicity.pdf

"**Abstract**: We summarize the findings of an animal study which Pfizer submitted to the Japanese health authorities in 2020, and which pertained to the distribution and elimination of a model mRNA vaccine. We show that this study clearly presaged grave risks of blood clotting and other adverse effects. The failure to monitor and assess these risks in the subsequent clinical trials, and the grossly negligent review process in conjunction with the emergency use authorizations, have predictably resulted in an unprecedented medical disaster…

Summary: Pfizer's animal data clearly presaged the following risks and dangers:

- blood clotting shortly after vaccination, potentially leading to heart attacks, stroke, and venous thrombosis
- grave harm to female fertility
- grave harm to breastfed infants
- cumulative toxicity after multiple injections

With the exception of female fertility, which can simply not be evaluated within the short period of time for which the vaccines have been in use, all of the above risks have been substantiated since the vaccines have been rolled out—all are manifest in the reports to the various adverse event registries [9]. Those registries also contain a very considerable number of reports on abortions and stillbirths shortly after vaccination, which should have prompted urgent investigation.

We must emphasize again that each of these risks could readily be inferred from the cited limited preclinical data, but were not followed up with appropriate in- depth investigations. In particular, the clinical trials did not monitor any laboratory parameters that could have provided information on these risks, such as those related to blood coagulation (e.g. D-dimers/thrombocytes), muscle cell damage (e.g. troponin/creatine kinase), or liver damage (e.g. γ-glutamyltransferase). That the various regulatory agencies granted emergency use authorization based on such incomplete and insufficient data amounts to nothing less than gross negligence.

Of particularly grave concern is the very slow elimination of the toxic cationic lipids. In persons repeatedly injected with mRNA vaccines containing these lipids—be they directed against

COVID, or any other pathogen or disease—this would result in cumulative toxicity. There is a real possibility that cationic lipids will accumulate in the ovaries. The implied grave risk to female fertility demands the most urgent attention of the public and of the health authorities.

Since the so-called clinical trials were carried out with such negligence, the real trials are occurring only now—on a massive scale, and with devastating results. This vaccine, and others, are often called "experimental." Calling off this failed experiment is long overdue. Continuing or even mandating the use of this poisonous vaccine, and the apparently imminent issuance of full approval for it are crimes against humanity."

mRNA Technology

Note: The citations below are presented in reverse, chronological order.

[148] ***Open Letter and Notice of Liability from Doctors and Scientists to the EMA and the Members of the European Parliament Regarding COVID-19 Vaccination***
Doctors for COVID Ethics
September 13, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Letter-and-Notice-of-Liability-to-EMA-and-MEPs.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"[A] key point to note is that if we inject a live traditional vaccine into a person who is already immune—due to either a previous vaccination, or to prior infection with the corresponding wild-type virus—the extent of cell destruction will be much reduced. Such a person will already have antibodies to the virus; these will recognize the viral protein antigens and will bind and inactivate most of the vaccine virus particles before they manage to infect a cell. Therefore, even though the killer T-cells may be all riled up, they will not find very many infected cells to pounce on.

The crucial difference between a conventional live virus vaccine and a gene-based COVID vaccine—and in particular an mRNA vaccine—is that the latter contains no protein antigens whatsoever; instead, it only contains the blueprint for their synthesis inside the infected cells. Therefore, if such a vaccine is injected into a person with antibodies and existing T-cell immunity, the vaccine particles will 'fly under the radar' of the antibody defence and reach our body cells unimpeded. The cells will then produce the spike protein, and subsequently be destroyed and attacked by the killer T-cells. The antibodies, rather than preventing the carnage, will join in by also binding to the cell-associated spike protein and directing the complement system (see later) and other immune effector mechanisms against these cells. In a nutshell, **pre-existing immunity** mitigates the risk of conventional vaccines, but it **amplifies the risk of gene-based vaccines** [*emphasis added*].

Importantly, before COVID, this risky gene-based vaccine technology had never before been used on a wide scale against infectious disease and is inherently experimental. The COVID-19 vaccination program is thus **the largest human experiment ever performed in history** [*emphasis added*]."

[149] ***Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues***
Proceedings of the National Academy of Sciences
Liguo Zhang, Alexsia Richards, *et al*.
May 25, 2021
https://www.pnas.org/content/118/21/e2105968118
Response by Rhys Parry, *et al.*, August 3, 2021:
https://www.pnas.org/content/118/33/e2109066118
Response to Parry, *et al.*, by Zhang, Richards, *et al.*, August 17, 2021
https://www.pnas.org/content/118/33/e2109497118

> "**Significance**: An unresolved issue of SARS-CoV-2 disease is that patients often remain positive for viral RNA as detected by PCR many weeks after the initial infection in the absence of evidence for viral replication. We show here that **SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of the infected cell** and be expressed as chimeric transcripts fusing viral with cellular sequences [*emphasis added*]. Importantly, such chimeric transcripts are detected in patient-derived tissues. Our data suggest that, in some patient tissues, the majority of all viral transcripts are derived from integrated sequences. Our data provide an insight into the consequence of SARS-CoV-2 infections that may help to explain why patients can continue to produce viral RNA after recovery."

[150] ***SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome***
Whitehead Institute for Biomedical Research (Cambridge, MA)
Liguo Zhang, Alexsia Richards, *et al*., December 13, 2020
https://www.biorxiv.org/content/10.1101/2020.12.12.422516v1.full

> "**Summary**: … [W]e describe evidence that SARS-CoV-2 RNAs can be reverse transcribed in human cells by reverse transcriptase (RT) from LINE-1 elements or by HIV-1 RT, and that these DNA sequences can be integrated into the cell genome and subsequently be transcribed. Human endogenous LINE-1 expression was induced upon SARS-CoV-2 infection or by cytokine exposure in cultured cells, suggesting a molecular mechanism for SARS-CoV-2 retro-integration in patients. This novel feature of SARS-CoV-2 infection may explain why patients can continue to produce viral RNA after recovery and suggests a new aspect of RNA virus replication."

CDC Definitions of 'Vaccine' and 'Vaccination'

[151] **ADDED since 10/14/2021**
CDC Emails: Our Definition of Vaccine is "Problematic"
Techno Fog
November 2, 2021
https://technofog.substack.com/p/cdc-emails-our-definition-of-vaccine

"The CDC caused an uproar in early September 2021, after it changed its definitions of 'vaccination' and 'vaccine.' For years, the CDC had set definitions for vaccination/vaccine that discussed immunity. This all changed on September 1, 2021.

The prior CDC Definitions of Vaccine and Vaccination (August 26, 2021):

> **Vaccine**: A product that stimulates a person's immune system to **produce immunity** to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose.
>
> **Vaccination**: The act of introducing a vaccine into the body to **produce immunity** to a specific disease.

The CDC Definitions of Vaccine and Vaccination since September 1, 2021:

> **Vaccine**: A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.
>
> **Vaccination**: The act of introducing a vaccine into the body to **produce protection** from a specific disease…

To many observers, it appeared the CDC changed the definitions because of the waning effectiveness of the COVID-19 vaccines. For example, the effectiveness of the Pfizer vaccine falls over time, with an Israeli study reported in August 2021 as showing the vaccine being "only 16% effective against symptomatic infection for those individuals who had two doses of the shot back in January.

Internal CDC E-Mails

CDC emails we obtained via the Freedom of Information Act reveal CDC worries with how the performance of the COVID-19 vaccines didn't match the CDC's own definition of 'vaccine'/'vaccination'…"

***Note**: In the following 6m video, Peter Doshi, Senior Editor at the British Medical Journal, also provides Merriam-Webster's definition of '**vaccine'** from 2006 to January 18, 2021: "a preparation of killed microrganisms, living attenuated organisms, or living fully virulent organisms that is administered to **produce or artificially increase immunity** to a particular disease."*
https://www.bitchute.com/video/OvM5meOXk9o/

Manufacturers: Past Violations

[152] **ADDED since 10/14/2021**
Violation Tracker Parent Company Summaries
Good Jobs First
As of November 14, 2021
https://www.goodjobsfirst.org/violation-tracker
About Us: "Good Jobs First is a national policy resource center for grassroots groups and public officials, promoting corporate and government accountability in economic development and smart growth for working families."

Pfizer: https://violationtracker.goodjobsfirst.org/parent/pfizer

Penalty total since 2000: $4,660,896,333

Number of records: 71

Healthcare-related offenses: 10 records for $3,373,675,000

Johnson & Johnson: https://violationtracker.goodjobsfirst.org/prog.php?parent=johnson-and-johnson

Penalty total since 2000: $9,248,447,763

Number of records: 59

Healthcare-related offenses: 12 records for $8,136,511,000

[153] **ADDED since 10/14/2021**
Corporate Rap Sheets
Corporate Research Project
https://www.corp-research.org/home-page

Pfizer: https://www.corp-research.org/pfizer

Excerpt: "In the area of product safety, Pfizer's biggest scandal involved defective heart valves sold by its Shiley subsidiary that led to the deaths of more than 100 people. During the investigation of the matter, information came to light suggesting that the company had deliberately misled regulators about the hazards. Pfizer also inherited safety and other legal controversies through its big acquisitions, including a class action suit over Warner-Lambert's Rezulin diabetes medication, a big settlement over PCB dumping by Pharmacia, and thousands of lawsuits brought by users of Wyeth's diet drugs.

Also on Pfizer's list of scandals are a 2012 bribery settlement; massive tax avoidance; and lawsuits alleging that during a meningitis epidemic in Nigeria in the 1990s the company tested a risky new drug on children without consent from their parents."

See also '**Product Safety**' at link above.

Johnson & Johnson: https://www.corp-research.org/jnj

Excerpt: "Johnson & Johnson, which originally made its name in mundane products such as bandages and baby powder and shampoo, grew into a healthcare powerhouse by acquiring pharmaceutical and medical device businesses. Yet those purchases were

largely responsible for the deterioration of a company once regarded as a model of social responsibility into a symbol of unreliability with a seemingly endless string of scandals involving tainted and deficient products. Those scandals have forced the company to pay out several billion dollars in civil settlements and criminal fines. It faces more penalties for its alleged role in the opioid crisis."

See also '**Product Safety and Contamination Issues**' at link above.

'Breakthrough' Cases, Hospitalizations and Deaths

[154] ***COVID-19 Vaccine Breakthrough Case Investigation and Reporting***
Centers for Disease Control and Prevention
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

"**Defining a vaccine breakthrough infection**: For the purpose of this surveillance, a **vaccine breakthrough infection** is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person **≥14 days after they have completed all recommended doses** of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine [*emphasis added*]..."

As of May 1, 2021, CDC transitioned from monitoring all reported vaccine breakthrough cases to focus on identifying and investigating **only hospitalized or fatal cases** due to any cause [*emphasis added*]."

[155] **ADDED since 10/14/2021**
The Possibility of COVID-19 after Vaccination: Breakthrough Infections
Centers for Disease Control and Prevention
Updated September 7, 2021
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html

"People who get vaccine breakthrough infections can be contagious."

[156] ***Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England***
Public Health England
Jamie Lopez Bernal, Nick Andrews, *et al*.
March 2, 2021
https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1.full-text

"**Participants**: All adults in England aged 70 years and older (over 7.5 million). All COVID-19 testing in the community among eligible individuals who reported symptoms between 8th December 2020 and 19th February 2021 was included in the analysis…

Results: Individuals aged >=80 years vaccinated with BNT162b2 prior to 4th January, had a higher odds of testing positive in the first 9 days after vaccination (odds ratio up to 1.48, 95%CI 1.23-1.77), indicating that those initially targeted had a higher underlying risk of infection...

Individuals aged >=70 years vaccinated from 4th January had a similar underlying risk of

COVID-19 to unvaccinated individuals…

Results for BNT162b2 for vaccinations administered prior to the 4th of January are shown in Table 2 and Figure 2, this analysis was restricted to 80+ year olds as younger age groups were not eligible for vaccination prior to 4th of January. The **odds of testing positive among vaccinated individuals increased** during the early period up to days 7-9, reaching 1.48 (95%CI 1.23-1.77) [*emphasis added – see Table 2 below*]."

Note: 1.0 is the standard rate without inoculations.

Table 2: Adjusted odds ratios for confirmed case by interval after vaccination for BNT162b2, vaccinations administered prior to 4th January 2021, age >=80 years

	Interval after dose (days)	Vaccinated prior to 4th Jan				
		controls	cases	OR (95% CI)	aOR (95% CI)	OR vs day 4-9
	unvaccinated	15,718	8,988	base	base	
dose 1	d1:0-3	277	167	1.17 (0.96-1.42)	1.22 (1.00-1.48)	
	d1:4-6	241	179	1.26 (1.03-1.54)	1.28 (1.05-1.56)	
	d1:7-9	252	257	1.47 (1.23-1.76)	1.48 (1.23-1.77)	
	d1:10-13	361	284	1.12 (0.95-1.31)	1.13 (0.96-1.33)	0.82 (0.67-1.01)
	d1:14-20	462	336	1.03 (0.89-1.19)	1.06 (0.92-1.23)	0.77 (0.63-0.94)
	d1:21-27	288	118	0.60 (0.48-0.75)	0.64 (0.51-0.79)	0.46 (0.35-0.60)
	d1:28-34	290	72	0.40 (0.30-0.52)	0.41 (0.32-0.54)	0.30 (0.22-0.41)
	d1:35-41	274	65	0.45 (0.34-0.60)	0.49 (0.37-0.66)	0.36 (0.26-0.49)
	d1:42+	396	59	0.34 (0.25-0.47)	0.39 (0.29-0.55)	0.28 (0.20-0.40)
dose 2	d2:0-3	116	45	0.55 (0.39-0.77)	0.59 (0.41-0.83)	0.42 (0.29-0.62)
	d2:4-6	80	30	0.52 (0.34-0.80)	0.57 (0.37-0.88)	0.41 (0.26-0.65)
	d2:7-13	201	28	0.20 (0.13-0.29)	0.21 (0.14-0.32)	0.15 (0.10-0.23)
	d2:14+	634	41	0.13 (0.09-0.18)	0.15 (0.11-0.21)	0.11 (0.07-0.15)

d1= interval after dose 1, d2= interval after dose 2. OR: odds ratios period adjusted by week of onset. aOR: odds ratios adjusted for age, period, sex, region, ethnicity, care home, imd quintile

Note: The citations below are presented in reverse, chronological order.

[157] **ADDED since 10/14/2021**
Vaccination Status of COVID-19 Deaths in Ireland between 1st April 2021 and 30th October 2021
Health Protection Surveillance Center (Ireland)
November 2021
https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/surveillance/vaccinationstatusweeklyreports/Death%20and%20Vaccination%20Report.pdf

"Between April 1st and October 30th 2021

- 535 persons with a laboratory confirmed COVID-19 infection, were notified to the Health Protection Surveillance Centre (HPSC) as having died due to COVID-19.
- **313/535 (58.5%) deaths were notified in persons who had received at least one dose** of COVID-19 vaccine prior to death [*emphasis added*].
- 253/535 (47.3%) of the notified deaths had an epidemiological date 14 days or more after receiving both doses of a 2-dose regimen or 1 dose of a 1-dose regimen and are considered as vaccine breakthrough infections – see technical note."

[158] **ADDED since 10/14/2021**

Shedding of Infectious SARS-CoV-2 Despite Vaccination
University of Wisconsin-Madison
Kasen K. Riemersma, Brittany E. Grogan, *et al*.
November 6, 2021
https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v6.full-text

"**Abstract**: The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (**68%**) and 246 of 389 (**63%**) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, **finding no difference in infectious virus titer between groups** [*emphasis added*]."

[159] **ADDED since 10/14/2021**

COVID-19 vaccine surveillance report, Week 44
UK Health Security Agency
November 4, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1032671/Vaccine_surveillance_report_-_week_44.pdf

"**Results**: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated."

Table 2. COVID-19 cases by vaccination status between week 40 and week 43 2021
Please note that corresponding rates by vaccination status can be found in Table 5.

Cases reported by specimen date between week 40 and week 43 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date
Under 18	397484	23778	336893	20041	15954	818
18-29	75211	7955	24097	701	8809	33649
30-39	113717	8476	25832	665	7252	71492
40-49	159478	8580	15717	291	4204	130686
50-59	114282	5853	6701	81	1925	99722
60-69	63474	3353	2484	23	835	56779
70-79	37535	2037	917	16	260	34305
≥80	14043	1002	471	7	224	12339

Table 3. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 40 and week 43 2021
Please note that corresponding rates by vaccination status can be found in Table 5.

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 40 and week 43 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date
Under 18	581	20	539	12	9	1
18-29	323	7	212	3	30	71
30-39	665	9	425	5	37	189
40-49	1006	16	472	5	45	468
50-59	1233	18	474	1	51	689
60-69	1308	7	318	2	29	952
70-79	1802	5	198	3	32	1564
≥80	1804	3	168	0	33	1600

Table 4. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 40 and week 43 2021

Please note that corresponding rates by vaccination status can be found in Table 5.

(a)

Death within 28 days of positive COVID-19 test by date of death between week 40 and week 43 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date
Under 18	6	0	6	0	0	0
18-29	9	0	7	0	0	2
30-39	25	1	17	0	2	5
40-49	73	1	37	0	1	34
50-59	179	4	81	0	5	89
60-69	420	3	118	0	14	285
70-79	809	2	115	0	18	674
≥80	1564	4	157	0	45	1358

[160] **ADDED since 10/14/2021**

SARS-CoV-2 vaccine protection and deaths among US veterans during 2021

Science (George Mason University)

Barbara A. Cohn, Piera M. Cirillo, Caitlin C. Murphy, Nickilou Y. Krigbaum, and Arthur W. Wallace

November 4, 2021

https://www.science.org/doi/10.1126/science.abm0620

"**Abstract**: We report SARS-CoV-2 vaccine effectiveness against infection (VE-I) and death (VE-D) by vaccine type (n = 780,225) in the Veterans Health Administration, covering 2.7% of the U.S. population. From February to October 2021, **VE-I declined from 87.9% to 48.1%**, and the decline was greatest for the Janssen vaccine resulting in a VE-I of 13.1% [*emphasis added*]."

[161] **ADDED since 10/14/2021**

Public Health Scotland COVID-19 Statistical Report As at 01 November 2021

Public Health Scotland

November 3, 2021

https://publichealthscotland.scot/media/9994/21-11-03-covid19-publication_report.pdf

Page 43: In Scotland for the period 10/2/2021 through 10/29/2021, Table 19 indicates a total of **552** "acute hospital admissions" with COVID-19 amongst the unvaccinated and **1,731** such admissions amongst recipients of two vaccination doses.

Table 19: Age-standardised rate of acute hospital admissions where an individual had a COVID-19 positive PCR test up to 14 days prior, on admission, or during their stay in hospital, by week and vaccination status, 02 October 2021 to 29 October 2021

	Unvaccinated		1 Dose		2 Doses	
Week/Vaccination Status	No. hospitalised	Age Standardised Hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised Hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised Hospitalisation Rate per 100,000 with 95% confidence intervals
02 October - 08 October 2021	161	**19.07** (14.81 - 23.34)	21	**19.22** (7.62 - 30.83)	441	**8.71** (7.87 - 9.54)
09 October - 15 October 2021	118	**15.49** (11.44 - 19.54)	16	**11.01** (3.85 - 18.18)	402	**7.89** (7.10 - 8.67)
16 October - 22 October 2021	131	**19.69** (15.10 - 24.27)	22	**13.90** (4.46 - 23.34)	449	**8.76** (7.94 - 9.58)
23 October - 29 October 2021	142	**20.12** (15.56 - 24.67)	16	**10.46** (1.67 - 19.25)	439	**8.44** (7.65 - 9.24)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 9. The data displayed within the greyed-out section (1 week) are considered preliminary and are subject to change as more data is updated. Age-standardised hospitalisation rates are per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 9).

Page 47: In Scotland for the period 9/25/2021 through 10/22/2021, Table 20 indicates a total of **64** "COVID-19 related deaths" amongst the unvaccinated and **454** such deaths amongst recipients of two vaccination doses.

Table 20: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 25 September 2021 to 22 October 2021

	Unvaccinated		1 Dose		2 Doses	
Week/Vaccination Status	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
25 September - 01 October 2021	22	**6.59** (3.54 - 9.63)	4	**9.04** (0.05 - 18.03)	114	**2.23** (1.82 - 2.64)
02 October - 08 October 2021	19	**5.05** (2.48 - 7.61)	0	**0.00** (0.00 - 0.00)	106	**2.10** (1.70 - 2.51)
09 October - 15 October 2021	15	**5.03** (2.27 - 7.79)	4	**9.22** (-0.05 - 18.48)	120	**2.35** (1.93 - 2.77)
16 October - 22 October 2021	8	**1.90** (0.44 - 3.36)	4	**10.58** (0.17 - 21.00)	114	**2.20** (1.79 - 2.60)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 9. A confirmed COVID-19 related death is defined as an individual who has tested positive by PCR for SARS-CoV-2 at any time point and has COVID-19 listed as an underlying or contributory cause of death on the death certificate. Age-standardised mortality rates per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 9). This definition is for the purposes of evaluating the impact of the COVID-19 vaccine on confirmed COVID-19 deaths. The numbers reported in this section may differ from other published COVID-19 death data. Data are based on date of registration. In Scotland deaths must be registered within 8 days although in practice, the average time between death and registration is around 3 days. More information on days between occurrence and registration can be found on the NRS website.

[162] **ADDED since 10/14/2021**

Viral loads of Delta-variant SARS-CoV-2 breakthrough infections after vaccination and booster with BNT162b2

Nature Medicine
Matan Levine-Tiefenbrun, Idan Yelin, *et al*.
November 2, 2021
https://www.nature.com/articles/s41591-021-01575-4

> "**Abstract**: … By analyzing viral loads of over 16,000 infections during the current, Delta-variant-dominated pandemic wave in Israel, we found that BTIs [*breakthrough infections*] in recently fully vaccinated individuals have lower viral loads than infections in unvaccinated individuals. However, this effect starts to decline 2 months after vaccination and **ultimately vanishes 6 months or longer after vaccination** [*emphasis added*]."

[163] **ADDED since 10/14/2021**

Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study

Infectious Diseases (The Lancet)
Anika Singanayagam, Seran Hakki, *et al*.
October 29, 2021
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext

> "**Background**: The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community…
>
> **Interpretation**: … [F]ully vaccinated individuals with breakthrough infections have **peak viral load similar to unvaccinated cases** and **can efficiently transmit infection** in household settings, including to fully vaccinated contacts."

[164] **ADDED since 10/14/2021**

COVID-19 vaccine surveillance report, Week 43

UK Health Security Agency

October 28, 2021

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1029606/Vaccine-surveillance-report-week-43.pdf

"**Results**: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated…"

Table 2. COVID-19 cases by vaccination status between week 39 and week 42 2021

Cases reported by specimen date between week 39 and week 42 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
Under 18	411,079	24,798	355,008	16,640	13,812	821
18-29	68,780	7,713	22,436	686	8,532	29,413
30-39	102,344	7,858	23,748	645	6,856	63,237
40-49	145,641	7,989	14,336	291	3,962	119,063
50-59	102,009	5,330	6,091	81	1,767	88,740
60-69	54,020	2,968	2,167	22	702	48,161
70-79	32,909	1,822	794	14	254	30,025
≥80	13,231	936	434	7	219	11,635

Table 3. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 39 and week 42 2021

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 39 and week 42 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
Under 18	633	17	592	12	11	1
18-29	324	8	212	2	28	74
30-39	708	10	446	2	47	203
40-49	991	14	495	5	40	437
50-59	1,139	13	447	1	46	632
60-69	1,177	12	288	3	33	841
70-79	1,642	1	195	3	34	1,409
≥80	1,724	2	157	0	38	1,527

Table 4. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 39 and week 42 2021

(a)

Death within 28 days of positive COVID-19 test by date of death between week 39 and week 42 2021	Total**	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
Under 18	5	0	4	1	0	0
18-29	11	1	7	0	0	3
30-39	25	0	18	0	1	6
40-49	65	1	35	0	1	28
50-59	159	3	74	0	5	77
60-69	374	3	105	0	16	250
70-79	736	2	101	0	21	612
≥80	1,397	5	143	0	40	1,209

[165] **ADDED since 10/14/2021**

Waning Immunity after the BNT162b2 Vaccine in Israel

The New England Journal of Medicine (NEJM)
Yair Goldberg, Micha Mandel, *et al*.
October 27, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2114228

"**Conclusions**: These findings indicate that immunity against the delta variant of SARS-CoV-2 waned in all age groups a few months after receipt of the second dose of vaccine…

Discussion: … [A]pproximately **two thirds of the cases of severe Covid-19** in Israel during the study period [*July 11 to 31, 2021*] **occurred in persons who had received two doses of the BNT162b2 vaccine** [*Pfizer-BioNTech - emphasis added*]."

[166] **ADDED since 10/14/2021**

SARS-CoV-2 Vaccine Breakthrough Surveillance and Case Information Resource

Washington State Department of Health
October 27, 2021
https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/data-tables/420-339-VaccineBreakthroughReport.pdf

"Vaccine breakthrough occurs when someone gets infected with an organism they are fully vaccinated against. For the COVID-19 vaccine, this means someone tests positive for SARS-CoV-2 two weeks or more after receiving the full series of an authorized COVID-19 vaccine…

At a Glance (data from January 17, 2021 - October 16, 2021) - 59,543 SARS-CoV-2 vaccine breakthrough cases have been identified in Washington State."

[167] **ADDED since 10/14/2021**

Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study

The Lancet (University of Umea)
Peter Nordstrom, Marcel Ballin, and Anna Nordstrom
October 25, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3949410

"**Methods**: A retrospective cohort study was conducted using Swedish nationwide registries. The cohort comprised 842,974 pairs (N=1,684,958), including individuals vaccinated with 2 doses of ChAdOx1 nCoV-19, mRNA-1273 [*Moderna*], or BNT162b2 [*Pfizer*], and matched unvaccinated individuals. Cases of symptomatic infection and severe Covid-19 (hospitalization or 30-day mortality after confirmed infection) were collected from 12 January to 4 October 2021.

Findings: **Vaccine effectiveness of BNT162b2 against infection waned progressively** from 92% at day 15-30 **to 47% at day 121-180**, and from day 211 and onwards **no effectiveness could be detected**… The effectiveness waned slightly slower for mRNA-1273, being estimated to 59% (95% CI, 18-79) from day 181 and onwards. In contrast, effectiveness of ChAdOx1 nCoV-19 was generally lower and waned faster, with no effectiveness detected from day 121 and onwards… Overall, vaccine effectiveness was lower and waned faster among men and older individuals. For the outcome severe Covid-19, effectiveness waned from 89% at day 15-30 to **42% from day 181 and onwards**, with sensitivity analyses showing notable waning among men, **older frail individuals**, and **individuals with comorbidities**."

[168] **ADDED since 10/14/2021**
Press-conference video (2m): Remarks by Florida Attorney General, Dr. Joseph A. Ladapo
October 25, 2021
https://www.bitchute.com/video/DKPJqkwZdezW/

Ladapo: "As we now know, these vaccines are not preventing transmission. Sure, they reduce the likelihood of transmission -- and even that is sort of questionable depending on how far out you go -- but they're not preventing it. I've heard some leaders say things like, 'We'll create safe workplaces by mandating these vaccines.' Well, they're really decoupled. Because the infections can still happen whether people are vaccinated or not. I mean, that's very obvious.

And you remember, these people were also telling you that all these breakthrough infections were rare. Well, they're obviously not rare. In fact, they're common, and so that's the truth.

So this idea… that the vaccine mandates are needed to create safe workplaces is a complete lie, it's continued to be repeated, and you should know that it's not at all backed up by science. In fact, the science says something that's completely the opposite. And that's a fact.

Part of the reason that some people are not comfortable with these vaccines is because of the climate of scientific dishonesty about the science -- whether it's natural immunity, denial of that in the face of data… or in the case of the vaccines, open, honest discussions about both effectiveness and safety… There's been dishonesty around that…

The reality of how safe these vaccines are is absolutely not public… Healthy people who have had adverse reactions after the vaccine, there's been a concerted effort to prevent these types of stories, these experiences, from receiving the attention that they obviously should receive...

It's completely ridiculous. Many Americans can sense that there's been total dishonesty about the safety of the vaccines."

[169] **ADDED since 10/14/2021**
COVID-19 vaccine surveillance report, Week 42
UK Health Security Agency
October 21, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf

"**Results**: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated…

Table 2. COVID-19 cases by vaccination status between week 38 and week 41 2021

Cases reported by specimen date between week 38 and week 41 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date	Rates among persons vaccinated with 2 doses (per 100,000)	Rates among persons not vaccinated (per 100,000)
Under 18	397,882	24,292	351,148	10,698	11,001	743	314.1	3,013.6
18-29	62,885	7,512	20,902	758	8,404	25,309	462.1	615.4
30-39	92,257	7,346	21,726	636	6,545	56,004	956.7	751.1
40-49	130,904	7,297	13,022	293	3,800	106,492	1,731.3	772.9
50-59	88,020	4,790	5,399	80	1,632	76,119	1,075.3	528.6
60-69	45,155	2,614	1,872	24	617	40,028	704.1	347.1
70-79	27,360	1,559	658	12	215	24,916	537.9	267.6
≥80	11,907	854	382	7	215	10,449	406.8	304.1

* Individuals whose NHS numbers were unavailable to link to the NIMS

** Interpretation of the case rates in vaccinated and unvaccinated population is particularly susceptible to changes in denominators and should be interpreted with extra caution

… Seropositivity estimates for N antibody will underestimate the proportion of the population previously infected due to… (iii) recent observations from UK Health Security Agency (UKHSA) surveillance data that N antibody levels appear to be **lower in individuals who acquire infection following 2 doses of vaccination** [*emphasis added*]."

[170] **ADDED since 10/14/2021**

Public Health Scotland COVID-19 Statistical Report As at 18 October 2021

Public Health Scotland

October 20, 2021

https://publichealthscotland.scot/media/9821/21-10-20-covid19-publication_report.pdf

Page 48: In Scotland for the period 9/11/2021 through 10/8/2021, Table 20 indicates a total of 96 "COVID-19 related deaths" amongst the unvaccinated and 436 such deaths amongst recipients of two vaccination doses.

Table 20: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 11 September 2021 to 08 October 2021

Week/Vaccination Status	Unvaccinated		1 Dose		2 Doses	
	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
11 September - 17 September 2021	26	**7.73** (4.47 - 10.98)	4	**5.13** (0.00 - 10.70)	101	**1.94** (1.55 - 2.31)
18 September - 24 September 2021	29	**8.63** (5.19 - 12.06)	8	**14.72** (3.69 - 25.75)	121	**2.37** (1.94 - 2.80)
25 September - 01 October 2021	22	**6.87** (3.71 - 10.03)	4	**8.88** (0.05 - 17.71)	114	**2.22** (1.81 - 2.63)
02 October - 08 October 2021	19	**5.29** (2.62 - 7.97)	0	**0.00** (0.00 - 0.00)	100	**1.96** (1.57 - 2.35)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 9. A confirmed COVID-19 related death is defined as an individual who has tested positive by PCR for SARS-CoV-2 at any time point and has COVID-19 listed as an underlying or contributory cause of death on the death certificate. Age-standardised mortality rates per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 9). This definition is for the purposes of evaluating the impact of the COVID-19 vaccine on confirmed COVID-19 deaths. The numbers reported in this section may differ from other published COVID-19 death data. Data are based on date of registration. In Scotland deaths must be registered within 8 days although in practice, the average time between death and registration is around 3 days. More information on days between occurrence and registration can be found on the NRS website.

[171] **ADDED since 10/14/2021**

Antibody levels decrease after two doses of Pfizer vaccine – study

Jerusalem Post
Rossella Tercatin
October 7, 2021
https://www.jpost.com/health-and-wellness/coronavirus/antibody-levels-decrease-after-two-doses-of-pfizer-vaccine-study-681260

> "Antibody levels decrease rapidly after two doses of the Pfizer coronavirus vaccine, a study by researchers at the Sheba Medical Center published Wednesday in the *New England Journal of Medicine* showed…
>
> Over 4,800 staff members of Sheba participated in the study…
>
> 'We saw that the decline in antibody level is very rapid,' Regev-Yochay [*one of the study's authors*] said at a press briefing."

[172] **ADDED since 10/14/2021**

Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study

The Lancet
Sara Y. Tartof, Jeff M. Slezak, *et al*.
October 4, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext

> "**Background**: Vaccine effectiveness studies have not differentiated the effect of the delta (B.1.617.2) variant and potential waning immunity in observed reductions in effectiveness against SARS-CoV-2 infections. We aimed to evaluate overall and variant-specific effectiveness of BNT162b2 (tozinameran, Pfizer–BioNTech) against SARS-CoV-2 infections and COVID-19-related hospital admissions by time since vaccination among members of a large US health-care system…
>
> **Findings**: … **Effectiveness against infections declined** from 88% (95% CI 86–89) during the first month after full vaccination to **47% (43–51) after 5 months** [*emphasis added*]. Among sequenced infections, vaccine effectiveness against infections of the delta variant was high during the first month after full vaccination (93% [95% CI 85–97]) but declined to 53% [39–65] after 4 months."

[173] ***Waning Immufne Humoral Response to BNT162b2 Covid-19 Vaccine over 6 Months***

New England Journal of Medicine (NEJM)
Einav G. Levin, Yaniv Lustig, *et al*.
October 6, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2114583

> "**Methods**: We conducted a 6-month longitudinal prospective study involving vaccinated health care workers who were tested monthly for the presence of anti-spike IgG and neutralizing antibodies. Linear mixed models were used to assess the dynamics of antibody levels and to determine predictors of antibody levels at 6 months.
>
> **Results**: The study included 4868 participants, with 3808 being included in the linear mixed-model analyses. The level of IgG antibodies decreased at a consistent rate, whereas the

neutralizing antibody level decreased rapidly for the first 3 months with a relatively slow decrease thereafter…

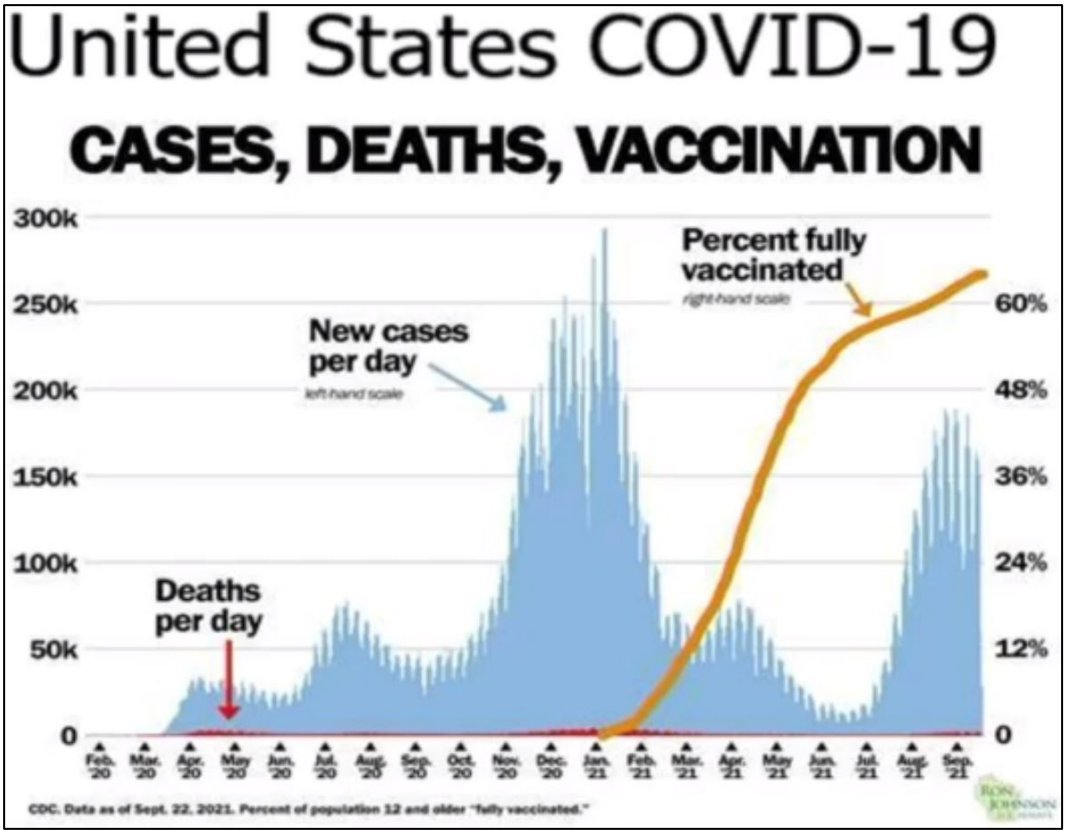
Conclusions: Six months after receipt of the second dose of the BNT162b2 [*Pfizer*] vaccine, **humoral [*immune*] response was substantially decreased**, especially among men, among persons 65 years of age or older, and among persons with immunosuppression."

[174] ***Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar***
New England Journal of Medicine (NEJM)
Hiam Cernaitelly, Patrick Tang, *et al*.
October 6, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2114114

"**Results**: Estimated BNT162b2 [*Pfizer*] effectiveness against any SARS-CoV-2 infection was negligible in the first 2 weeks after the first dose. It increased to 36.8% (95% confidence interval [CI], 33.2 to 40.2) in the third week after the first dose and reached its peak at 77.5% (95% CI, 76.4 to 78.6) in the first month after the second dose. Effectiveness declined gradually thereafter, with the decline accelerating after the fourth month to reach approximately **20% in months 5 through 7** after the second dose [*emphasis added*]…

Discussion: … By far the dominant variant during the study was B.1.351 [*beta*], and a **similar pattern of waning of protection** was observed for B.1.1.7 [*alpha*], B.1.351, and B.1.617.2 [*delta*] [*emphasis added*]."

[175] **Video (65m): Dr. Peter McCullough presentation at 78th Annual Meeting of Association of American Physicians and Surgeons (AAPS)**
AAPS
October 2, 2021
https://odysee.com/@alpha:8/Dr-McCullough-78th-AAPS:d



[176] **ADDED since 10/14/2021**
Durability of immune responses to the BNT162b2 mRNA vaccine
National Institutes of Health (NIH), Stanford University, and Emory University
Mehul S. Suthar, Prabhu S. Arunachalam, *et al*.
September 30, 2021
https://www.biorxiv.org/content/10.1101/2021.09.30.462488v1.full

> "**Abstract**: … Here, we analyzed antibody responses to the homologous Wu strain as well as several variants of concern, including the emerging Mu (B.1.621) variant, and T cell responses in a subset of these volunteers at six months (day 210 post-primary vaccination) after the second dose. Our data demonstrate a **substantial waning of antibody responses** and **T cell immunity** to SARS-CoV-2 and its variants, at 6 months following the second immunization with the BNT162b2 vaccine [*emphasis added*]. Notably, a significant proportion of vaccinees have neutralizing titers below the detection limit, and suggest a 3rd booster immunization might be warranted to enhance the antibody titers and T cell responses"

[177] ***Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021***
Eurosurveillance
Pnina Shitrit, Neta S Zuckerman, Orna Mor, Bat-Sheva Gottesman, and Michal Chowers
September 30, 2021
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822#html_fulltext

"We present an investigation of a coronavirus disease (COVID-19) outbreak that started from one unidentified COVID-19 patient, with extensive, rapid nosocomial spread among vaccinated, including individuals wearing surgical masks.

Setting: Meir Medical Center has 780 beds, most rooms accommodate three to four patients, 1 m apart with separation curtain partitions between beds. Starting in March 2020, patients have been encouraged to wear surgical masks. Although use was inconsistent, it was enforced during patient–staff encounters for both sides. On the dedicated COVID-19 ward, dedicated staff members worked with full personal protective equipment (PPE): N-95 mask, face shield, gown, gloves and hair cover…

Demographic and clinical information: Of the 42 cases diagnosed in this outbreak, **38 were fully vaccinated** with two doses of the Comirnaty vaccine, one was recovered with one vaccination and three were unvaccinated… Twenty-three were patients, 16 staff members and three family members… Among the patients (median age: 77 years; range: 42–93; median time from second vaccine dose to infection: 176 days; range: 143-188), **eight became severely ill, six critically ill** and **five of the critically ill died** [*emphasis added*].

Discussion: … [T]his communication emphasises several points. It challenges the assumption that high universal vaccination rates will lead to herd immunity and prevent COVID-19 outbreaks. This was probably true for the wild-type SARS-CoV-2 virus, but in the outbreak described here, 96.2% of the exposed population was vaccinated. Infection advanced rapidly (many cases became symptomatic within 2 days of exposure), and viral load was high. Another accepted view is that, when facing a possible mismatch between the SARS-CoV-2 variant and vaccine or waning immunity, the combination of vaccine and face mask should provide the necessary protection. Although some transmission between staff members could have occurred without masks, all transmissions between patients and staff occurred between masked and vaccinated individuals, as experienced in an outbreak from Finland."

[178] **ADDED since 10/14/2021**
The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission
University of Oxford and the Department of Health and Social Care (UK)
David W. Eyre, Donald Taylor, *et al*.
September 29, 2021
https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1.full-text

"**Methods**: We performed a retrospective observational cohort study of contacts of SARS-CoV-2-infected index cases using contact testing data from England.

Results: … Transmission reductions declined over time since second vaccination, for Delta reaching similar levels to unvaccinated individuals by 12 weeks for ChAdOx1 and attenuating substantially for BNT162b2. Protection from vaccination in contacts also declined in the 3 months after second vaccination.

Duration of protection and transmission reductions

[H]igher probabilities of PCR-positive results in contacts 14 days after second vaccination for Delta vs. Alpha meant that by 12 weeks post second ChAdOx1 dose there was **no evidence that onward Delta transmission rates differed between those not vaccinated and those having received two ChAdOx1 doses** and the impact of BNT162b2 had also attenuated substantially."

[179] **ADDED since 10/14/2021**
No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant
University of California- Davis, -Berkeley, and -San Francisco
Charlotte B. Acharya, John Schrom, *et al*.
September 29, 2021
https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1

"**Discussion**: In our study, mean viral loads as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge, regardless of vaccine status, age, or gender… Our study is consistent with other recent reports showing similar viral loads among vaccinated and unvaccinated individuals in settings with transmission of the Delta variant."

[180] ***Sharp decline in antibody levels after seven months for double vaccinated***
Sveriges Television (SVT), Swedish public television
Josefin Lennen Merckx
September 28, 2021
https://www.svt.se/nyheter/inrikes/kraftig-nedgang-i-antikroppsnivaer-efter-sju-manader-for-dubbelvaccinerade

"In total, more than 2,000 healthcare workers are included in the COMMUNITY study. The goal is to learn more about immunity after COVID-19 and about the effects of vaccines.

The latest interim report of 464 people shows how quickly antibody levels have slowed down in double vaccinated people who have not had COVID.

For Pfizer vaccinated, antibody levels halved after three months.

After seven months, only 15% of the original levels remained – a **decrease of as much as 85%** [*emphasis added*].

'It is fully expected that antibody levels will drop over time, but I am surprised that it has dropped so significantly in such a relatively healthy and young group,' says Charlotte Thålin...

Since the staff who received Astra Zeneca's vaccine received the second dose later, the researchers have only been able to follow them for three months. But the decline was even greater. After three months, Astravaccinated had only one-fifth of pfizer vaccine antibody levels."

[181] ***Covid-19 in Wales: A third of positive cases are unvaccinated***
BBC News
September 24, 2021
https://www.bbc.com/news/uk-wales-58680204

> "Nearly 13% of hospital patients with confirmed Covid were unvaccinated.
>
> PHW said the vaccines had helped keep Covid hospital numbers much lower during the third wave.
>
> Although 80% of patients have been double-dosed with a vaccine, public health officials said this is not evidence that the vaccine is not working…"

[182] ***SARS-CoV-2 variants of concern and variants under investigation in England – Technical briefing 23***
Public Health England
September 17, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1018547/Technical_Briefing_23_21_09_16.pdf

> **Note**: All figures below are taken from p. 18, 'Table 5. Attendance to emergency care and deaths of sequenced and genotyped Delta cases in England by vaccination status (1 February 2021 to 12 September 2021).'
>
> **593,572 Total Delta cases**. Of this number:
>
> - 26.5% were diagnosed at least 14 days after their second inoculation (157,400 / 593,572)
> - 43.4% were 'unvaccinated' (257,357 / 593,572)
>
> **2,542 Total deaths within 28 days of positive specimen date**. Of this number:
>
> - **63.5%** were diagnosed at least 14 days after their second inoculation (1,613 / 2,542)
> - **28.4%** were 'unvaccinated' (722 / 2,542) [*emphasis added*]

[183] ***COVID vaccine immunity is waning — how much does that matter?***
Nature magazine
Elie Dolgin
September 17, 2021
https://www.nature.com/articles/d41586-021-02532-4

> "Immunological studies have documented a steady decline of antibody levels among vaccinated individuals. Long-term follow-up of vaccine trial participants has revealed a growing risk of breakthrough infection. And health-care records from countries such as Israel, the United Kingdom and elsewhere all show that COVID-19 vaccines are losing their strength, at least when it comes to keeping a lid on transmissible disease.

That's without accounting for the Delta threat either — and it's clear that vaccine–induced antibodies do a worse job at recognizing SARS-CoV-2 variants compared with the ancestral strain of the virus4. What remains unclear, however, is to what degree the immune system's safeguards that protect vaccinated people against severe disease, hospitalization and death might be fading as well."

[184] **Commentary: *Shockingly, CDC Now Lists Vaccinated Deaths as Unvaccinated***
Joseph Mercola
September 16, 2021
https://www.lewrockwell.com/2021/09/joseph-mercola/shockingly-cdc-now-lists-vaccinated-deaths-as-unvaccinated/

"**How CDC Counts Breakthrough Cases**: According to the CDC, you're not counted as fully vaccinated until a full 14 days have passed since your second injection in the case of Pfizer or Moderna, or 14 days after your first dose of Janssen. This is how the CDC defines a vaccine breakthrough case:

'… a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after they have completed all recommended doses of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine.'

In other words, if you've received one dose of Pfizer or Moderna and develop symptomatic COVID-19, get admitted to the hospital and/or die from COVID, you're counted as an unvaccinated case. If you've received two doses and get ill within 14 days, you're still counted as an unvaccinated case…

Different Testing Guidelines for Vaxxed and Unvaxxed: It's not just the CDC's definition of a breakthrough case that skews the data. Even more egregious and illogical is the fact that the CDC even has two different sets of testing guidelines — one for vaccinated patients and another for the unvaccinated.

Since the beginning of the pandemic, the CDC has recommended a PCR test cycle threshold (CT) of 40. This flies in the face of scientific consensus, which has long been that a CT over 35 will produce 97% false positives, essentially rendering the test useless.

In mid-May 2021, the CDC finally lowered its recommended CT count, but only for patients who have received one or more COVID shots. So, if you have received a COVID injection, the CDC's guidelines call for your PCR test to be run at a CT of 28 or less. If you are unvaccinated, your PCR test is to be run at a CT of 40, which grossly overestimates the true prevalence of infection.

The end result is that unvaccinated individuals who get tested are FAR more prone to get false positives, while those who have received the jab are more likely to get an accurate diagnosis of infection."

[185] ***Health Ministry chief says coronavirus spread reaching record heights***
The Times of Israel
Stuart Winer
September 14, 2021
https://www.timesofisrael.com/health-ministry-chief-says-coronavirus-spread-reaching-record-heights/

> "Health Ministry Director-General Nachman Ash said Tuesday that the current wave of coronavirus infections is surpassing anything seen in previous outbreaks and that he is disappointed that a recent downward trend appeared to be reversing.
>
> Ash's remarks via video call to the Knesset Constitution, Law, and Justice Committee came as Health Ministry figures showed that over 10,000 new COVID-19 cases were diagnosed the day before and that the positive test rate was climbing.
>
> Pointing out that there is an average of 8,000 new infections each day, with occasional peaks over 10,000, he said, 'That is a record that did not exist in the previous waves,' including the massive third wave at the end of last year."

[186] ***The COVID-19 Hospitalization Metric in the Pre- and Post-vaccination Eras as a Measure of Pandemic Severity: A Retrospective, Nationwide Cohort Study***
Boston Healthcare System
Nathanael Fillmore, Jennifer La, *et al*.
September 13, 2021
https://assets.researchsquare.com/files/rs-898254/v1/f2800895-4df3-4945-85ae-c1be66aaca23.pdf?c=1631889328

> "**Setting**: Multi-center, nationwide study conducted in the healthcare system of the US Department of Veterans Affairs (VA) from March 1, 2020, through June 30, 2021...
>
> **Exposure**: SARS-CoV-2 vaccination status at the time of hospitalization. Patients were regarded as fully vaccinated starting 14 days after receiving the second of a 2-dose regimen or 14 days after receipt of a single-dose vaccine.
>
> **Results**: … Among 15,196 admissions on or after 1/21/2021 (**unvaccinated, 11,569; vaccinated, 3,627**), 7,908 met the case definition for moderate-to-severe disease (**unvaccinated, 6,362; vaccinated, 1,546**)."

[187] ***Covid-19 Vaccine Mandates Are Now Pointless: Covid-19 vaccines do not keep people from catching the prevailing Delta variant and passing it to others***
Nina Pierpont, MD, PhD
September 9, 2021
https://theexpose.uk/wp-content/uploads/2021/09/Pierpont-Why-mandated-vaccines-are-pointless-final-1.pdf

> "These three different studies in three countries with three different population sampling methods produced the same result: with the current, dominant Delta strain, vaccinated people become infected and carry just as much infectious virus in their upper respiratory tracts when infected as unvaccinated people. The reproducibility of this finding makes it a very strong finding…

Blaming the unvaccinated for the rapid spread of the Delta variant has no merit whatsoever, since both vaccinated and unvaccinated infected people are equally infectious to others, and vaccinated and unvaccinated people are represented in illness samples in proportion to their representation in the general population, showing they are equally likely to become infected."

[188] **ADDED since 10/14/2021**
Hospitalisation among vaccine breakthrough COVID-19 infections
Infectious Diseases – The Lancet (Yale School of Medicine)
Prerak V. Juthani, Akash Gupta, *et al*.
September 7, 2021
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00558-2/fulltext

"We did a systematic review of patients admitted to hospital with SARS-CoV-2 (confirmed by a positive PCR test at the time of admission) between March 23 and July 1, 2021… Patients were considered fully vaccinated if the final dose (either second dose of BNT162b2 or mRNA-1273, or first dose of Ad.26.COV2.S) was administered at least 14 days before symptom onset or a positive PCR test for SARS-CoV-2…

Patients deemed to have a breakthrough SARS-CoV-2 infection—ie, the 54 patients who were fully vaccinated—were evaluated for illness severity. Among this cohort, we found that 25 (46%) patients were asymptomatic (admitted to hospital for a non-COVID-19-related diagnosis but with an incidental positive PCR test for SARS-CoV-2), four (7%) had mild disease, 11 (20%) had moderate disease, and 14 (26%) had severe or critical illness."

[189] **ADDED since 10/14/2021**
The Oxford/AstraZeneca COVID-19 vaccine: what you need to know
World Health Organization
September 2, 2021
https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know

"**How efficacious is the vaccine?** The AZD1222 vaccine against COVID-19 has an efficacy of 63.09% against symptomatic SARS-CoV-2 infection."

[190] ***Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel***
Israel Ministry of Health
Yair Goldberg, Micha Mandel, *et al*.
August 30, 2021
https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1.full-text

"**Background**: Starting December 2020, Israel began a mass vaccination campaign against coronavirus administering the Pfizer BNT162b2 vaccine, which led to a sharp curtailing of the outbreak. After a period with almost no SARS-CoV-2 infections, a resurgent COVID-19 outbreak initiated mid June 2021. Possible reasons for the breakthrough were reduced vaccine effectiveness against the Delta variant, and waning immunity. The aim of this study was to quantify the extent of waning immunity using Israel's national-database…

Results: The rates of both documented SARS-CoV-2 infections and severe COVID-19 exhibit a statistically significant increase as time from second vaccine dose elapsed. Elderly individuals (60+) who received their second dose in March 2021 were 1.6 (CI: [1.3, 2]) times more

protected against infection and 1.7 (CI: [1.0, 2.7]) times more protected against severe COVID-19 compared to those who received their second dose in January 2021. Similar results were found for different age groups.

Conclusions: These results indicate a strong effect of waning immunity in all age groups after six months [*emphasis added*]."

[191] **ADDED since 10/14/2021**
Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK
University of Oxford
August 2021
https://www.ndm.ox.ac.uk/files/coronavirus/covid-19-infection-survey/finalfinalcombinedve20210816.pdf

"**Abstract**: … With Delta, infections occurring following two vaccinations had similar peak viral burden to those in unvaccinated individuals."

[192] ***'Majority' of those dying have had both jabs***
The Scottish Mail
Gareth Rose
August 29, 2021
https://www.pressreader.com/uk/the-scottish-mail-on-sunday/20210829/282183654147043

"The vast majority of Scots now dying from Covid are fully vaccinated, figures show. Three quarters of those who died in the most recent week for which data was available had received both doses…

Public Health Scotland does not directly publish weekly figures of vaccinated and unvaccinated deaths. But this paper has calculated in the month up to August 12, 144 out of 236 deaths were of people with both doses, compared with 80 unvaccinated, and 12 with just one dose."

[193] ***Significant proportions of people admitted to hospital, or dying from covid-19 in England are vaccinated—this doesn't mean the vaccines don't work***
British Medical Journal
Kit Yates
August 25, 2021
https://blogs.bmj.com/bmj/2021/08/25/significant-proportions-of-people-admitted-to-hospital-or-dying-from-covid-19-in-england-are-vaccinated-this-doesnt-mean-the-vaccines-dont-work/

"More vaccinated people are dying of the delta variant of covid than unvaccinated people, according to a recent report from Public Health England. The report shows that 489 of 742 people (65.9%) who died of the delta variant within 28 days of a positive covid test between 1 February 2021 and 2 August 2021, had received at least one dose of the vaccine. 54.1% (402 of 742) had received both doses."

[194] ***Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant***
University of Wisconsin-Madison
Kasen K. Riemersma, Brittany E. Grogan, *et al*.
August 24, 2021
https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v1.full.pdf

> "**Abstract**: … Understanding how and why the virus is spreading in settings where there is high vaccine coverage has important public health implications. It is particularly important to assess whether vaccinated individuals who become infected can transmit SARS-CoV-2 to others… We find **no difference in viral loads** when comparing unvaccinated individuals to those who have vaccine 'breakthrough' infections [*emphasis added*]. Furthermore, individuals with vaccine breakthrough infections frequently test positive with viral loads consistent with the ability to shed infectious viruses…"

[195] ***Does the FDA think these data justify the first full approval of a covid-19 vaccine?***
British Medical Journal
Peter Doshi
August 23, 2021
https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/

> "[T]he recent reports from Israel's Ministry of Health caught my eye. In early July, they reported that efficacy [*of the Pfizer product*] against infection and symptomatic disease 'fell to 64%.' By late July, **it had fallen to 39%** where Delta is the dominant strain. This is very low. For context, the FDA's expectation is of 'at least 50%' efficacy for any approvable vaccine [*emphasis added*].
>
> Now Israel, which almost exclusively used Pfizer vaccine, has begun administering a third "booster" dose to all adults over 40. And starting 20 September 2021, the US plans to follow suit for all 'fully vaccinated' adults eight months past their second dose…
>
> Enter Pfizer's preprint. As an RCT reporting 'up to six months of follow-up,' it is notable that evidence of waning immunity was already visible in the data by the 13 March 2021 data cut-off."

[196] ***Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence***
nference and Mayo Clinic
Arjun Puranik, Patrick J. Lenehan, *et al*.
August 21, 2021
https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v3.full-text

> "In July, vaccine effectiveness against hospitalization has remained high (mRNA-1273: 81%, 95% CI: 33-96.3%; BNT162b2: 75%, 95% CI: 24-93.9%), but effectiveness against infection was lower for both vaccines (mRNA-1273: **76%**, 95% CI: 58-87%; BNT162b2: **42%**, 95% CI: 13-62%) [*emphasis added*], with a more pronounced reduction for BNT162b2."

[197] ***Chris Whitty warns of 'very sick' Covid patients as he urges people to get a jab***
Evening Standard
Aine Fox
August 20, 2021
https://www.standard.co.uk/news/uk/england-delta-donald-trump-government-public-health-england-b951620.html

> According to Public Health England, as of August 15, 2021: "Of the 113 deaths of people under 50, 72 (64%) were unvaccinated, 11 (10%) had received one jab and 27 (24%) had received both. Of the 3,173 people aged 50 or over admitted to hospital in England up to the middle of this month who were either confirmed or likely to have had the Delta variant, 989 (31%) were not jabbed. A total of 318 (10%) had received one dose of vaccine and **1,838 (58%) had received two** [*emphasis added*]."

[198] ***Significant reduction in humoral immunity among healthcare workers and nursing home residents 6 months after COVID-19 BNT162b2 mRNA vaccination***
Case Western Reserve School of Medicine
David H. Canaday, Oladayo A. Oyebanji, *et al*.
August 20, 2021
https://www.medrxiv.org/content/10.1101/2021.08.15.21262067v3.full-text

> "**Abstract**: High COVID-19 mortality among nursing home (NH) residents led to their prioritization for SARS-CoV-2 vaccination; most NH residents received BNT162b2 mRNA vaccination under the Emergency Use Authorization due to first to market and its availability. With NH residents' poor initial vaccine response, the rise of NH breakthrough infections and outbreaks, characterization of the durability of immunity to inform public health policy on the need for boosting is needed. We report on humoral immunity from 2 weeks to 6-months post-vaccination in 120 NH residents and 92 ambulatory healthcare worker controls with and without pre-vaccination SARS-CoV-2 infection. Anti-spike and anti-receptor binding domain (RBD) IgG, and serum neutralization titers, were assessed using a bead-based ELISA method and pseudovirus neutralization assay. **Anti-spike, anti-RBD and neutralization levels dropped more than 84% over 6 months' time in all groups** irrespective of prior SARS-CoV-2 infection [*emphasis added*]."

[199] ***The CDC Only Tracks a Fraction of Breakthrough COVID-19 Infections, Even as Cases Surge***
ProPublica
Jenny Deam and Bianca Fortis
August 20, 2021
https://www.propublica.org/article/the-cdc-only-tracks-a-fraction-of-breakthrough-covid-19-infections-even-as-cases-surge

> "A May 1 decision by the CDC to **only track breakthrough infections that lead to hospitalization or death** has left the nation with a muddled understanding of COVID-19's impact on the vaccinated [*emphasis added*] …
>
> Today there remains no full understanding on how the aggressively contagious delta variant spreads among the nearly 200 million partially or fully vaccinated Americans like Ingram, or on how many are getting sick.
>
> The nation is flying blind yet again, critics say, because on May 1 of this year — as the new

variant found a foothold in the U.S. — the Centers for Disease Control and Prevention mostly stopped tracking COVID-19 in vaccinated people, also known as breakthrough cases, unless the illness was severe enough to cause hospitalization or death."

[200] **ADDED since 10/14/2021**
COVID vaccines protect against Delta, but their effectiveness wanes
Nature
Katharine Sanderson
August 19, 2021
https://www.nature.com/articles/d41586-021-02261-8

"Researchers at the University of Oxford, UK, and the country's Office for National Statistics analysed a vast data set comprising the results of 2,580,021 PCR tests…

The vaccine developed by Oxford and the pharmaceutical company AstraZeneca in Cambridge, UK, was 69% effective against a high viral load 14 days after the second dose, falling to 61% by 90 days."

[201] ***Covid-19: Fully vaccinated people can carry as much delta virus as unvaccinated people, data indicate***
British Medical Journal
Shaun Griffin
August 19, 2021
https://www.bmj.com/content/374/bmj.n2074

"Adults who have been fully vaccinated against SARS-CoV-2 can carry the same viral load of the delta variant as those who are unvaccinated, a preliminary analysis of UK data suggests."

[202] ***Over 12,000 breakthrough COVID-19 cases reported in Massachusetts as of August 14***
WWLP News
Colin A. Young
August 17, 2021
https://www.wwlp.com/news/massachusetts/over-12000-breakthrough-covid-19-cases-reported-in-massachusetts-as-of-august-14/

"In the week from Aug. 7 to Aug. 14, DPH counted 2,672 new breakthrough infections, about a 20 percent increase over the 2,232 breakthrough infections reported the previous week… The 2,672 newly-reported breakthrough cases represent nearly 40 percent of the state's recent one-week total of new cases… (The Massachusetts Department of Public Health) cautioned Tuesday that there are probably more breakthrough infections and hospitalizations among fully vaccinated people than it counts and can report."

[203] ***A grim warning from Israel: Vaccination blunts, but does not defeat Delta***
Science magazine
Meredith Wadman
August 16, 2021
https://www.science.org/news/2021/08/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

"What is clear is that 'breakthrough' cases are not the rare events the term implies. As of 15 August, 514 Israelis were hospitalized with severe or critical COVID-19, a 31% increase from just 4 days earlier. Of the 514, 59% were fully vaccinated. Of the vaccinated, 87% were 60 or older. 'There are so many breakthrough infections that they dominate and most of the hospitalized patients are actually vaccinated,' says Uri Shalit, a bioinformatician at the Israel Institute of Technology (Technion) who has consulted on COVID-19 for the government…

Yet boosters are unlikely to tame a Delta surge on their own, says Dvir Aran, a biomedical data scientist at Technion. In Israel, the current surge is so steep that 'even if you get two-thirds of those 60-plus [boosted], it's just gonna give us another week, maybe 2 weeks until our hospitals are flooded.'"

[204] ***COVID cabinet approves new restrictions as cases soar***
Jerusalem Post
Maayan Jaffe-Hoffman
August 12, 2021
https://www.jpost.com/israel-news/israel-hits-400-serious-covid-cases-ahead-of-corona-cabinet-meeting-676412

"On Wednesday morning, the Health Ministry reported 694 people were being treated in Israeli hospitals for the virus, among them 400 in serious condition, with **64% of those patients defined as serious cases being fully vaccinated**, compared with 32% who were not [*emphasis added*]."

[205] ***SARS-CoV-2 variants of concern and variants under investigation in England***
Public Health England
August 6, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1009243/Technical_Briefing_20.pdf

From p. 18 (Table 5. Attendance to emergency care and deaths of confirmed and provisional Delta cases in England by vaccination status):

- Total number of unvaccinated cases: 151,054
- Total number of unvaccinated fatalities: 253 (205 + 48)
- Total number of double-vaccinated cases (i.e., people having received 2 CV shots): 47,008
- Total number of double-vaccinated fatalities: 402

Note: Based on these figures, the Case Fatality Rates for this sample population would appear to be as follows (please do your own math):

CFR for unvaccinated cases: 0.167% ([253/151,054] * 100), or 1 in 599

CFR for double-vaccinated cases: 0.855% ([402/47,008] * 100), or 1 in 117

[206] ***Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021***
Morbidity and Mortality Weekly Report
Catherine M. Brown, Johanna Vostok, *et al*.
August 6, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf

> "**What is added by this report?** In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; **346 (74%) occurred in fully vaccinated persons** [*emphasis added*]. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not."

[207] ***Israel's Public Health Chief Says Evidence Points to Waning COVID Vaccine Immunity***
Haaretz
Ben Samuels
August 1, 2021
https://www.haaretz.com/israel-news/coronavirus-delta-variant-is-50-percent-more-infectious-israeli-top-official-says-1.10068650

> "Dr. Sharon Alroy-Preis, Israel's director of public health services, said Sunday that evidence points to the waning immunity in the COVID-19 vaccine... She added that 50 percent of the current infections are vaccinated individuals. 'Previously we thought that fully vaccinated individuals are protected, but we now see that vaccine effectiveness is roughly 40 percent.'"

[208] ***Correlation of SARS-CoV-2 Breakthrough Infections to Time-from-vaccine; Preliminary Study***
KI Research Institute, KSM Research and Innovation Center (Israel)
Barak Mizrahi, Roni Lotan, *et al*.
July 31, 2021
https://www.medrxiv.org/content/10.1101/2021.07.29.21261317v1.full-text

> "**Abstract**: … Leveraging the centralized computerized database of Maccabi Healthcare Services (MHS), we assessed the correlation between time-from-vaccine and incidence of breakthrough infection. We found that the risk for infection was significantly higher for early vaccinees compared to those vaccinated later…
>
> **Main**: Individuals who were vaccinated in January 2021 had a 2.26-fold increased risk (CI 1.80-3.01) for breakthrough infection compared to individuals who were vaccinated in April 2021 (Figure 1).
>
> In this cohort of MHS members, all of whom are vaccinated with the BioNTech/Pfizer mRNA BNT162b2 vaccine in a two-dose regimen, we identified a significant correlation between time-from-vaccine and afforded protection against SARS-CoV-2 infection. The risk for breakthrough infection was significantly higher for early vaccinees compared to those vaccinated later."

[209] ***CDC Scaled Back Hunt for Breakthrough Cases Just as the Delta Variant Grew***
Bloomberg
Drew Armstrong, Rebecca Torrence, and Fiona Rutherford
July 30, 2021
https://www.bloomberg.com/news/articles/2021-07-30/cdc-scaled-back-hunt-for-breakthrough-cases-just-as-the-delta-variant-grew

> "While the Centers for Disease Control and Prevention stopped comprehensively tracking what are known as vaccine breakthrough cases in May, the consequences of that choice are only now beginning to show.
>
> At the time, the agency had identified only 10,262 cases across the U.S. where a fully vaccinated person had tested positive for Covid. But in the months since, the number of vaccine breakthrough cases has grown, as has the risk that they present. And while the CDC has stopped tracking such cases, many states have not. Bloomberg gathered data from 35 states and identified **111,748 vaccine breakthrough cases** through the end of July [*emphasis added*], more than 10 times the CDC's end-of-April tally."

[210] ***Improving communications around vaccine breakthrough and vaccine effectiveness***
Centers for Disease Control and Prevention (CDC)
July 29, 2021
https://context-cdn.washingtonpost.com/notes/prod/default/documents/54f57708-a529-4a33-9a44-b66d719070d9/note/753667d6-8c61-495f-b669-5308f2827155.#page=1

> Slide 3: "At current incidence, **35,000 symptomatic infections per week** among 162 million vaccinated Americans [*emphasis added*]."
>
> Slide 22: "Breakthrough infections may be as transmissible as unvaccinated cases"

[211] ***UK scientists back Covid boosters as study finds post-jab falls in antibodies***
The Guardian
Ian Sample
July 22, 2021
https://www.theguardian.com/world/2021/jul/22/uk-scientists-back-covid-boosters-as-study-finds-post-jab-falls-in-antibodies

> "The UCL Virus Watch study found that antibodies generated by two doses of the Oxford/AstraZeneca and Pfizer/BioNTech vaccines started to wane as early as six weeks after the second shot, in some cases falling more than 50% over 10 weeks."

[212] **Correspondence:** ***Spike-antibody waning after second dose of BNT162b2 or ChAdOx1***
The Lancet
Madhumita Shrotri, Annalan M D Navaratnam, *et al*.
July 15, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01642-1/fulltext

> "A significant trend of declining S-antibody levels was seen with time for both ChAdOx1 ($p<0{\cdot}001$) and BNT162b2 ($p<0{\cdot}001$; figure; appendix), with levels reducing by about five-fold for ChAdOx1, and by about two-fold for BNT162b2, between 21–41 days and 70 days or more after the second dose. This trend remained consistent when results were stratified by sex, age, and clinical vulnerability (appendix). For BNT162b2, S-antibody levels reduced from a median

of 7506 U/mL (IQR 4925–11 950) at 21–41 days, to 3320 U/mL (1566–4433) at 70 or more days. For ChAdOx1, S-antibody levels reduced from a median of 1201 U/mL (IQR 609–1865) at 0–20 days to 190 U/mL (67–644) at 70 or more days…

Our data suggest waning of S-antibody levels in infection-naive individuals over a 3–10-week period after a second dose of either ChAdOx1 or BNT162b2… "

[213] ***Natural infection vs vaccination: Which gives more protection?***
Arutz Sheva
David Rosenberg
July 13, 2021
https://www.israelnationalnews.com/News/News.aspx/309762

"Nearly 40% of new COVID patients were vaccinated - compared to just 1% who had been infected previously.

Coronavirus patients who recovered from the virus were far less likely to become infected during the latest wave of the pandemic than people who were vaccinated against COVID, according to numbers presented to the Israeli Health Ministry…

Health Ministry data on the wave of COVID outbreaks which began this May show that Israelis with immunity from natural infection were far less likely to become infected again in comparison to Israelis who only had immunity via vaccination…

With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with COVID. By contrast, Israelis who were vaccinated were **6.72 times more likely to get infected after the shot than after natural infection** [*emphasis added*]."

[214] **ADDED since 10/14/2021**
An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021
Eurosurveillance
Iivo Hetemäki, Sohvi Kääriäinen, *et al*.
July 2021
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.30.2100636

"We describe here an outbreak caused by the Delta variant that originated from one inpatient in a secondary care hospital and spread within the hospital and to three primary care facilities; we describe our experiences in controlling it. Cases were detected among patients, healthcare workers (HCW) and in the community. Both symptomatic and asymptomatic infections were found among vaccinated HCW, and secondary transmission occurred from those with symptomatic infections despite use of personal protective equipment (PPE)…

In conclusion, this outbreak demonstrated that, **despite full vaccination and universal masking of HCW**, breakthrough infections by the Delta variant via symptomatic and asymptomatic HCW occurred [*emphasis added*], causing nosocomical infections. As the Delta variant continues to spread in Europe, we suggest that utilization of FFP2/3 respirators while treating COVID-19 patients should be included in national guidelines."

[215] ***Hospital manager: "Over 90% of our patients are vaccinated, the vaccine wears off in front***

of our eyes"
Maariv
July 2021
https://www.maariv.co.il/corona/corona-israel/Article-855728

> "The director of Herzog Hospital in Jerusalem, Dr. Kobi Habib, spoke today (Tuesday) with Anat Davidov on her program… 'Most of our patients are adults over the age of 70, but not only, over 90% of them are vaccinated.' He added, 'There is less good news, which is that the vaccine is quite dissipating in front of our eyes and it becomes less and less effective over time.'"

[216] ***COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021***
Centers for Disease Control and Prevention
May 25, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7021e3-H.pdf

> "A total of **10,262 SARS-CoV-2 vaccine breakthrough infections** had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, **995 (10%) patients were known to be hospitalized**, and **160 (2%) patients died** [*emphasis added*]."

[217] ***Israeli data shows South African variant able to 'break through' Pfizer vaccine***
The Times of Israel
Nathan Jeffay
April 10, 2021
https://www.timesofisrael.com/real-world-israeli-data-shows-south-african-variant-better-at-bypassing-vaccine/

> "The South African variant of the coronavirus is notably more adept at 'breaking through' the Pfizer-BioNTech vaccine than other variants are, Israeli scientists have found, in a first-of-its-kind real-world study… A team from Tel Aviv University and the Clalit healthcare organization sequenced the swabs of 150 Israelis who tested positive for COVID-19 despite having been vaccinated. In their study, the prevalence of the South African strain among vaccinated individuals who were infected despite their inoculation was eight times higher than its prevalence in the unvaccinated infected population."

[218] **ADDED since 10/14/2021**
BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting
New England Journal of Medicine
Noa Dagan, Noam Barda, *et al*.
February 24, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2101765

> "**Background**: … In this study, data from Israel's largest health care organization were used to evaluate the effectiveness of the BNT162b2 mRNA vaccine…
>
> **Results**: Each study group included 596,618 persons. Estimated vaccine effectiveness for the

study outcomes at days 14 through 20 after the first dose and at 7 or more days after the second dose was as follows: for documented infection, 46%..."

VAERS and other Adverse-Event Reporting Systems

About VAERS

[219] ***About VAERS (Vaccine Adverse Event Reporting System)***
Department of Health and Human Services (HHS)
https://vaers.hhs.gov/about.html

> "Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA)."

[220] ***Report an Adverse Event to VAERS***
Department of Health and Human Services (HHS)
https://vaers.hhs.gov/reportevent.html

> "Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) **punishable by fine and imprisonment** [*emphasis added*]."

[221] **18 U.S. Code § 1001 - Statements or entries generally**
https://www.law.cornell.edu/uscode/text/18/1001

> "(a)Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—
>
> (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
>
> (2) makes any materially false, fictitious, or fraudulent statement or representation; or
>
> (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;
> shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both. If the matter relates to an offense under chapter 109A, 109B, 110, or 117, or section 1591, then the term of imprisonment imposed under this section shall be not more than 8 years."

VAERS and the Underreporting of Adverse Events

[222] ***Guide to Interpreting VAERS Data***
Department of Health and Human Services (HHS)
https://vaers.hhs.gov/data/dataguide.html

> "VAERS is a passive reporting system, meaning that reports about adverse events are not automatically collected, but require a report to be filed to VAERS… 'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to **the fact that VAERS receives reports for only a small fraction of actual adverse events** [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[223] **Video and transcript: Interview with Eileen Iorio, Stan Gotshall, and Wayne Rhode**
Children's Health Defense
August 17, 2021
Provides an overview of some of the known problems with the VAERS system, including indications of under-reporting of adverse events, such as the 'Lazarus Report' by Harvard Pilgrim Health Care.
https://childrenshealthdefense.org/transcripts/the-defender-show-vaccine-safety-advocate-tells-rfk-jr-vaers-protects-vaccine-makers-not-kids/

[224] ***Electronic Support for Public Health–Vaccine Adverse vent Reporting System (ESP:VAERS)***
Harvard Pilgrim Health Care, Inc.
Ross Lazarus
September 30, 2010
https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

> "**Scope**: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs…
>
> **Results**: … Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, **fewer than 1% of vaccine adverse events are reported**. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed [*emphasis added*]. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.
>
> Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the **CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation** [*emphasis added*]."

[225] ***The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices***
Committee on Government Reform (US)
October 12, 2000
https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

"**Childhood Vaccine Studies**: The Act called for the Institute of Medicine [IOM] to review existing studies and medical literature and provide a foundation for recommendations on vaccine injury causation. In reports issued in 1991 and 1994, IOM published several conclusions regarding the scarcity of knowledge about vaccine safety, citing severe limits in data and research capability. Of the 76 adverse events IOM reviewed for a causal relationship, 50 (66 percent) had no or inadequate research.

Specifically, IOM Committees identified the following limitations of existing knowledge: 1) Inadequate understanding of biologic mechanisms underlying adverse events; 2) Insufficient or inconsistent information from case reports and case series; 3) Inadequate size or length of follow-up of many population-based epidemiological studies; 4) Limitations of existing surveillance systems to provide persuasive evidence of causation, and 5) Few published epidemiological studies.

IOM warned that 'if research capacity and accomplishments [are] not improved, future reviews of vaccine safety [will be] similarly handicapped.' IOM recommends: 'More research could be done on potential long-term adverse effects from vaccines as well as the potential of vaccines to induce or worsen immune disorders.' CDC agrees that there remains 'uncertainty about estimates of the risk associated with vaccination' and that to 'continue research to improve the understanding of vaccine risks is critical.'…

Vaccine Adverse Events Reporting System: … While the Vaccine Adverse Events Reporting System [VAERS] may be lauded as the "front line" of vaccine safety, the lack of enforcement provisions and effective monitoring of reporting practices preclude accurate assessments of the extent to which adverse events are actually reported. Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only **a fraction of the serious adverse events** [*emphasis added*].

The quality of VAERS data has been questioned. Because reports are submitted from a variety of sources, some inexperienced in completing data forms for medical studies, many reports omit important data and contain obvious errors. Assessment is further complicated by the administration of multiple vaccines at the same time, following currently recommended vaccine schedules, because there may be no conclusive way to determine which vaccine or combination of vaccines caused the specific adverse event."

VAERS and COVID-19 Inoculations

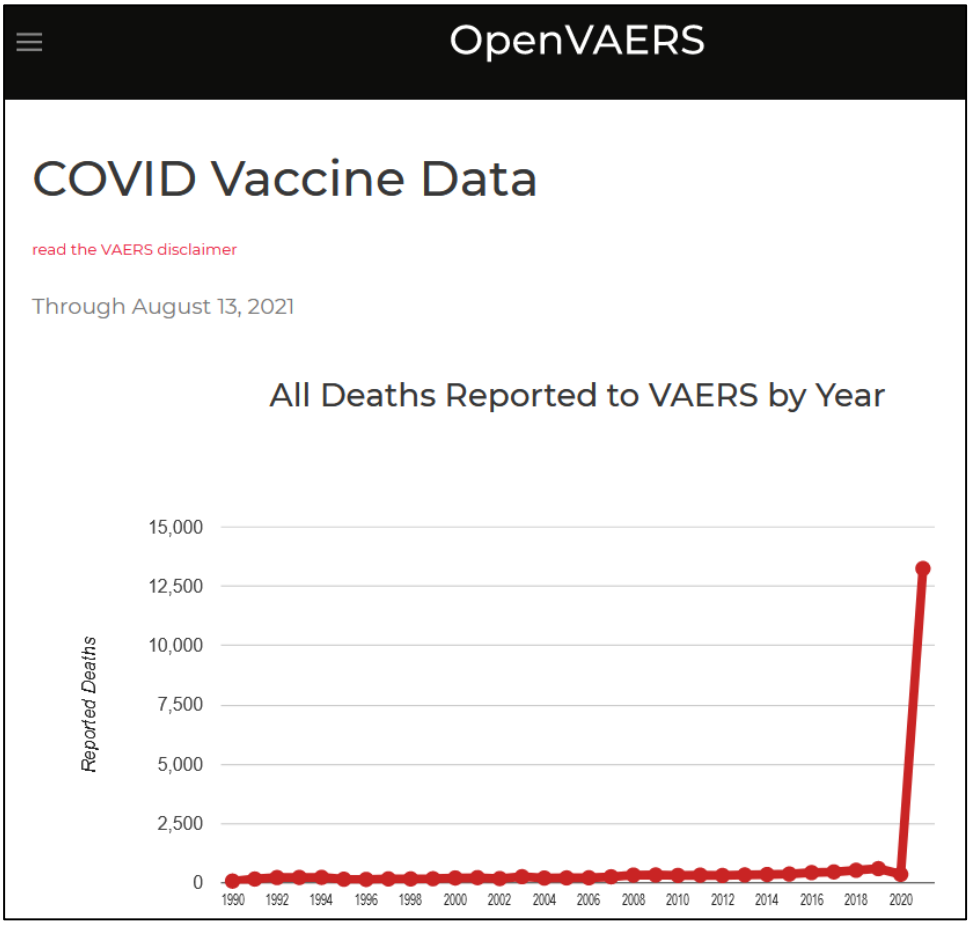
[226] **#OpenVAERS**
https://www.openvaers.com/

"VAERS is the Vaccine Adverse Event Reporting System put in place in 1990. It is a voluntary reporting system that has been estimated to account for only 1% (see the Lazarus Report) of vaccine injuries. OpenVAERS is built from the HHS data available for download at vaers.hhs.gov. The OpenVAERS Project allows browsing and searching of the reports without the need to compose an advanced search (more advanced searches can be done at medalerts.org or vaers.hhs.gov)."

Through October 1, 2021:

- 16,310 Post-COVID Vaccine Reported Deaths / 25,347 Total VAERS Reported Deaths
- 75,605 Post-COVID Vaccine Reported Hospitalizations / 153,579 Total VAERS Reported Hospitalizations
- 778,683 COVID Vaccine Adverse Event Reports

[227] ***All Deaths Reported to VAERS by Year***
OpenVAERS
https://www.openvaers.com/covid-data/mortality



[228] ***Urgent Open Letter to the EMA, MHRA, FDA, and CDC***
Doctors for COVID Ethics
July 21, 2021
https://www.globalresearch.ca/jaccuse-governments-worldwide-are-lying-to-you-the-people-to-the-populations-they-purportedly-serve/5750650
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

> "1. Official sources, namely EudraVigilance (EU, EEA, Switzerland), MHRA (UK) and VAERS (USA), have now recorded **more Injuries and Deaths from the 'Covid' vaccine roll-out than from all previous vaccines combined** since records began [*emphasis added*]…
>
> 2. The Signal of Harm is now indisputably overwhelming, and, in line with universally accepted ethical standards for clinical trials, Doctors for Covid Ethics demands that the 'Covid' vaccine programme be halted immediately."

[229] ***The epidemiology of fatalities reported to the Vaccine Adverse Event Reporting System 1990–1997***
Pharmacoepidemiology & Drug Safety
Linda E. Silvers, Susan S. Ellenberg, *et al*.
October 25, 2001
https://pubmed.ncbi.nlm.nih.gov/11760487/

> "**Results**: A total of 1266 fatalities were reported to VAERS during July 1990 through June 1997."

[230] ***Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997–2013***
Clinical Infectious Diseases
Pedro L. Moro, Jorge Arana, *et al*.
May 28, 2015
https://academic.oup.com/cid/article/61/6/980/451431

> From 'Table 1. Death Reports in the Vaccine Adverse Event Reporting System Among Persons Vaccinated 1 July 1997–31 December 2013':
>
> **Total reports**: 2149

Note: The citations below are presented in reverse, chronological order.

[231] **ADDED since 10/14/2021**
New VAERS analysis reveals hundreds of serious adverse events that the CDC and FDA never told us about
Steve Kirsch and Albert Benavides
November 9, 2021
https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds
Team of Vaccine Safety Experts: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

> "In a brand new VAERS data analysis …, we found hundreds of serious adverse events that were completely missed by the CDC that should have been mentioned in the informed consent document that are given to patients. And we found over 200 symptoms that occur at a higher relative rate than myocarditis (relative to all previous vaccines over the last 5 years). All together,

there were over 4,000 VAERS adverse event codes that were elevated by these vaccines by a factor of 10 or more over baseline that the CDC should have warned people about…

Here's what the evidence shows:

1. The COVID vaccines are the most dangerous vaccines in human history. They are 800 times more deadly than the smallpox vaccine which was the previous record holder. The vaccines have killed over 150,000 Americans and permanently disabled even more…

5. The serious events we highlight below are all consistent with the mechanism of action that Robert Malone and I first described in the Darkhorse podcast. Namely, that **the spike protein** that is produced in response to the delivery of the mRNA **is cytotoxic and results in blood clots, inflammation and scarring throughout your body** [emphasis added] which then **creates a wider range of severe adverse events than any vaccine in human history**…

9. The serious events are primarily centered around menstruation, blood clots, inflammation and scarring, cardiovascular damage, and neurological damage, just as we predicted in the podcast in June of 2021.

10. There are hundreds of serious adverse events that are caused by these vaccines. This of course is shocking to people since the CDC has repeatedly said you can't ascribe causality to data in VAERS. Not true. The VAERS data analysis (temporal data, the dose dependency, and the elevated reporting rates compared to baseline) provide ample signal to enable us to show causality on all of these events using the five Bradford-Hill criteria applicable to vaccines…

13. It is unlikely that anyone in the world will want to debate us publicly on any of the claims above (or on any of my articles or on any of Mathew's articles), but if you are a prominent supporter of the false narrative and want a public debate, we are here for you. Our team would be thrilled to accept the challenge as we have no desire to spread misinformation. If we got it wrong, we are happy to correct our mistakes if you can explain to us clearly the mistake we made and the correction you suggest (e.g., the "right" answer). Yet even with multiple million dollar incentives (listed in this article), nobody seems to be interested in showing how we got it wrong. Everyone talks about how bad the vaccine misinformation problem is, but nobody is willing to do anything to show that we got it wrong…

What we found in the VAERS analysis below can be verified by anyone because it is all publicly accessible…

You can easily verify any entry yourself via manual queries to any VAERS interface (my favorite is MedAlerts, but others such as openvaers and the HHS site give the same results)."

[232] **ADDED since 10/14/2021**
Estimating the number of COVID vaccine deaths in America
Jessica Rose and Mathew Crawford
September 2021
https://downloads.regulations.gov/CDC-2021-0089-0024/attachment_1.pdf
Updated November 1, 2021: https://www.skirsch.com/covid/Deaths.pdf

"**Summary**: Using the VAERS database and independent rates of anaphylaxis events from a Mass General study, we computed a **41X under-reporting factor for serious adverse events** in VAERS, leading to an **estimate of over 150,000 excess deaths caused by the vaccine** [*emphasis added*].

The estimates were validated multiple independent ways.

There is no evidence that these vaccines save more lives than they cost. Pfizer's own study showed that adverse events consistent with the vaccine were greater than the lives saved by the vaccine to yield a net negative benefit. Without an overall statistically significant all-cause mortality benefit, and evidence of an optional medical intervention that has likely killed over 150,000 Americans so far, vaccination mandates are not justifiable and should be opposed by all members of the medical community.

Early treatments using a cocktail of repurposed drugs with proven safety profiles are a safer, more effective alternative which always improves all-cause mortality in the event of infection and there are also safe, simple, and effective protocols for prophylaxis."

[233] ***Safety Signals for COVID Vaccines Are Loud and Clear. Why Is Nobody Listening?***
Children's Health Defense
Josh Guetzkow
September 29, 2021
https://childrenshealthdefense.org/defender/safety-signals-covid-vaccines-full-transparency-cdc-fda/

"On Aug. 30, the CDC Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer/BioNTech's mRNA COVID-19 vaccine for people 16 years and older.

In comments I submitted to the committee along with my collaborators, we provided evidence of large safety signals from VAERS, using published CDC methods to analyze the data.

In this article, I describe the safety signals highlighted in our comments, which raise pressing questions about the CDC's and FDA's COVID vaccine safety monitoring efforts.

To begin with, there has been an unprecedented increase in the number of adverse event reports to VAERS associated with COVID-19 vaccines…

It is hard to imagine how anyone can look at these numbers and not be at least a little bit concerned. Yet many people are dismissive, saying the unprecedented number of reports is due to the unprecedented number of vaccinations being administered.

I crunched the numbers, and even after taking into account the total number of vaccinations, the number of reports for COVID vaccines still towers over previous years…

For each adverse event type, the table [] shows the COVID-to-flu ratio, which simply shows how many more events were reported per million doses of COVID-19 vaccines compared to the number per million doses of seasonal influenza vaccines…

Table 1 (below) shows a comparison of VAERS reports for COVID-19 vaccines versus flu vaccines per million doses administered for a range of different event types and age groups.

For each adverse event type, the table shows the COVID-to-flu ratio, which simply shows how many more events were reported per million doses of COVID-19 vaccines compared to the number per million doses of seasonal influenza vaccines..

The first thing to notice is that for every type of adverse event for every age group, there were more reports per million doses of COVID-19 vaccines than for flu vaccines. If you look at the bottom row for all age groups (12 and older), you see that for every million vaccine doses administered, there were **19 times more reports to VAERS for COVID-19 vaccines than for flu vaccines, 28 times more serious events, 91 times more deaths**, 3 times more reports of Guillain-Barré syndrome (GBS), 276 times more reports of coagulopathy; 126 times as many reports of myocardial infarction; and 136 times more reports of myopericarditis [*emphasis added*]."

Ages	All Reports	Serious Reports	Death	GBS	Coagulopathy	Myocardial Infarction	Myo-pericarditis
12-17	25	34	32	7	74	n.e.	1251
18-49	26	25	64	3	226	403	81
50-64	18	26	85	3	239	121	22
65+	11	30	98	3	370	88	10
Overall	19	28	91	3	276	126	136

Notes: The COVID-to-Flu ratio is the ratio of the COVID-19 reporting rate to the flu reporting rate per million vaccine doses. All differences between COVID-19 and flu reporting rates are statistically significant. Myocardial infarctions for 12-17 year-olds is non-estimable (n.e.) because there were no reports of M.I. for flu vaccines in that age group. GBS is Guillan-Barré Syndrome. Flu reporting rates represent the total reports to VAERS across the 2015/16 to 2019/20 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group from Dec. 15, 2020 through Aug. 6, 2021. Vaccine doses estimated using data from the CDC and the US Census Bureau. COVID-19 vaccination totals are from Aug. 5, 2021. All reports with SARS-CoV-2 infection or COVID-19 were excluded from counts. Only reports that originated from U.S. states and D.C. were included.

[234] **Virtual meeting (video): *Vaccines and Related Biological Products Advisory Committee*, *remarks by Dr. Jessica Rose***
Food and Drug Administration (FDA)
September 17, 2021
https://youtu.be/WFph7-6t34M?t=14985

Rose (starting at 4:09:45): "My name is Dr. Jessica Rose, and I'm a viral immunologist and computational biologist. I've taken it upon myself to become a VAERS analyst to organize the data into comprehensive figures to convey information to the public, in both published works and video mediums…

There's an **over 1,000% increase in the total number of adverse events** for 2021, and we are not done with 2021 [*emphasis added*]. This is highly anomalous on both fronts [*events and deaths*]. These increased reporting rates are not due to increased rates in injections and not due to simulated reporting…

The onus is on the public-health officials – the FDA, the CDC and policymakers – to answer for these anomalies and acknowledge the clear risk signals emerging from VAERS data, and to confront the issue of COVID-injectable products' use risk that, in my opinion, outweigh any potential benefit associated with these products, especially for children."

[235] **Civil Action: *Whistleblower 'Jane Doe' Declaration***
July 13, 2021
https://renzlaw.godaddysites.com/45k-whistleblower-suit

> "I am a computer programmer with subject matter expertise in the healthcare data analytics field, an honor that allows me access to Medicare and Medicaid data maintained by the Centers for Medicare and Medicaid Services (CMS). I earned a B.S. degree in Mathematics and have, over the last 25 years, developed over 100 distinct healthcare fraud detection algorithms, both in the public and private sector. It has been my mission to protect federal tax dollars by preventing and detecting healthcare fraud, a process which leads to both recovery of overpayments and law enforcement leads… When the COVID-19 vaccine clearly became associated with patient death and harm, I was naturally inclined to investigate the matter.
>
> **It is my professional estimate that VAERS** (the Vaccine Adverse Event Reporting System) database, while extremely useful, **is under-reported by a conservative factor of at least 5** [*emphasis added*]. On July 9, 2021, there were 9,048 deaths reported in VAERS. I verified these numbers by collating all of the data from VAERS myself, not relying on a third party to report them. In tandem, I queried data from CMS medical claims with regard to vaccines and patient deaths, and have assessed that the deaths occurring within 3 days of vaccination are higher than those reported in VAERS by a factor of at least 5. This would indicate the true number of vaccine-related deaths was at least 45,000. Put in perspective, the swine flu vaccine was taken off the market which only resulted in 53 deaths.
>
> I declare **under penalty of perjury** under the laws of the United States of America that the foregoing is true and correct [*emphasis added*]."

[236] ***Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database Interim: Results and Analysis***
PAMBAYESIAN Project
Scott Mclachlan, Magda Osman, *et al*.
June 2021
https://www.researchgate.net/publication/352837543_Analysis_of_COVID-19_vaccine_death_reports_from_the_Vaccine_Adverse_Events_Reporting_System_VAERS_Database_Interim_Results_and_Analysis

> "**Abstract**: Clinically trained reviewers have undertaken a detailed analysis of a sample of the early deaths reported in VAERS (250 out of the 1644 deaths recorded up to April 2021). The focus is on the extent to which the reports enable us to understand whether the vaccine genuinely caused or contributed to the deaths. Contrary to claims that most of these reports are made by lay-people and are hence clinically unreliable, we identified health service employees as the reporter in at least 67%. The sample contains only people vaccinated early in the programme, and hence is made up primarily of those who are elderly or with significant health conditions. Despite this, there were only 14% of the cases for which a vaccine reaction could be ruled out as a contributing factor in their death…
>
> **3. Analysis of the VAERS data for COVID-19 Vaccines**: … Figure 4 highlights that **50% died in less than 48 hours after receiving their COVID-19 vaccination**. This increases to 80% when we extend to the first week post-vaccination [*emphasis added*]. A further 10% of deaths occurred in the second week…

Conclusions: [T]he only patients where a vaccine allergic reaction be ruled out as contributing to death were 34 (14%) who were all either already bedridden, at end of life, and expected to die anyway from a serious comorbid like lung cancer or were on palliative hospice care."

[237] **Letter to the Chief Executive of the UK Medicines and Healthcare Products Regulatory Agency: *Urgent preliminary report of Yellow Card data up to 26th May 2021***
Evidence-based Medicine Consultancy, Ltd.
Tess Lawrie
June 9, 2021
https://ebmcsquared.org/urgent-preliminary-report-of-yellow-card-data
Note: This link also includes subsequent correspondence between Lawrie and the Chief Executive, Dr. June Raine.

"As the Director of the Evidence-based Medicine Consultancy Ltd and EbMC Squared CiC, I am writing to share with you this urgent preliminary report on the Yellow Card data up to 26th May 2021. Please note that EbMC Squared CiC is a Community Interest Company that conducts research mandated by the public and funded by public donations. We have no conflicts of interest and do not engage in industry-funded work…

We are aware of the limitations of pharmacovigilance data and understand that information on reported Adverse Drug Reactions [*ADR*] should not be interpreted as meaning that the medicine in question generally causes the observed effect or is unsafe to use. We are sharing this preliminary report due to the urgent need to communicate information that should lead to cessation of the vaccination roll out while a full investigation is conducted. According to the recent paper by Seneff and Nigh, potential acute and long-term pathologies include:

- Pathogenic priming, multisystem inflammatory disease and autoimmunity
- Allergic reactions and anaphylaxis
- Antibody dependent enhancement
- Activation of latent viral infections
- Neurodegeneration and prion diseases
- Emergence of novel variants of SARSCoV2
- Integration of the spike protein gene into the human DNA

The nature and variety of ADRs reported to the Yellow Card System are consistent with the potential pathologies described in this paper and supported by other recent scientific papers on vaccine-induced harms, which are mediated through the vaccine spike protein product. It is now apparent that **these products in the blood stream are toxic to humans**. An immediate halt to the vaccination programme is required whilst a full and independent safety analysis is undertaken to investigate the full extent of the harms [*emphasis added*], which the UK Yellow Card data suggest include thromboembolism, multisystem inflammatory disease, immune suppression, autoimmunity and anaphylaxis, as well as Antibody Dependent Enhancement (ADE)."

[238] ***A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals***
Science, Public Health Policy, and The Law
Jessica Rose
May 2021
https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_a0a813acbfdc4534a8cb50cf85193d49.pdf

"**Abstract**: Following the global roll-out and administration of the Pfizer/BioNTech (BNT1 62b2) and Moderna (mRNA-1 273) COVID-1 9 vaccines1 on December 17, 2020 in the United States, and of the Janssen COVID-19 Vaccine PF (produced by Johnson & Johnson) on April 1st, 2021, tens of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS). This work summarizes this data to date and serves as information for the public and a reminder of the relevance of any adverse events, including deaths that occur as a direct result of biologicals as prophylactic treatments. This is especially relevant in the context of technologically novel treatments in the experimental phase of development. Analysis suggests that the vaccines are likely the cause of reported deaths, spontaneous abortions, anaphylactic reactions and cardiovascular, neurological and immunological AEs…

Conclusion: … [D]ue to both the problems of under-reporting and the lag in report processing, this analysis reveals a strong signal from the VAERS data that the risk of suffering an SAE [*Severe Adverse Event*] following injection is significant and that the overall risk signal is high."

Other Adverse-Event Reporting Systems and Related Issues

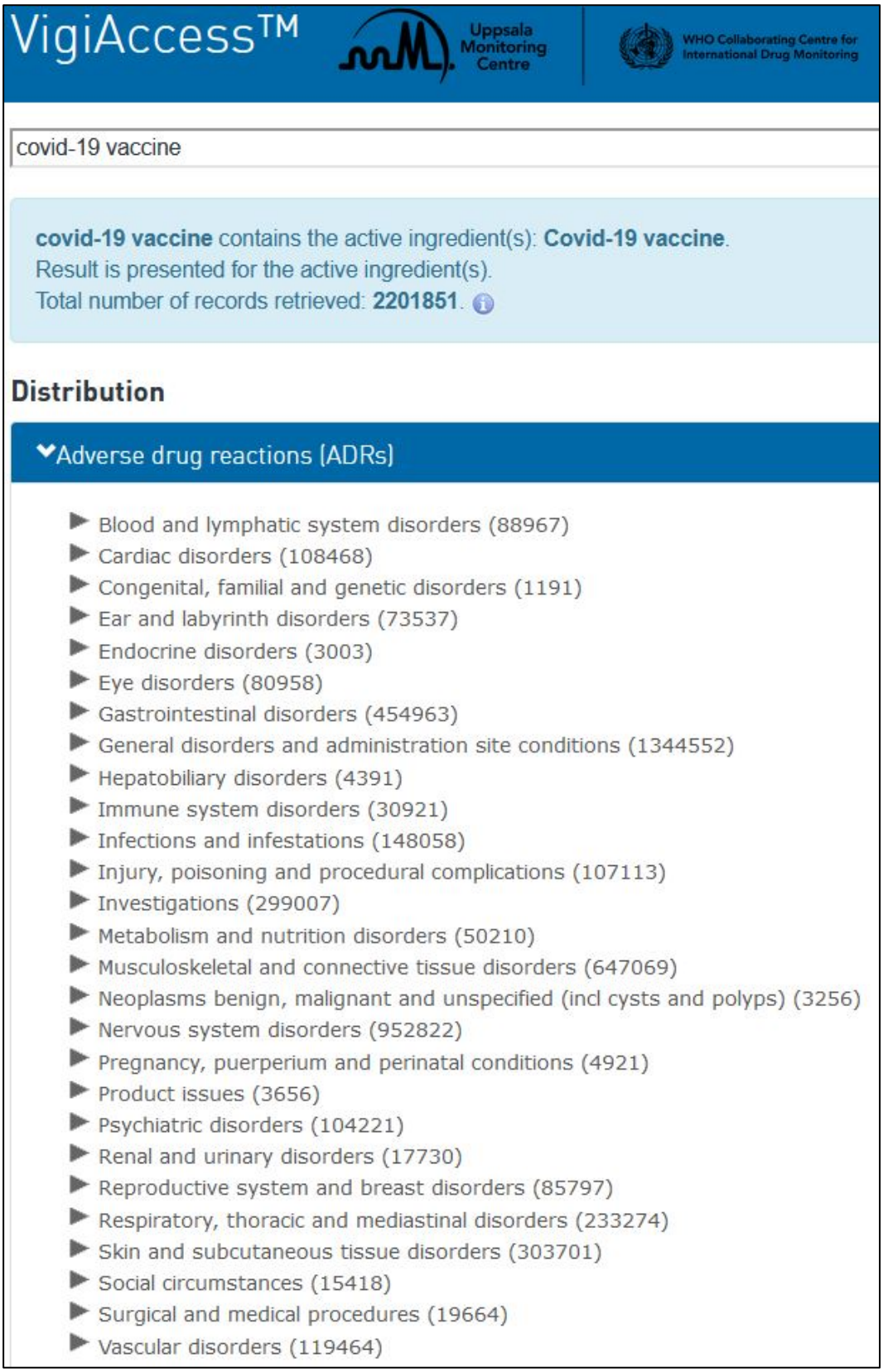
[239] **VigiAccess**
http://vigiaccess.org/

"VigiAccess was launched by the World Health Organization (WHO) in 2015 to provide public access to information in VigiBase, the WHO global database of reported potential side effects of medicinal products. Side effects – known technically as adverse drug reactions (ADRs) and adverse events following immunization (AEFIs) – are reported by national pharmacovigilance centres or national drug regulatory authorities that are members of the WHO Programme for International Drug Monitoring (PIDM). WHO PIDM was created in 1968 to ensure the safer and more effective use of medicinal products…

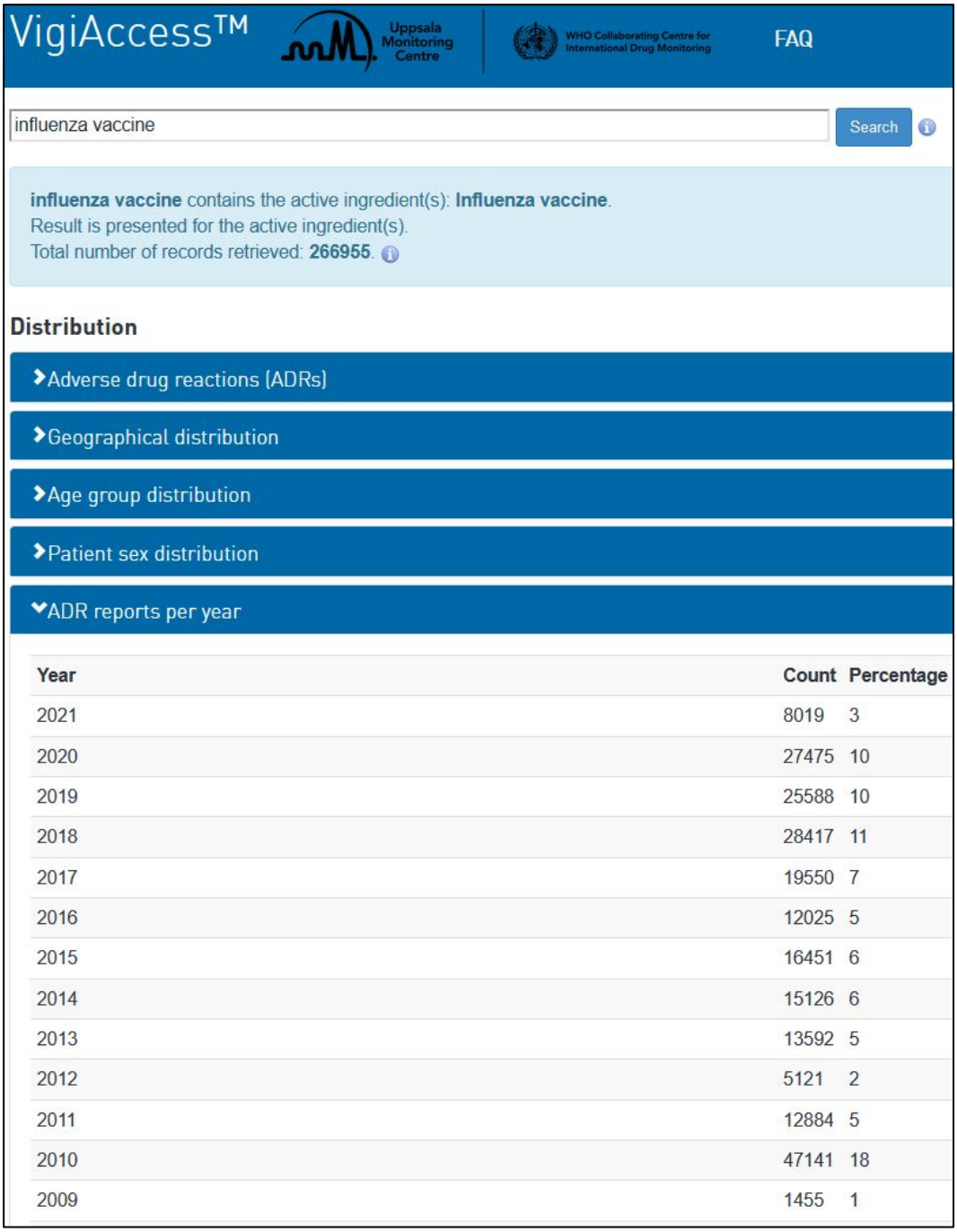
Special note regarding COVID-19 vaccine data: To see VigiBase data on COVID-19 vaccines, **search for "covid-19 vaccine"** [*emphasis added*]. Please note that VigiAccess, as a result of the terminology used to structure the information, will group the data for vaccines by disease (for example, "Measles vaccine", "Mumps vaccine"). This means that even searches for exact tradenames, such as "Comirnaty" or "Covishield", will result in the total number of cases reported for all COVID-19 vaccines. It is not possible in VigiAccess to separate the numbers for specific vaccines.

Note: On October 7, 2021, a query of VigiAccess for 'covid-19 vaccine' (as explained above) produced the results below. The 'Total number of records retrieved' was 2,201,851, and the total for each type of adverse event is presented in parentheses. For comparison, the results of a query for 'influenza vaccine' are also provided, which show 266,955 'Total number of records retrieved' for the years 1968-2021.

Results of a VigiAccess query for 'covid-19 vaccine'



Results of a VigiAccess query for 'influenza vaccine' (1968-2021)



Year	Count	Percentage
2021	8019	3
2020	27475	10
2019	25588	10
2018	28417	11
2017	19550	7
2016	12025	5
2015	16451	6
2014	15126	6
2013	13592	5
2012	5121	2
2011	12884	5
2010	47141	18
2009	1455	1

[240] **The Yellow Card scheme: *Coronavirus vaccine - weekly summary of Yellow Card reporting***
Medicines and Healthcare products Regulatory Agency (MHRA - UK)
https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

"**Overview**: The Yellow Card scheme is the system for recording adverse incidents with medicines and medical devices in the UK...

As of 15 September 2021, for the UK, 114,752 Yellow Cards have been reported for the Pfizer/BioNTech vaccine, 231,920 have been reported for the COVID-19 Vaccine AstraZeneca, 15,916 for the COVID-19 Vaccine Moderna and 1088 have been reported where the brand of

the vaccine was not specified."

[241] **EudraVigilance**
European Medicines Agency (EMA)
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance
Reports on Moderna: https://tinyurl.com/2rj68cr9
Reports on Pfizer: https://tinyurl.com/3jwcnurv
Reports on Astrazeneca: https://tinyurl.com/awws49v6

> **About**: "EudraVigilance is the European data processing network and management system for reporting and evaluation of suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network."

[242] **Video (9m): 2019 Global Vaccine Safety Summit**
World Health Organization
December 2-3, 2019
https://www.bitchute.com/video/hGodcJHccnhh/
"**Purpose of the event**: … the Global Vaccine Safety Summit will be an opportunity to take stock of GACVS accomplishments and look towards priorities for the next decade.
Attendees: The Summit is meant for vaccine safety stakeholders from around the world, including current and former members of the Global Advisory Committee on Vaccine Safety (GACVS), immunisation programme managers, national regulatory authorities, pharmacovigilance staff from all WHO regions, and representatives of UN agencies, academic institutions, umbrella organizations of pharmaceutical companies, technical partners, industry representatives and funding agencies."
https://www.who.int/news-room/events/detail/2019/12/02/default-calendar/global-vaccine-safety-summit

> **Dr. Heidi Larson, Director of The Vaccine Confidence Project**: "There's a lot of safety science that's needed, and without the good science, we can't have good communication… So we need much more investment in safety science…"
>
> **Dr. Soumya Swaminathan, Chief Scientist, WHO**: "I think we cannot overemphasize the fact that we really don't have very good safety monitoring systems in many countries, and this adds to the miscommunication and misapprehensions because we're not able to give clear-cut answers when people ask questions about the deaths that have occurred due to a particular vaccine..."
>
> **Dr. Bassey Okposen, Program Manager, National Emergency Routine Immunization Coordination Centre (NERICC), Abuja, Nigeria**: "I cast back my mind to our situation in Nigeria, where at six weeks, ten weeks, fourteen weeks, a child is being given different antigens from different companies, and these vaccines have different adjuvants, different preservatives, and so on… Something crosses my mind – is there a possibility of these adjuvants, preservatives cross-reacting amongst themselves? Has there ever been a study on the possibilities of cross-reactions [*inaudible*] that you can share the experience with us? ..."
>
> **Dr. Robert Chen, MD, Scientific Director, Brighton Collaboration (response to Okposen)**:

"Now the only way to tease that out is if you have a large population database, like the vaccine safety data link, as well as some of the other national databases, that are coming to being worthy. Actual vaccine exposure is trapped down to that level of specificity of who is the manufacturer? What is the lot number? Uh, etcetera, etcetera. And there's initiative to try to make the vaccine label information barcoded, so that it includes that level of information, so that in the future, when we do these type of studies we're able to tease that out. And in order to, each time you subdivide, then the sample size gets more and more challenging. And that's what I said earlier today, about that we're really only in the beginning of the era of large data sets where, hopefully, you can start to kind of harmonize the databases from multiple studies. And there is actually an initiative underway … to try to get more national vaccine safety databases linked together so we can start to answer these types of questions that you just raised…"

Larson: "The other thing that's a trend and an issue is not just confidence in providers, but confidence of health-care providers. We have a very wobbly health professional frontline that is starting to question vaccines and the safety of vaccines… When the frontline professionals are starting to question, or they don't feel like they have enough confidence about the safety to stand up to it to the person asking them the questions. I mean most medical-school curriculums, even nursing curriculums, I mean, **in medical school, you're lucky if you have a half day on vaccines**, nevermind keeping up to date with all this [*emphasis added*]."

Known and Emerging Side-Effects of COVID-19 Inoculations

Venous Thromboembolism (Blood Clotting)

Note: The citations below are presented in reverse, chronological order.

[243] **ADDED since 10/14/2021**
Research Letter: *Age- and Sex-Specific Incidence of Cerebral Venous Sinus Thrombosis Associated With Ad26.COV2.S COVID-19 Vaccination*
JAMA Internal Medicine (Mayo Clinic)
Aneel A. Ashrani, Daniel J. Crusan, *et al*.
November 1, 2021
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785610

> "Recent reports suggest a possible association between Ad26.COV2.S (Johnson & Johnson/Janssen) COVID-19 vaccination and cerebral venous sinus thrombosis (CVST). Estimates of postvaccination CVST risk require accurate age- and sex-specific prepandemic CVST incidence rates; however, reported rates vary widely. We compared the age- and sex-specific CVST rates after Ad26.COV2.S vaccination with the prepandemic CVST rate in the population…
>
> **Results**: … The overall [*prepandemic*] age- and sex-adjusted CVST incidence was **2.34** per 100 000 person-years (PY)…
>
> The overall incidence rate of post–Ad26.COV2.S vaccination CVST was **8.65** per 100 000 PY (95% CI, 5.88-12.28 per 100 000 PY) at 15 days, **5.02** per 100 000 PY (95% CI, 3.52-6.95 per 100 000 PY) at 30 days…"

[244] ***CVST After COVID-19 Vaccine: New Data Confirm High Mortality Rate***
Medscape
Sue Hughes
September 30, 2021
https://www.medscape.com/viewarticle/959992

> "A new series of cases of cerebral venous sinus thrombosis (CVST) linked to the adenoviral vector COVID-19 vaccines has been reported, confirming the severity of the reaction and the associated high mortality rate.
>
> This new series comes from an international registry of consecutive patients who experienced CVST within 28 days of COVID-19 vaccination between March 29 and June 18, 2021, from 81 hospitals in 19 countries…
>
> 'This is a reliable description on the clinical condition of these patients with CVST associated with COVID-19 vaccination. It is striking that this [*is*] a **much worse condition than CVST not associated with COVID-19 vaccination**, with a much higher rate of intracerebral hemorrhage and coma and a much higher mortality rate [*emphasis added*],' senior author Jonathan M. Coutinho, MD, Amsterdam University Medical Centers… told Medscape Medical News.'

These data confirm the observations from an earlier UK cohort in which cases of cerebral venous thrombosis linked to COVID-19 vaccination occurred…

In the cohort of 116 patients with CVST after COVID-19 vaccination, 78 (67.2%) had thrombosis with TTS [*thrombocytopenia syndrome*] and were thus classified as having had a vaccine-related adverse event. These patients were frequently comatose at presentation (24%) and often had intracerebral hemorrhage (68%) and concomitant thromboembolism (36%); 47% died during hospitalization...

Mortality rates were much higher among the patients deemed to have had a vaccine-related CVST. The in-hospital mortality rate was 47%, compared with 5% among the patients in the same cohort who did not have TTS and 3.9% among the prepandemic control group."

[245] ***Characteristics and Outcomes of Patients With Cerebral Venous Sinus Thrombosis in SARS-CoV-2 Vaccine–Induced Immune Thrombotic Thrombocytopenia***
JAMA Neurology
Mayte Sanchez van Kammen, Diana Aguiar de Sousa, *et al*.
September 28, 2021
https://jamanetwork.com/journals/jamaneurology/fullarticle/2784622

"**Conclusions and Relevance**: In this cohort study of patients with CVST, a distinct clinical profile and high mortality rate was observed in patients meeting criteria for TTS after SARS-CoV-2 vaccination."

[246] ***The Dangers of Covid-19 Booster Shots and Vaccines: Boosting Blood Clots and Leaky Vessels***
Doctors for COVID Ethics
September 17, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Vaccine-immune-interactions-and-booster-shots_Sep-2021.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"**1. Summary**: … Eminent independent scientists and researchers in the fields of immunology and microbiology have been writing to medical regulators since early 2021, warning of vaccine-related blood clotting and bleeding, including that the official data on blood abnormalities post-vaccination likely represent 'just the tip of a huge iceberg.' Those scientists' warnings pre-dated vaccine suspensions around the world due to acute disease from aberrant blood clotting post-vaccination. The warnings were based on established immunological science, applied to the novel mechanism of action of the gene-based COVID-19 vaccines.

Now, more than six months later, new discoveries in the immunology of SARS-CoV-2 have caught up with the rushed vaccination schedule, confirming and extending the experts' prior warnings. The good news is that we are more comprehensively protected against COVID-19 by our own pre-existing immunity than was previously understood. On the other hand, this pre-existing immunity aggravates the risk that COVID-19 vaccines will induce blood clotting and/or leaky blood vessels. This risk must be **expected to escalate with each revaccination. Vaccine-induced harm to our blood vessels is unlikely to be rare** [*emphasis added*].

Perhaps the most pertinent finding is that, due to the discovery of a widespread memory-type antibody response to SARS-CoV-2, the antibodies induced by the COVID-19 vaccines can be expected to activate the so-called complement system. This can bring about the destruction of

any cell that manufactures the SARS-CoV-2 spike protein, particularly in the circulation. If that happens to the endothelia, that is, the cell layer that lines the inner surfaces of our blood vessels, then those vessels may begin to leak and clots will form. Given that 2021 research showed the spike protein to enter the bloodstream shortly after vaccination, this dangerous endothelial involvement in spike-production is highly likely, and should be expected to occur.

2.1. How and why COVID-19 vaccines incite immunological attack on blood vessel walls. What is wrong with booster shots? … a convergence of evidence from peer reviewed studies published in 2021 reveals that pre-existing immunity to SARS-CoV-2 involves not only T-cells but also memory antibodies, in 99% of people studied… This has profound consequences for the risk-benefit analysis of the vaccines…

2.2. Updated Immune Profile of COVID-19 and its Vaccines: Importantly for COVID-19 vaccination, the 2021 discoveries reveal that the SARS-CoV-2 virus responsible for COVID-19 is not truly new to our immune systems. The finding that the overwhelming majority of people show a memory-type antibody profile to COVID-19 vaccines proves that our immune systems have seen viruses similar to SARS-CoV-2 before. As a result, our bodies have stored an immune memory of that family of viruses, equipping us to fight back more rapidly and powerfully the next time we encounter a similar virus again. As SARS-Cov-2 is of the coronavirus family, this indicates that we possess lasting cross-immunity from previous exposure to other coronaviruses…

2.4. Four Immunological Problems with COVID-19 Vaccines: … While the now clearly established widespread cross-immunity against SARS-CoV-2 implies that most of us are safe from severe COVID-19 disease, it also means that we are vulnerable to the harms of gene-based vaccines. Due to recall immunity against the virus, **vaccination will cause our immune systems to fight aggressively against not only the SARS-CoV-2 spike protein, but against ourselves**. This deleterious autoimmune attack must be expected to intensify with each repeated injection."

[247] ***Cerebral venous thrombosis after vaccination against COVID-19 in the UK: a multicentre cohort study***
The Lancet
Richard J. Parry, Arina Tamborska, *et al*.
August 6, 2021
https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2901608-1

"**Background**: A new syndrome of vaccine-induced immune thrombotic thrombocytopenia (VITT) has emerged as a rare side-effect of vaccination against COVID-19. Cerebral venous thrombosis is the most common manifestation of this syndrome but, to our knowledge, has not previously been described in detail. We aimed to document the features of post-vaccination cerebral venous thrombosis with and without VITT and to assess whether VITT is associated with poorer outcomes…

Interpretation: Cerebral venous thrombosis is more severe in the context of VITT…

Results: … **The primary outcome of death or dependency** [hospital staff needed] **occurred more frequently in patients with VITT-associated cerebral venous thrombosis** (33 [47 percent] of 70 patients) compared with the non-VITT control group (four [16 percent] of 25 patients; p=0·0061) [*emphasis added*]. More patients died during admission in the VITT-

associated cerebral venous thrombosis group (20 [29 percent] of 70 patients) than in the non-VITT group (one [4 percent] of 25 patients; p=0·011)…

Discussion: [P]atients with VITT-associated cerebral venous thrombosis were younger than those without VITT. Other key findings were that, compared with non-VITT patients, those with VITT-associated cerebral venous thrombosis had more extensive venous thrombosis and higher rates of multiple infarcts, multiple intra cerebral haemorrhages, and extracranial thrombosis. VITT was associated with significantly more death or dependency at the end of hospital admission."

[248] **Video (8m): Interview with Dr. Charles Hoffe**
July 7, 2021
https://www.bitchute.com/video/A6GbcUl6blpJ/

"The clots I'm talking about are microscopic at the capillary level, and they're scattered throughout your capillary network. So they're not going to show on any scan. They're just too small and too scattered. So the only way to find out if this particular mechanism of clotting was actually happening was to do this blood test called the D-dimer (which only shows new blood clots, not old blood clots)… So I have now been (testing patients) who have had their covid shots … between the previous four and seven days and doing (the D-dimer test)… On the ones I have so far, 62% of them have evidence of clotting, which means these blood clots are not rare… The most alarming part of this is that there are some parts of the body like the brain, spinal cord, heart and lungs which cannot re-generate. When those tissues are damaged by blocked vessels they are permanently damaged… These shots are causing huge damage and the worst is yet to come."

[249] ***Antibody epitopes in vaccine-induced immune thrombotic thrombocytopaenia***
Nature magazine
Angela Huynh, John G. Kelton, Donald M. Arnold, Mercy Daka, and Ishac Nazy
July 7, 2021
https://www.nature.com/articles/s41586-021-03744-4

"**Abstract**: … Our data indicate that VITT [*vaccine-induced immune thrombotic thrombocytopaenia*] antibodies can mimic the effect of heparin by binding to a similar site on PF4; this allows PF4 tetramers to cluster and form immune complexes, which in turn causes Fcγ receptor IIa (FcγRIIa; also known as CD32a)-dependent platelet activation. These results provide an explanation for VITT-antibody-induced platelet activation that could contribute to thrombosis."

[250] ***COVID-19 vaccine-induced immune thrombotic thrombocytopenia: An emerging cause of splanchnic vein thrombosis***
Annals of Hepatology
Mateo Porres-Aguilar, Alejandro Lazo-Langner, Arturo Pandura, and Misael Uribe
April 30, 2021
https://www.sciencedirect.com/science/article/pii/S1665268121000557

"[T]wards end of February 2021, a significant number of venous thromboses (VTE) in unusual sites (cerebral venous-sinus thrombosis [CVST], and splanchnic vein thrombosis [SVT]) in combination with thrombocytopenia were observed in individuals that received the Aztra Zeneca coronavirus disease 2019 (COVID-19) vaccine…

Investigators found that these thrombotic thrombocytopenic syndromes shared striking similarities with severe heparin-induced thrombocytopenia (HIT), a well-known hypercoagulable disorder caused by platelet-activating antibodies that recognize multimolecular complexes like those formed by PF-4 and anionic heparin, triggering prothrombotic events, with the exception that the above-described patients never were exposed to heparin, a variant known as autoimmune HIT...

Finally, authors proposed to name this new entity **Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)** [*emphasis added*]…

Several international societies, including the International Society for Thrombosis and Haemostasis (ISTH) have recently published their guidance for the diagnosis and management of VITT, which currently represents a 'rare entity/phenomenon', but can affect patients of all ages and both sexes.

We recommend that clinicians be familiarized and be extremely alert and raise awareness among other colleagues regarding the clinical and laboratory features that may trigger a clinical concern for VITT, having an exceptionally low threshold for further investigations in these patients since they could present with non-specific signs and symptoms of VTE in unusual sites like CVST or SVT."

[251] **Open Letter: *Doctors and Scientists Write to the European Medicines Agency, Warning of COVID-19 Vaccine Dangers for a Third Time***
Doctors for COVID Ethics
April 24, 2021
https://doctors4covidethics.org/doctors-and-scientists-write-to-the-european-medicines-agency-warning-of-covid-19-vaccine-dangers-for-a-third-time/
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"Our most serious concern re ALL the gene-based vaccines is that you convey the impression that cerebral venous sinus thrombosis (CVST) *[ed. blood-clot formation in the brain's venous sinuses]* is a very rare adverse event. In fact the opposite is probably true. The cardinal symptoms of CVST dominate the list of adverse reactions: piercing headache, nausea and vomiting, impaired consciousness, impaired speech, impaired vision, impaired hearing, paralysis of varying degrees in various locations, and loss of motor control (including such severe loss that victims mimic the symptoms of Huntington's Chorea). It is imperative that proper medical attention is given to every individual who presents with any of the above symptoms. It is the indirigible duty of the European Medicines Agency to disseminate the above information to medical doctors and responsible authorities…

A further serious concern is that peripheral 'clot' formation is not alluded to by you at all. It is evident that 'clot' formation in the deep veins of the legs and arms can lead to life-threatening pulmonary embolism. Further, thrombus formation in the small vessels of the lungs can lead to a clinical picture resembling atypical pneumonia. In addition, it is vitally important to understand that any one of 1a. 1b. 1c. or any combination of these can lead via consumption of coagulation factors to the clinical picture of disseminated intravascular coagulation (DIC) which is actually characterised by massive bleeding events into the skin and into other organs of the body. It is imperative that all the above diagnoses are actively searched for and that all cases displaying symptoms consistent with any of these diagnoses are recorded properly as adverse vaccine-related events."

[252] ***Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination***
New England Journal of Medicine
Nina Schultz, Ingvild H. Servoll, *et al*.
April 9, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2104882

> "**Discussion**: … Although rare, VITT [*vaccine-induced immune thrombotic thrombocytopenia*] is a new phenomenon with devastating effects for otherwise healthy young adults and requires a thorough risk–benefit analysis. The findings of our study indicate that VITT may be more frequent than has been found in previous studies in which the safety of the ChAdOx1 nCoV-19 vaccine has been investigated."

[253] ***Letter to EMA by Professsor Sucharit Bhakdi and colleagues***
Sucharit Bhakdi, Marco Chiesa, Stephen Frost, Margareta Griesz-Brisson, Martin Haditsch, Stefan Hockertz, Lissa Johnson, Ulrike Kämmerer, Michael Palmer, Karina Reiss, Andreas Sönnichsen, and Michael Yeadon
February 28, 2021
https://viruswaarheid.nl/belangrijk/letter-to-ema-28-february-2021/

> "… We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
>
> 4. If such evidence is not available, it must be expected that endothelial damage with subsequent triggering of blood coagulation via platelet activation will ensue at countless sites throughout the body. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
>
> 5. If such evidence is not available, it must be expected that this will lead to a drop in platelet counts, appearance of D-dimers in the blood, and to myriad ischaemic lesions throughout the body including in the brain, spinal cord and heart. Bleeding disorders might occur in the wake of this novel type of DIC-syndrome including, amongst other possibilities, profuse bleedings and haemorrhagic stroke. We request evidence that all these possibilities were excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
>
> 6. The SARS-CoV-2 spike protein binds to the ACE2 receptor on platelets, which results in their activation [6]. Thrombocytopenia has been reported in severe cases of SARS-CoV-2 infection [7]. Thrombocytopenia has also been reported in vaccinated individuals [8]. We request evidence that the potential danger of platelet activation that would also lead to disseminated intravascular coagulation (DIC) was excluded with all three vaccines prior to their approval for use in humans by the EMA…
>
> Should all such evidence not be available, we demand that approval for use of the gene-based vaccines be withdrawn until all the above issues have been properly addressed by the exercise of due diligence by the EMA."

Myocarditis (Inflammation of the Heart Muscle)

[254] ***Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19***

Vaccine, mRNA) and Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
Food and Drug Administration (FDA)
Revised September 22, 2021
https://www.fda.gov/media/144414/download

"Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:
• severe allergic reactions
• non-severe allergic reactions such as rash, itching, hives, or swelling of the face
• myocarditis (inflammation of the heart muscle)
• pericarditis (inflammation of the lining outside the heart)
• injection site pain
• tiredness
• headache
• muscle pain
• chills
• joint pain
• fever
• injection site swelling
• injection site redness
• nausea
• feeling unwell
• swollen lymph nodes (lymphadenopathy)
• diarrhea
• vomiting
• arm pain
• fainting in association with injection of the vaccine
These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials."

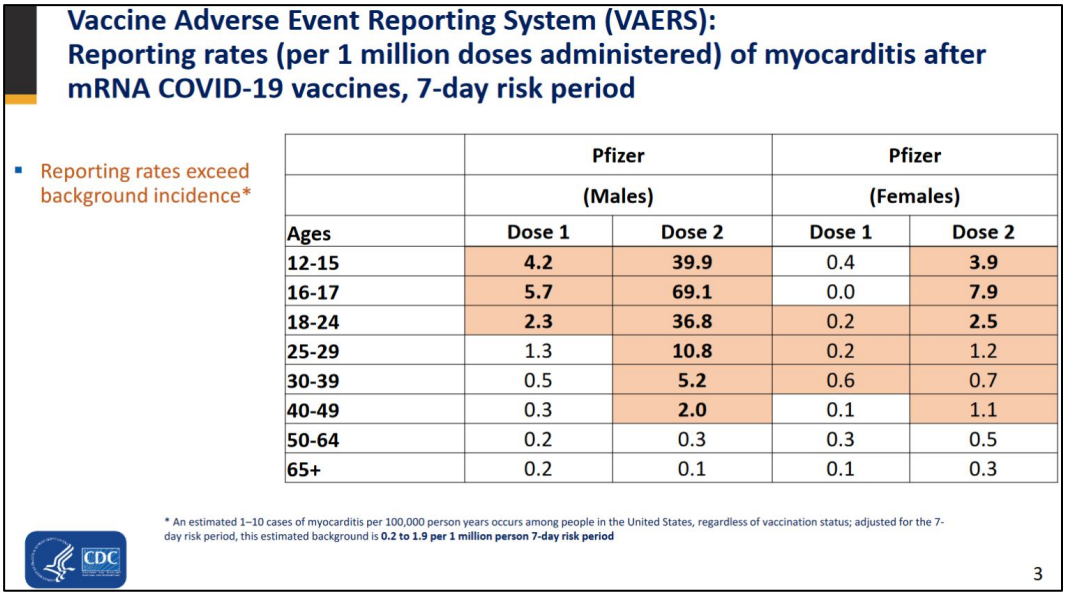
Note: The citations below are presented in reverse, chronological order.

[255] **ADDED since 10/14/2021**
Germany, France Restrict Moderna's Covid Vaccine For Under-30s Over Rare Heart Risk—Despite Surging Cases
Forbes
Robert Hart
November 10, 2021
https://www.forbes.com/sites/roberthart/2021/11/10/germany-france-restrict-modernas-covid-vaccine-for-under-30s-over-rare-heart-risk-despite-surging-cases/

"Germany and France are the latest European countries to restrict the use of Moderna's Covid-19 vaccine in younger people, joining a string of Nordic nations including Finland, Sweden, Denmark and Norway. All cite studies indicating a very limited risk of heart inflammation in young recipients of mRNA coronavirus vaccines, which includes Pfizer and Moderna shots."

[256] **ADDED since 10/14/2021**
mRNA COVID-19 Vaccine-Associated Myocarditis

Centers for Disease Control and Prevention
Mathew Oster
November 2, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/04-COVID-Oster-508.pdf



Vaccine Adverse Event Reporting System (VAERS):
Reporting rates (per 1 million doses administered) of myocarditis after mRNA COVID-19 vaccines, 7-day risk period

- Reporting rates exceed background incidence*

	Pfizer (Males)		Pfizer (Females)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	**4.2**	**39.9**	0.4	**3.9**
16-17	**5.7**	**69.1**	0.0	**7.9**
18-24	**2.3**	**36.8**	0.2	**2.5**
25-29	1.3	**10.8**	0.2	1.2
30-39	0.5	**5.2**	0.6	0.7
40-49	0.3	**2.0**	0.1	1.1
50-64	0.2	0.3	0.3	0.5
65+	0.2	0.1	0.1	0.3

* An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is **0.2 to 1.9 per 1 million person 7-day risk period**

3

[257] **ADDED since 10/14/2021**
Video (15m): *Lt. Col. Theresa Long, MD opinion regarding federal vaccine mandates*
US Congressional statement – Roundtable discussion on COVID-19 vaccines
November 2, 2021
https://rumble.com/von59h-lt.-col.-theresa-long-md-mph-fs.html

"My opinion is formed from my medical education, training, and my first-hand experience treating soldiers injured by the vaccine…

I believe the COVID vaccine is a greater threat to the soldiers' health and military readiness than the virus itself…

In June of 2021, the CDC announced that they were holding an emergency meeting to discuss higher than expected myocarditis in 16-to-24 year olds. Despite this announcement, the military did not even pause their vaccination efforts. Why?

I made numerous efforts to get senior medical leaders to, at the very least, inform soldiers of the risks. Leadership ignored my concerns. This is very troubling for many reasons.

You can't have informed consent if you don't tell your patients of the risks and benefits of a treatment or procedure."

[258] **ADDED since 10/14/2021**
COVID-19 vaccine weekly safety report
Department of Health (Australia)
October 28, 2021
https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-28-10-2021

"We are carefully monitoring and reviewing reports of:

- myocarditis and pericarditis following mRNA vaccines, particularly in younger age groups
- thrombosis with thrombocytopenia syndrome (TTS) following Vaxzevria (AstraZeneca)
- Guillain-Barre Syndrome (GBS) following Vaxzevria (AstraZeneca)
- immune thrombocytopenia (ITP) following Vaxzevria (AstraZeneca)"

[259] **ADDED since 1/14/2021**
Sweden Public Health Agency Indefinitely Halts Use of Moderna mRNA-1273 on Young People 30 & Below
TrialSiteNews
October 27, 2021
https://trialsitenews.com/sweden-publish-health-agency-indefinitely-halts-use-of-moderna-mrna-1273-on-young-people-30-below/

"Sweden's Public Health Agency extended a moratorium indefinitely on the use of the Moderna mRNA-1293 vaccine to anyone age 30 and under… Heart inflammation in younger people is a known adverse effect associated with the Moderna vaccine, with young males facing higher risks…

TrialSite reported that on October 6 Sweden halted the use of the mRNA COVID-19 vaccine on people under the age of 30 due to safety concerns. Just a couple of days later TrialSite shared with global audiences that **Iceland made the same move, along with the rest of the Scandinavian countries**, to either halt or in the case of Norway, discourage the use of the Moderna vaccine in younger people **due to the safety risks** [*emphasis added*]."

[260] **ADDED since 10/14/2021**
Briefing Document: *Vaccines and Related Biological Products Advisory Committee Meeting*
US Food and Drug Administration
October 26, 2021
https://www.fda.gov/media/153447/download

"Post-EUA safety surveillance reports received by FDA and CDC identified increased risks of myocarditis and pericarditis, particularly within 7 days following administration of the second dose of the 2-dose primary series. Reporting rates for medical chart-confirmed myocarditis and pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and have been highest in males 12 through 17 years of age (~71.5 cases per million second primary series doses among males age 16-17 years and 42.6 cases per million second primary series doses among males age 12-15 years as per CDC presentation to the ACIP on August 30, 2021). In an FDA analysis of the Optum healthcare claims database, the estimated excess risk of myocarditis/pericarditis approached **200 cases**

per million fully vaccinated males 16-17 years of age and **180 cases per million** fully vaccinated males 12-15 years of age [*emphasis added*]."

[261] ***Use of Moderna's COVID-19 vaccine in Iceland***
Iceland Directorate of Health
October 8, 2021
https://www.landlaeknir.is/um-embaettid/frettir/frett/item47717/Notkun-COVID-19-boluefnis-Moderna-a-Islandi

"In recent days, data from the Nordic countries on increased incidence of heart inflammation and gollum house inflammation after vaccination with Moderna vaccine have been presented…

Since there is sufficient availability of Pfizer's vaccine in Iceland for both stimulation vaccinations of defined priority groups and the basic vaccinations of those who have not yet been vaccinated, **the quarantine officer has decided that Moderna vaccines will not be used in this country** while further information is obtained on the safety of Moderna's vaccine [*emphasis added*] during stimulation vaccinations."

[262] ***A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products***
Current Problems in Cardiology
Jessica Rose and Peter McCullough
October 1, 2021
https://www.sciencedirect.com/science/article/pii/S0146280621002267

"**Abstract**: Following the global rollout and administration of the Pfizer Inc./BioNTech BNT162b2 and Moderna mRNA-1273 vaccines on December 17, 2020, in the United States, and of the Janssen Ad26.COV2.S product on April 1st, 2021, in an unprecedented manner, hundreds of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS). We used VAERS data to examine cardiac AEs, primarily myocarditis, reported following injection of the first or second dose of the COVID-19 injectable products. Myocarditis rates reported in VAERS were significantly higher in youths between the ages of 13 to 23 ($p<0.0001$) with ~80% occurring in males. Within 8 weeks of the public offering of COVID-19 products to the 12-15-year-old age group, we found **19 times the expected number of myocarditis cases** in the vaccination volunteers over background myocarditis rates for this age group. In addition, a 5-fold increase in myocarditis rate was observed subsequent to dose 2 as opposed to dose 1 in 15-year-old males [*emphasis added*]. A total of 67% of all cases occurred with BNT162b2. Of the total myocarditis AE reports, 6 individuals died (1.1%) and of these, 2 were under 20 years of age - 1 was 13. These findings suggest a markedly higher risk for myocarditis subsequent to COVID-19 injectable product use than for other known vaccines, and this is well above known background rates for myocarditis. COVID-19 injectable products are novel and have a genetic, pathogenic mechanism of action causing uncontrolled expression of SARS-CoV-2 spike protein within human cells. When you combine this fact with the temporal relationship of AE occurrence and reporting, biological plausibility of cause and effect, and the fact that these data are internally and externally consistent with emerging sources of clinical data, it supports a conclusion that the COVID-19 biological products are deterministic for the myocarditis cases observed after injection."

[263] ***Heart inflammation rates higher after Moderna COVID-19 vaccine - Canada data***
Reuters
Manas Mishra
October 1, 2021
https://www.reuters.com/business/healthcare-pharmaceuticals/heart-inflammation-rates-higher-after-moderna-covid-19-shot-than-pfizer-vaccine-2021-10-01/

> "Canadian health officials said on Friday data suggests reported cases of rare heart inflammation were relatively higher after Moderna's (MRNA.O) COVID-19 vaccine compared with the Pfizer/BioNTech shots….
>
> The data also indicated heart inflammation occurs more often in adolescents and adults under 30 years of age, and more often in males."

[264] ***Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to August 7, 2021***
Public Health Ontario
September 2021
https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en

> "**Highlights**:
>
> - Since the start of the COVID-19 immunization program in Ontario, there have been 314 reports of myocarditis or pericarditis following receipt of COVID-19 mRNA vaccines in Ontario…
> - The highest reporting rate of myocarditis/pericarditis was observed in males aged 18-24 years following second dose. The reporting rate in this group following the Pfizer-BioNTech vaccine as second dose was **37.4 per million doses** and was **263.2 per million** following the Moderna vaccine as second dose [*emphasis added*]."

[265] ***Affidavit of LTC. Theresa Long M.D. in Support of a Motion for a Preliminary Injunction Order***
September 24, 2021
https://www.deepcapture.com/2021/09/affidavit-of-ltc-theresa-long-m-d-in-support-of-a-motion-for-a-preliminary-injunction-order/

> "I, Lieutenant Colonel Theresa Long, MD, MPH, FS being duly sworn, depose and state as follows:
>
> 1. I make this affidavit, as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034, in support of the above referenced MOTION as expert testimony in support thereof…
>
> 18. … mRNA vaccines produced by Pfizer and Moderna both have been linked to myocarditis, especially in young males between 16-24 years old. The majority of young new Army aviators are in their early twenties. We know there is a risk of myocarditis with each mRNA vaccination…
>
> 20. Research shows that most individuals with myocarditis do not have any symptoms. Complications of myocarditis include dilated cardiomyopathy, arrhythmias, sudden cardiac death and carries a **mortality rate of 20% at one year and 50% at 5 years** [*emphasis*

added]…

35. … I am also drawing my own conclusions that will be put into practice in my current role as an Army flight surgeon knowing full well the horrific repercussions this decision may befall me in terms of my career, my relationships and life as an Army doctor.

36. … I find the illnesses, injuries and fatalities [I] observed to be the proximate and causal effect of the Covid 19 vaccinations…

38. I can report of knowing over fifteen military physicians and healthcare providers who have shared experiences of having their safety concerns ignored and being ostracized for expressing or reporting safety concerns as they relate to COVID vaccinations. The politicization of SARs-CoV-2, treatments and vaccination strategies have completely compromised long-standing safety mechanisms, open and honest dialogue, and the trust of our service members in their health system and healthcare providers.

39. The subject matter of this Motion for a Preliminary Injunction and its devastating effects on members of the military compel me to conclude and conduct accordingly as follows:

b) All three of the EUA Covid 19 vaccines (Comirnaty is not available), in the age group and fitness level of my patients, are more risky, harmful and dangerous than having no vaccine at all, whether a person is Covid recovered or facing a Covid 19 infection; …

d) Due to the Spike protein production that is engineered into the user's genome, each such recipient of the Covid 19 Vaccines already has micro clots in their cardiovascular system that present a danger to their health and safety; …

g) That due to the fact that there is no functional myocardial screening currently being conducted, it is my professional opinion that substantial foreseen risks currently exist, which require proper screening of all flight crews; …

k) That, in accordance with the foregoing, I hereby recommend to the Secretary of Defense that all pilots, crew and flight personnel in the military service who required hospitalization from injection or received any Covid 19 vaccination be grounded similarly for further dispositive assessment.

l) That this Court should grant an immediate injunction to stop the further harm to all military personnel to protect the health and safety of our active duty, reservists and National Guard troops."

[266] ***Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting***
New England Journal of Medicine
Moam Barda, Moa Dagan, *et al*.
September 16, 2021
https://www.nejm.org/doi/10.1056/NEJMoa2110475

"**Results**: In the vaccination analysis, the vaccinated and control groups each included a mean of 884,828 persons. Vaccination was most strongly associated with an elevated risk of myocarditis…"

[267] **ADDED since 10/14/2021**
Updated Signal assessment report on Myocarditis, pericarditis with Tozinameran (COVID-19 mRNA vaccine (nucleoside-modified) – COMIRNATY)
European Medicines Agency (Pharmacovigilance Risk Assessment Committee)
September 2, 2021
https://www.ema.europa.eu/en/documents/prac-recommendation/updated-signal-assessment-report-myocarditis-pericarditis-tozinameran-covid-19-mrna-vaccine_en.pdf

"**1. Background**…

In Israel, a comparison of hospital admissions incidences rate due to myocarditis in vaccinees compared to non-vaccinees was performed in all ages groups, and the data suggested a potential signal with the vaccinees. There has not been a general comparison of hospitalizations by vaccine status.

The Israeli interim assessment was that there is a likely causal association between the **second dose of mRNA vaccine** (in Israel all cases were with Pfizer vaccine) and **myocarditis**. This association appears stronger in young males (16-19) as opposed to females and attenuates with increasing age. The numerical estimate is still being finalized, but is approximately between **1 In 10,000** to **1 in 6,000** second doses of vaccine [*emphasis added*]…

The Incidence rates for myocarditis only were obtained from IMRD UK (primary care healthcare records), noting the following. The myocarditis diagnosis is likely to be made in secondary care, so there is a risk of underreporting in primary care records. Rates from ACCESS databases that include both primary and secondary care are for myocarditis and pericarditis combined, hence they couldn't be used…

The results showed an elevated OE [*observed/expected*] ratio (**> 5**) in the male 18-24 age group, **statistically significant** [*emphasis added*]."

[268] ***SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis***
medRxiv
Tracy Beth Hoeg, Allison Krug, *et al*.
August 30, 2021
https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1.full.pdf

"**Objectives**: Establishing the rate of post-vaccination cardiac myocarditis in the 12-15 and 16-17-year-old population in the context of their COVID-19 hospitalization risk is critical for developing a vaccination recommendation framework that balances harms with benefits for this patient demographic…

Results: … For boys 12-15 without medical comorbidities receiving their second mRNA vaccination dose, the **rate of CAE is 3.7 to 6.1 times higher** than their 120-day COVID-19 hospitalization risk as of August 21, 2021… For boys 16-17 without medical comorbidities, the **rate of CAE is currently 2.1 to 3.5 times higher** than their 120-day COVID-19 hospitalization risk. [*emphasis added*]…

Principal findings: The main finding of this study was the cardiac adverse event (CAE) rates of 162/million and 94/million post- Pfizer-BioNTech BNT162b2 vaccination dose two for the 12-15- and 16–17-year-old boys, respectively. Approximately **86% of these resulted in**

hospitalization for both age groups [*emphasis added*]...

Conclusions: Post-vaccination CAE rate was highest in young boys aged 12-15 following dose two. For boys 12-17 without medical comorbidities, the likelihood of post vaccination dose two CAE is 162.2 and 94.0/million respectively. This incidence exceeds their expected 120-day COVID-19 hospitalization rate at both moderate (August 21, 2021 rates) and high COVID-19 hospitalization incidence."

[269] **News Release: *FDA Approves First COVID-19 Vaccine***
Food and Drug Administration (FDA)
August 23 2021
https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

"Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes."

[270] ***Intravenous injection of COVID-19 mRNA vaccine can induce acute myopericarditis in mouse model***
Clinical Infectious Diseases (Oxford)
Can Li, Yanxia Chen, *et al*.
August 19, 2021
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab707/6353927

"**Methods**: We compared the clinical manifestations, histopathological changes, tissue mRNA expression and serum levels of cytokine/chemokine in Balb/c mice at different time points after intravenous(IV) or intramuscular(IM) vaccine injection with normal saline(NS) control.

Results: Though significant weight loss and higher serum cytokine/chemokine levels were found in IM group at 1 to 2 days post-injection(dpi), only IV group developed histopathological changes of myopericarditis as evidenced by cardiomyocyte degeneration, apoptosis and necrosis with adjacent inflammatory cell infiltration and calcific deposits on visceral pericardium, while evidence of coronary artery or other cardiac pathologies was absent. SARS-CoV-2 spike antigen expression by immunostaining was occasionally found in infiltrating immune cells of the heart or injection site, in cardiomyocytes and intracardiac vascular endothelial cells, but not skeletal myocytes. The histological changes of myopericarditis after the first IV-priming dose persisted for 2 weeks and were markedly aggravated by a second IM- or IV-booster dose. Cardiac tissue mRNA expression of IL-1β, IFN-β, IL-6 and TNF-α increased significantly from 1dpi to 2dpi in IV but not IM group, compatible with presence of myopericarditis in IV group. Ballooning degeneration of hepatocytes was consistently found in IV group. All other organs appeared normal.

Conclusions: This study provided in-vivo evidence that inadvertent intravenous injection of COVID-19 mRNA-vaccines may induce myopericarditis."

[271] **Correspondence: *Myocarditis after Covid-19 mRNA Vaccination***
New England Journal of Medicine
Amanda K. Verma, Kory J. Lavine, and Chieh-Yu Liu
August 18, 2021
https://www.nejm.org/doi/full/10.1056/NEJMc2109975

> "The Centers for Disease Control and Prevention recently reported cases of myocarditis and pericarditis in the United States after coronavirus disease 2019 (Covid-19) messenger RNA (mRNA) vaccination.1 In recently published reports, diagnosis of myocarditis was made with the use of noninvasive imaging and routine laboratory testing.2-5 Here, we report two cases of histologically confirmed myocarditis after Covid-19 mRNA vaccination…
>
> In these two adult cases of histologically confirmed, fulminant myocarditis that had developed within 2 weeks after Covid-19 vaccination, a direct causal relationship cannot be definitively established because we did not perform testing for viral genomes or autoantibodies in the tissue specimens. However, no other causes were identified by PCR assay or serologic examination."

[272] ***Association of Myocarditis With BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children***
JAMA Cardiology
Audrey Dionne, Frencesca Sperotto, *et al*.
August 10, 2021
https://jamanetwork.com/journals/jamacardiology/fullarticle/2783052?utm_campaign=articlePDF

> "**Objective**: To review results of comprehensive cardiac imaging in children with myocarditis after COVID-19 vaccine…
>
> Although vaccine-associated cases of myocarditis to date have had uncomplicated short-term course, the long-term prognosis remains unclear. Of note, CMR [*cardiac magnetic resonance*] LGE [*late gadolinium enhancement*] was a frequent finding at time of diagnosis. In this clinical setting, LGE reflects an increased volume of distribution of the gadolinium-based contrast agent in the affected region likely related to myocyte necrosis and/or extracellular edema. In nonvaccine-associated myocarditis, the presence of LGE is associated with increased risk for adverse cardiovascular events during follow-up.10-12 Thus, longitudinal studies of patients with myocarditis after COVID-19 vaccine will be important to better understand long-term risks."

[273] ***Heart Inflammation Risk Following mRNA COVID-19 Vaccination Could Be Common***
Precision Vaccinations
Don Ward Hackett
August 5, 2021
https://www.precisionvaccinations.com/heart-inflammation-risk-following-mrna-covid-19-vaccination-could-be-common

> "A new study published by the Journal of the American Medical Association (JAMA) on August 4, 2021, found two distinct self-limited heart-related syndromes, myocarditis, and pericarditis, were observed after COVID-19 vaccination.
>
> The US Centers for Disease Control and Prevention (CDC) vaccine committee reported on June 23, 2021, a possible association between mRNA COVID-19 vaccines and myocarditis, primarily in younger male individuals, within a few days after the second vaccination, at an

incidence of about 4.8 cases per 1 million.

This new study shows a similar pattern, although at higher incidence, suggesting mRNA COVID-19 vaccine adverse event underreporting."

[274] ***Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military***
JAMA Cardiology
Jay Montgomery, Margaret Ryan, Renata Engler, *et al*.
June 29, 2021
https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601

"**Conclusions and Relevance**: In this case series, myocarditis occurred in previously healthy military patients with similar clinical presentations following receipt of an mRNA COVID-19 vaccine. Further surveillance and evaluation of this adverse event following immunization is warranted. Potential for rare vaccine-related adverse events must be considered in the context of the well-established risk of morbidity, including cardiac injury, following COVID-19 infection."

[275] ***COVID-19 Vaccine Safety Technical (VaST) Work Group***
Centers for Disease Control and Prevention (CDC)
Grace M. Lee and Robert H. Hopkins
June 23, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/04-COVID-Lee-508.pdf

"VaST Discussion and Interpretation:

- Data available to date suggest likely association of myocarditis with mRNA vaccination in adolescents and young adults.
- Clinical presentation of myocarditis cases following vaccination has been distinct, occurring most often within one week after dose 2, with chest pain as the most common.
- Further data are being compiled to understand potential risk factors, optimal management strategies, and long-term outcomes."

[276] ***COVID-19 Vaccine safety updates - Advisory Committee on Immunization Practices (ACIP)***
Centers for Disease Control and Prevention (CDC)
Grace M. Lee and Robert H. Hopkins
June 23, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf

Slide 28: "Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)"

Compares the expected vs. observed number of myocarditis or pericarditis events occurring within the first 6 days following the second dose of an mRNA inoculation.

- For males 12-17 years of age, the expected number of events was 0-4, but the **observed number** was **128**.
- For males 18-24 years of age, the expected number of events was 1-8, but the **observed number** was **219**.

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)

	Females			Males		
Age groups	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	2,189,726	0–2	19	2,039,871	0–4	128
18–24 yrs	5,237,262	1–6	23	4,337,287	1–8	219
25–29 yrs	4,151,975	0–5	7	3,625,574	1–7	59
30–39 yrs	9,356,296	2–18	11	8,311,301	2–16	61
40–49 yrs	9,927,773	2–19	18	8,577,766	2–16	34
50–64 yrs	18,696,450	4–36	18	16,255,927	3–31	18
65+ yrs	21,708,975	4–42	10	18,041,547	3–35	11
Not reported	—	—	1	—	—	8

CDC

* Assumes a 7-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 6 after vaccination)

† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

[277] **ADDED since 10/14/2021**
Myocarditis
Society of Cardiovascular Angiography and Interventions (SCAI)
January 11, 2015
http://www.secondscount.org/pediatric-center/pediatric-detail?cid=d0c36202-3ca1-4ea3-9d39-1525b56a0a58#.YYmMai-B1aF

"If myocarditis is caused by a virus, it may improve on its own. Medications may help the heart undergo this healing process. If the myocarditis improves, the child can lead a normal life thereafter. It is believed that about one-third of patients with myocarditis get better, one-third stay the same with reduced heart function, and **the condition severely deteriorates in about one-third of patients** [*emphasis added*]."

[278] ***Myocarditis - Early Biopsy Allows for Tailored Regenerative Treatment***
Deutsches Ärzteblatt International
U. Kuhl and H. Schultheiss
May 18, 2012
https://www.aerzteblatt.de/int/archive/article/125908

"**Prognosis**: … Acute myocarditis mostly does not sufficiently respond to symptomatic medication for heart failure, and mortality is high in spite of treatment. The long-term disease course depends on the pathogen, the extent and type of inflammation, and the initial injury to the myocardium. Focal borderline myocarditis often undergoes spontaneous clinical healing if no serious heart failure developed initially. The early mortality of fulminant lymphocytic

myocarditis requiring intensive care is in excess of 40% in the first 4 weeks. Untreated giant cell and eosinophilic myocarditis also have an extremely poor prognosis, with 4 year survival rates of less than 20%. Granulomatous necrotizing myocarditis is lethal if overlooked and untreated. Non-fulminant active myocarditis has a **mortality rate of 25% to 56% within 3 to 10 years**, owing to progressive heart failure and sudden cardiac death [*emphasis added*], especially if symptomatic heart failure manifests early on. In addition to impaired left ventricular (LV) and right ventricular (RV) function, virus persistence, chronic inflammation, and cardiodepressive autoantibodies are independent predictors of a poor prognosis."

Irregular Menstruation and Related Concerns

[279] **UPDATED since 10/14/2021**
#Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)
Pfizer, Inc.
Revised October 29, 2021
https://scdhec.gov/sites/default/files/media/document/Fact%20Sheet%20for%20Health%20Care%20Providers%20Administering%20Vaccine.pdf

"**11.1 Pregnancy – Risk Summary**: … Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are **insufficient to inform vaccine-associated risks in pregnancy** [*emphasis added*].

11.2 Lactation – Risk Summary: Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion."

[280] ***My Cycle Story: A Research Study***
https://mycyclestory.com/

"Clinical Trials Did not Study COVID-19 Vaccine Effects on Women's Reproductive Systems

There have also been reports of reactions from women who have NOT received the COVID-19 Vaccine. We are studying both.

We're an independent research group that is going to collect as much data as possible so that we can learn more about what's going on with Women's Cycles. With this information we will be able to share it with researchers, doctors, scientists and more to help discover possible causation and maybe even solutions."

Note: The citations below are presented in reverse, chronological order.

[281] **ADDED since 10/14/2021**
Spontaneous Abortions and Policies on COVID-19 mRNA Vaccine Use During Pregnancy
Institute for Pure and Applied Knowledge (IPAK)
Aleisha R. Brock and Simon Thornley
November 2021
https://www.thelastamericanvagabond.com/wp-content/uploads/2021/10/21-11-Brock-Thornley.pdf

"**Abstract**: … The use of mRNA vaccines in pregnancy is now generally considered safe for protection against COVID-19 in countries such as New Zealand, USA, and Australia. However, the influential CDC-sponsored article by Shimabukuro et al. (2021) used to support this idea, on

closer inspection, provides little assurance, particularly for those exposed in early pregnancy. The study presents falsely reassuring statistics related to the risk of spontaneous abortion in early pregnancy, since the majority of women in the calculation were exposed to the mRNA product after the outcome period was defined (20 weeks' gestation).

In this article, we draw attention to these errors and recalculate the risk of this outcome based on the cohort that was exposed to the vaccine before 20 weeks' gestation. Our re-analysis indicates a **cumulative incidence of spontaneous abortion 7 to 8 times higher** than the original authors' results ($p < 0.001$) and the typical average for pregnancy loss during this time period [*emphasis added*]. In light of these findings, key policy decisions have been made using unreliable and questionable data. We conclude that the claims made using these data on the safety of exposure of women in early pregnancy to mRNA-based vaccines to prevent COVID-19 are unwarranted and recommend that those policy decisions be revisited."

[282] ***Why didn't doctors listen to women about the link between Covid vaccines and periods?***
The Telegraph
Caroline Criado-Perez
September 17, 2021
https://www.msn.com/en-ph/health/medical/why-didnt-doctors-listen-to-women-about-the-link-between-covid-vaccines-and-periods/ar-AAOxleX

"This week, a study in the BMJ revealed that almost 35,000 British women have reported that following their vaccination against Covid, they have experienced more painful and/or irregular periods. A month later, they were back to normal…

This study is not the first we've heard of period disruption being linked to the jab. Ever since the vaccine roll-out began women have been all over social media, talking about how the vaccine seemed to have an impact on their menstrual cycle.

For most of these women, their vaccine shot was followed by a late period or a particularly heavy period. Other women experienced breakthrough bleeding (when you bleed outside of your period), some women whose contraception meant they had not had a period for years suddenly had to rush out for tampons. All of these women came to social media for advice or reassurance. But until this study, there has been little on offer, highlighting how little anyone has thought to consider the chance of a connection…

As with most clinical studies, the **Covid-19 vaccine trials did not investigate menstrual cycle effects** – in fact, in many trials women are wholesale excluded because of potential menstrual cycle effects [*emphasis added*]…

[E]nough women have now reported menstrual cycle effects that the issue has become impossible to ignore: the US National Institute of Health (NIH) has now allocated $1.67 million to research a possible link between COVID-19 vaccines and the menstrual cycle, as well as how long any impact might last. To put this in context, the NIH has to date spent almost $4.9 billion on COVID-19 research."

[283] ***Menstrual changes after covid-19 vaccination***
British Medical Journal
Victoria Male
September 16, 2021
https://www.bmj.com/content/374/bmj.n2211

> "Changes to periods and unexpected vaginal bleeding are not listed, but primary care clinicians and those working in reproductive health are increasingly approached by people who have experienced these events shortly after vaccination. **More than 30 000 reports of these events** had been made to MHRA's yellow card surveillance scheme for adverse drug reactions by 2 September 2021, across all covid-19 vaccines currently offered [*emphasis added*]…
>
> We are still awaiting definitive evidence, but in the interim how should clinicians counsel those who have experienced these effects? Initially, they should be encouraged to report any changes to periods or unexpected vaginal bleeding to the MHRA's yellow card scheme…
>
> One important lesson is that the effects of medical interventions on menstruation should not be an afterthought in future research."

[284] ***People said the covid vaccine affected their periods. Now more than $1.6 million will go into researching it.***
The Lily
Julianne McShane
September 7, 2021
https://www.thelily.com/people-said-the-covid-vaccine-affected-their-periods-now-more-than-16-million-will-go-into-researching-it/

> "The National Institutes of Health awarded funding to researchers at five institutions to study possible links…
>
> 'Our goal is to provide menstruating people with information, mainly as to what to expect, because I think that was the biggest issue: Nobody expected it to affect the menstrual system, because the information wasn't being collected in the early vaccine studies,' said Bianchi [*NIH*], who credited The Lily's early coverage of the issue, in April, with first making her and her staff aware of it…
>
> The NIH funding 'signifies that they're recognizing that there's an important gap in our understanding of how vaccines influence menstrual health and ultimately reproductive health,' according to Leslie Farland, an assistant professor in the department of epidemiology and biostatistics at the University of Arizona's College of Public Health.
>
> Earlier this year, a number of women and menstruators took to Facebook groups and Reddit threads to share their accounts of their post-vaccination periods. A Twitter thread authored by Kate Clancy, an associate professor of anthropology who studies reproductive justice at the University of Illinois, attracted **more than 1,000 responses from menstruators about how their cycles were altered following their vaccinations** [*emphasis added*] — another source of information that Bianchi said was crucial in shaping the agency's understanding of the prevalence of the issue."

[285] **Press briefing (video): Remarks by Dr. Anthony Fauci**
White House COVID-19 Response Team
August 31, 2021
https://youtu.be/ObhlcO5IZqw?t=595

> **Fauci (starting at 9:55)**: "I would like to update you now on COVID-19 vaccination and pregnancy. It is very clear now, as I'll show you in a moment, that there are severe, adverse outcomes for mother and baby during COVID-19 infection. Therefore, it is extremely important for pregnant women and women planning to get pregnant to get vaccinated."

Adverse Reactions - Other

[286] ***VAERS COVID Vaccine Data***
OpenVAERS
Total numbers for adverse events reported to VAERS by category (e.g., anaphylaxis, Bell's palsy, Guillain-Barré syndrome, thrombocytopenia, etc.).
https://www.openvaers.com/covid-data

[287] ***Case Series Drug Analysis Print - COVID-19 mRNA Pfizer- BioNTech vaccine analysis print***
Medicines and Healthcare products Regulatory Agency
Report Run Date: August 26, 2021
Total numbers for adverse events reported to the United Kingdom's 'Yellow-Card System" for the Pfizer vaccine (tabulated by category).
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012207/COVID-19_mRNA_Pfizer-_BioNTech_vaccine_analysis_print_final.pdf

[288] **C19 Vax Reactions**
https://www.c19vaxreactions.com/
Letter to CDC & FDA, May 24, 2021:
https://www.c19vaxreactions.com/uploads/1/3/7/7/137732232/letter_initials_2.pdf
Testimonials: https://www.c19vaxreactions.com/real-testimonials.html
Q&A video interviews: https://www.c19vaxreactions.com/qa.html

> "Who we are:
>
> - We are a large and ever growing group of Americans who were previously healthy and have been seriously injured by the COVID vaccines (Pfizer, Moderna, J&J as well as Astra Zeneca in the clinical trial stage in the United States).
> - We are pro-vaccine, pro-science and were excited for the opportunity to be vaccinated and to do our part in helping to end the pandemic.
> - We are completely independent of any other organization."

[289] **Interviews with Injured Healthcare Workers**
April 30, 2021: https://www.bitchute.com/video/X0fov5PnPMwO/
August 2, 2021: https://www.bitchute.com/video/8I4NlpjAsaL3/

[290] **Other video testimonials of injury**
https://1000covidstories.com/
http://seethetruth.club/evidence-of-vaccine-victims-in-video/
Israel: https://www.youtube.com/watch?v=S4BpEr8gztU

[291] **ADDED since 10/14/2021**
How concerned are you about adverse events related to the vaccines? Tell us what you think – your expectations and concerns.
Medscape
https://www.medscape.com/sites/public/covid-19/vaccine-insights/how-concerned-are-you-about-vaccine-related-adverse-events
Note: Medscape post with more than 2,700 comments by medical professionals.

> "Commenting is limited to medical professionals."

[292] **Video (2h38m): Press conference - *Cause of Death after COVID-19 Vaccination and Undeclared Components of the COVID-19 Vaccines***
Pathological Institute (Reutlingen, Germany)
September 20, 2021
https://pathologie-konferenz.de/en/

Note: The citations below are presented in reverse, chronological order.

[293] **ADDED since 10/14/2021**
New VAERS analysis reveals hundreds of serious adverse events that the CDC and FDA never told us about
Steve Kirsch and Albert Benavides
November 9, 2021
https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds
Team of Vaccine Safety Experts: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

> For excerpts, see [231]

[294] **ADDED since 10/14/2021**
Legal Letter on Behalf of Physicians Regarding Covid-19 Vaccine Injuries (to heads of the DHHS, CDC, and FDA)
Siri & Glimstad LLP (attorneys)
Aaron Siri and Elizabeth A. Brehm
October 27, 2021
Note: The letter is presented with eleven (11) written statements from physicians detailing their accounts of harms wrought by COVID-19 inoculations, as witnessed in their respective practices.
https://www.sirillp.com/wp-content/uploads/2021/10/Letter-on-Behalf-of-Physicians-Regarding-Covid-19-Vaccine-Injuri-fee0f6941b97b076398c4e8607f573b0.pdf

> "We write with the utmost urgency on behalf of physicians from across this country -- see the 11 declarations attached -- whose **firsthand reports of serious and fatal injuries from COVID-19 vaccines** to your public health agencies have not been taken seriously and remain unaddressed [*emphasis added*].

A. Injuries from Covid-19 Vaccines

The harms they have been reporting are not redness at the injection site. The harms are all serious. As detailed in the appended declarations signed by these physicians, they include serious cases of:

> small fiber neuropathy; loss of temperature sensation in extremities; constant shakiness to muscles; lesion on spinal cord; paresthesias; tachycardia; fatigue; heat intolerance; gastric paresis; joint pain; subjective fevers; brain fog; tremors; twitching; internal vibrations; tinnitus; blurred vision; dizziness and imbalance; headaches; balance difficulties; burning sensations; menstrual cycle irregularities; hair loss; bladder incontinence; cognitive impairment; persistent numbness and tingling in hands; constipation; irritability; weakness

Each of these harms has been confirmed, based on the clinical judgment of the patient's treating physician, as being caused by a Covid-19 vaccine.

These physicians and their patients all supported the Covid-19 vaccine. **Almost all of them are fully vaccinated** [*emphasis added*]. It is understandable that you would not want to admit that a product you have authorized, approved, and widely promoted caused harm, but we implore you to have the moral fortitude to rise above your personal interests…

These devastating injuries are detailed in the attached and, as noted, each has been confirmed, based on the clinical judgment of the patient's treating physician, as being caused by a Covid-19 vaccine. It is statistically improbable that any one physician should see numerous serious Covid-19 vaccine injuries if the safety claims regarding this vaccine were true. Yet, in just the appended declarations, there are 4 physicians that have collectively treated more than 18 patients with a serious Covid-19 vaccine injury."

[295] **ADDED since 10/14/2021**

Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines

Cell Discovery – Nature (Tongji University, Shanghai)
Jiping Liu, Junbang Wang, *et al*.
October 26, 2021
https://www.nature.com/articles/s41421-021-00329-3

"**Abstract**: Large-scale COVID-19 vaccinations are currently underway in many countries in response to the COVID-19 pandemic. Here, we report, besides generation of neutralizing antibodies, consistent alterations in hemoglobin A1c, serum sodium and potassium levels, coagulation profiles, and renal functions in healthy volunteers after vaccination with an inactivated SARS-CoV-2 vaccine. Similar changes had also been reported in COVID-19 patients, suggesting that vaccination mimicked an infection. Single-cell mRNA sequencing (scRNA-seq) of peripheral blood mononuclear cells (PBMCs) before and 28 days after the first inoculation also revealed consistent alterations in gene expression of many different immune cell types. Reduction of CD8+ T cells and increase in classic monocyte contents were exemplary. Moreover, scRNA-seq revealed increased NF-κB signaling and reduced type I interferon responses, which were confirmed by biological assays and also had been reported to occur after SARS-CoV-2 infection with aggravating symptoms. Altogether, our study recommends additional caution when vaccinating people with pre-existing clinical conditions,

including diabetes, electrolyte imbalances, renal dysfunction, and coagulation disorders…

Discussion: This is a comprehensive investigation of the pathophysiological changes, including detailed immunological alterations in people after COVID-19 vaccination. Results indicated that vaccination, in addition to stimulating the generation of neutralizing antibodies, also influenced various health indicators including those related to diabetes, renal dysfunction, cholesterol metabolism, coagulation problems, electrolyte imbalance, **in a way as if the volunteers experienced an infection**. scRNA-seq of PBMCs from volunteers before and after vaccination revealed **dramatic changes in immune cell gene expression** [*emphasis added*], not only echoing some of the clinical laboratory measures but also suggestive of increased NF-κB-related inflammatory responses, which turned out to be mainly taking place in classical monocytes. Vaccination also increased classical monocyte contents. Moreover, the gene set positively contributing to MVS scores, also known to be associated with severe symptom development, was highly expressed in monocytes. Type I interferon (IFN-α/β) responses, supposedly beneficial against COVID-19, were downregulated after vaccination. In addition, the negative MVS genes were highly expressed in lymphocytes (T, B, and NK cells), yet showed reduced expression after vaccination. Together, these data suggested that after vaccination, at least by day 28, other than generation of neutralizing antibodies, **people's immune systems, including those of lymphocytes and monocytes,** were perhaps in a **more vulnerable state** [*emphasis added*]…

Our study postulates that it is imperative to consider the potential long-term impact of vaccination to certain medical conditions or to general human health."

[296] **ADDED since 10/14/2021**

Video (2m): Interview with Dr. Ryan Cole, pathologist

August 25, 2021

https://twitter.com/ToTheLifeboats/status/1430589141344034816

Cole: "What we're seeing in the laboratory after people get these shots, we're seeing a very concerning, locked-in, low profile of these important killer T cells that you want in your body… **What we're seeing is a drop in your killer T cells**, your CD8 cells. And what do CD8 cells do? They keep all other viruses in check [*emphasis added*].

What am I seeing in the laboratory? I'm seeing an uptick of herpes family viruses, … I'm seeing shingles, I'm seeing mono, I'm seeing a huge uptick in human papilloma virus in the cervical biopsies and the cervical pap smears in women…

We're literally weakening the immune systems of these individuals. Now, most concerning of all, is there's a pattern of the types of immune cells in the body that keep cancer in check. Well, since January 1 in the laboratory, I've seen a **20x of endometrial cancers** over what I see on an annual basis [*emphasis added*]. A 20x increase. Not exaggerating at all because I look at my numbers, year over year…

I'm seeing invasive melanomas in younger patients. Normally we catch those early and they're thin melanomas. I'm seeing thick melanomas skyrocketing in the past month or two.

I'm already seeing the early signals and we are modifying the immune system to a weakened state. Great study out of Germany that looked at these profiles on young individuals, after the Pfizer [shot]…"

[297] ***COVID-19 Vaccine Associated Parkinson's Disease, A Prion Disease Signal in the UK Yellow Card Adverse Event Database***
Journal of Medical-Clinical Research & Reviews
J. Bart Classen
July 18, 2021
https://scivisionpub.com/pdfs/covid19-vaccine-associated-parkinsons-disease-a-prion-disease-signal-in-the-uk-yellow-card-adverse-event-database-1746.pdf

> "**Abstract**: Many have argued that SARS-CoV-2 spike protein and its mRNA sequence, found in all COVID-19 vaccines, are priongenic. The UK's Yellow Card database of COVID-19 vaccine adverse event reports was evaluated for signals consistent with a pending epidemic of COVID vaccine induced prion disease. Adverse event reaction rates from AstraZeneca's vaccine were compared to adverse event rates for Pfizer's COVID vaccines. The vaccines employ different technologies allowing for potential differences in adverse event rates but allowing each to serve as a control group for the other. The analysis showed a highly statistically significant and clinically relevant (2.6-fold) increase in Parkinson's disease, a prion disease, in the AstraZeneca adverse reaction reports compared to the Pfizer vaccine adverse reaction reports (p= 0.000024)..."

[298] **ADDED since 10/14/2021**
Letter to the Editor: ***Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination***
Journal of Infection (James Cook University, UK)
Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, and David R. Chadwick
April 22, 2021
https://www.journalofinfection.com/article/S0163-4453(21)00277-2/fulltext

> "**Findings**: In a survey-based observational study, healthcare workers in the United Kingdom reported AEs [*adverse events*] experienced after their first dose of BNT162b2/Pfizer vaccine. Prior COVID-19 infection, but not Long-COVID, were associated with increased risk of self-reported AEs including lymphadenopathy post-vaccination."

[299] ***Stage III Hypertension in Patients After mRNA-Based SARS-CoV-2 Vaccination***
Hypertension (American Heart Association)
Sylvain Meylan, Francoise Livio, *et al*.
March 25, 2021
https://www.ahajournals.org/doi/10.1161/HYPERTENSIONAHA.121.17316

> "We report a case series of 9 patients [*in Lausanne, Switzerland*] with stage III hypertension documented within minutes of vaccination during the first 30 days, of which 8 were symptomatic…
>
> Our case series suggests that a fraction of hypertensive patients may react with symptomatically significant increases in both systolic and diastolic blood pressure. A stress response is likely in view of the public debate, in addition to pain response and white coat effect—the latter being associated with age and female sex.2 However, the relatively low heart rate (median, 73 bpm) may soften this hypothesis…
>
> The mRNA vaccines have received intense scrutiny for immediate hypersensitivity reactions in the wake of an initial report signaling 21 cases of anaphylaxis.3 Hypertension, on the contrary,

has not been mentioned explicitly as an adverse event in both safety/immunogenicity trials. However, both phase I/II and III clinical trials for the mRNA vaccines included predominantly younger populations with a mean and median age of 31 and 52 years for the BNT162b2 vaccine4 and 31 and 51 for the mRNA-1273 vaccine.5 Although more data are needed to understand the extent and the mechanism of hypertension after mRNA-based vaccination, our data indicate that in elderly patients with a history of hypertension or significant prior cardiovascular comorbidities, prevaccination control of blood pressure and post-vaccination monitoring, including symptom screening, may be warranted."

[300] **ADDED since 10/14/2021**

Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey

Life journal (University of Manchester, UK)
Alexander G. Mathioudakis, Murad Ghrew, *et al*.
March 17, 2021
https://www.mdpi.com/2075-1729/11/3/249

"**Abstract**: An online survey was conducted to compare the safety, tolerability and reactogenicity of available COVID-19 vaccines in different recipient groups… A prior COVID-19 infection was associated with an increased risk of any side effect… It was also associated with an **increased risk of severe side effects leading to hospital care** [*emphasis added*]."

[301] **ADDED since 10/14/2021**

Research Letter: *Acute Allergic Reactions to mRNA COVID-19 Vaccines*

JAMA (Massachusetts General Hospital)
Kimberly G. Blumenthal, Lacey B. Robinson, *et al*.
March 8, 2021
https://jamanetwork.com/journals/jama/fullarticle/2777417

"**Results**: Of 64 900 employees who received their first dose of a COVID-19 vaccine... Acute allergic reactions were reported by **1365 employees overall (2.10%** [95% CI, 1.99%-2.22%]), more frequently with the Moderna vaccine compared with Pfizer-BioNTech (2.20%… vs 1.95%)… Anaphylaxis was confirmed in 16 employees (0.025%)"

Long-Term Concerns about COVID-19 Inoculations

Antibody Dependent Enhancement (ADE)

Note: The citations below are presented in reverse, chronological order.

[302] **Video (9m): *Expert testimony of Dr. Christina Parks, PhD***
Michigan House of Representatives hearing
August 25, 2021
https://rumble.com/vloa7j-must-watch-expert-testimony-on-mandatory-vaccination-and-medical-coercion.html

> **Parks (starting at 5:05)**: "Vaccines are made to a specific variant, and when that variant mutates, the vaccine no longer recognizes it. So it's like you're seeing a completely new virus. And because that's so, you actually get more severe symptoms when you're vaccinated against one variant, and then it mutates, and then your body sees the other variant. So there's the potential, and the science shows, that in fact with the flu, if you get vaccinated in multiple years, you are more likely to get severe disease, you are more likely to have more viral replication, and you are more likely to be hospitalized...
>
> We are seeing the same thing in COVID with the delta variant. And so we are mandating that people get a vaccine that could actually make them more sick when they're exposed to the virus? In fact, this week, a paper came out, and what it showed is that with this delta variant, when you're vaccinated, your body makes antibodies that are supposed to neutralize the virus. But they were supposed to neutralize the old variant. When they see this new variant, what they're doing is, the **antibodies are actually taking the virus and helping it infect the cells** [*emphasis added*]."

[303] ***Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam***
The Lancet
Nguyen Van Vinh Chau, Nghiem My Ngoc, *et al*.
August 10, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

> "**Methods**: We studied breakthrough infections among healthcare workers of a major infectious diseases hospital in Vietnam. We collected demographics, vaccination history and results of PCR diagnosis alongside clinical data. We measured SARS-CoV-2 (neutralizing) antibodies at diagnosis, and at week 1, 2 and 3 after diagnosis. We sequenced the viruses using ARTIC protocol.
>
> **Findings**: … Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases infected with old strains detected between March-April 2020…
>
> **Interpretation**: Breakthrough Delta variant infections are associated with **high viral loads**, prolonged PCR positivity, and **low levels of vaccine-induced neutralizing antibodies**, explaining the transmission between the vaccinated people [*emphasis added*].."

[304] **Letter to the Editor: *Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination?***
Journal of Infection
Nouara Yahi, Henri Chahinian, and Jacques Fantini
August 9, 2021
https://www.journalofinfection.com/article/S0163-4453(21)00392-3/fulltext

> "In conclusion, ADE may occur in people receiving vaccines based on the original Wuhan strain spike sequence (either mRNA or viral vectors) and then exposed to a Delta variant… [T]he possibility of ADE should be further investigated as it may represent a potential risk for mass vaccination during the current Delta variant pandemic."

[305] **Video (10m): Interview with Dr. Robert Malone, inventor of some important mRNA-vaccine technology**
July 28, 2021
https://rumble.com/vkfz1v-the-vaccine-causes-the-virus-to-be-more-dangerous.html

> **Malone**: "The escaped mutants that are escaping vaccine-selected pressure are most likely developing in the people that have been vaccinated, not in the unvaccinated… What you heard Fauci say is the nasal titers are the same in vaccine recipients and unvaccinated… What NBC News dropped yesterday was the statement sourced from an unnamed government official that the titers in the vaccinated are actually higher than in the unvaccinated… This is precisely what one would see if Antibody Dependent Enhancement was happening… (which) is where the vaccine causes the virus to become more infectious than would happen in the absence of vaccination, would cause the virus to replicate at higher levels than in the absence of infection. This is the vaccinologists' worst nightmare… I don't mean to sound alarmist, but what seems to be rolling out is the worst-case scenario where a vaccine (Pfizer), in the waning phase, is causing the virus to replicate more efficiently than it would otherwise, which is what we call Antibody Dependent Enhancement… and people have been warning about this since the outset of this rushed vaccine campaign."

[306] **Video (1m): Commentary from Dr. David Bauer of the Francis Crick Institute**
June 3, 2021
https://www.bitchute.com/video/KP1FfkARcoet/

> **Bauer**: "So the key message from our findings is that we found that recipients of the Pfizer vaccine, those who have had two doses, have about **5-6 fold lower amounts of neutralizing antibodies** [*emphasis added*]. Now these are the sort of 'gold-standard,' private-security antibodies of your immune system, which block the virus from getting into your cells in the first place. So we found that that's less for people with two doses. We also found that for people with only one dose of the Pfizer jab, that they are less likely to have high levels of these antibodies in their blood. And perhaps most importantly for all of us going forward is that we see that the older you are, the lower your levels are likely to be. And the time since you had your second jab, as time goes on, the lower your levels are also likely to be. So that's telling us that we're probably going to be needing to prioritize boosters for more older and more vulnerable people, coming up soon, especially if this new variant spreads."

[307] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Authorea
Roxana Bruno, Peter A. Mccullough, *et al*.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

"**Introduction**: … 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. 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."

[308] ***An infectivity-enhancing site on the SARS-CoV-2 spike protein targeted by antibodies***
Cell
Yafei Liu, Wai Tuck Soh, *et al*.
May 24, 2021
https://www.cell.com/cell/fulltext/S0092-8674(21)00662-0

"**Discussion**: Antibody-dependent enhancement (ADE) of viral infection has been reported for some viruses such as dengue virus (Wan et al., 2020), feline infectious peritonitis virus (FIPV) (Hohdatsu et al., 1998; Vennema et al., 1990), severe acute respiratory syndrome coronavirus (SARS) (Jaume et al., 2011; Kam et al., 2007), and Middle East respiratory syndrome (MERS) (Wan et al., 2020). Binding of the Fc receptor to anti-virus antibodies complexed with virions has been thought to be involved in ADE (Wang et al., 2017). However, Fc-receptor-mediated ADE is restricted to the infection of Fc-receptor-expressing cells such as monocytes or macrophages. In this study, we found a non-canonical, Fc-receptor-independent ADE mechanism. The antibodies against a specific site on the NTD of the SARS-CoV-2 spike protein were found to directly augment the binding of ACE2 to the spike protein, consequently increasing SARS-CoV-2 infectivity."

[309] ***Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19***
International Journal of Vaccine Theory, Practice, and Research
Stephanie Seneff and Greg Nigh
May 10, 2021
https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF~1.PDF

"**mRNA Vaccines, Spike Proteins, and Antibody-Dependent Enhancement (ADE)**: … In an extended correspondence published in Nature Biotechnology, Eroshenko et al. offer a comprehensive review of evidence suggesting that **ADE could become manifest with any vaccinations employed against SARS-CoV-2** [*emphasis added*]. Importantly, they note that

ADE has been observed with coronavirus vaccines tested in both in vitro and in vivo models (Eroshenko et al., 2020). Others have warned about the same possibility with SARS-CoV-2 vaccines. A theory for how ADE might occur in the case of a SARS-CoV-2 vaccine suggests that non-neutralizing antibodies form immune complexes with viral antigens to provoke excessive secretion of pro-inflammatory cytokines, and, in the extreme case, a cytokine storm causing widespread local tissue damage (Lee et al., 2020). One extensive review of ADE potentially associated with SARS-CoV-2 vaccines noted, "At present, there are no known clinical findings, immunological assays or biomarkers that can differentiate any severe viral infection from immune-enhanced disease, whether by measuring antibodies, T cells or intrinsic host responses" (Arvin et al. 2020; Liu et al.,2019)…

It has been reported that all three US vaccine manufacturers – Moderna, Pfizer, and Johnson & Johnson – are working to develop booster shots (Zaman 2021).With tens of millions of young adults and even children now with vaccine-induced coronavirus spike protein antibodies, there exists the possibility of triggering ADE related to either future SARS-CoV-2 infection or booster injection among this younger population. Time will tell."

[310] ***Doctors and Scientists Write to the European Medicines Agency, Warning of COVID-19 Vaccine Dangers for a Third Time***
Doctors for COVID Ethics
April 24, 2021
https://doctors4covidethics.org/doctors-and-scientists-write-to-the-european-medicines-agency-warning-of-covid-19-vaccine-dangers-for-a-third-time/
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"1e. Furthermore, long term adverse effects, in particular the danger of immune dependant [*sic*] enhancement of disease and adverse effects of subsequent vaccinations are impossible to predict. The European Medicines Agency, as the regulator re. vaccines for almost 450 million people across 27 European Union member states, must inform the public and the relevant authorities of this profoundly important issue."

[311] ***COVID-19 Vaccine: Critical Questions with Complicated Answers***
Biomolecules & Therapeutics
Mohammad Faisal Haidere, Zubair Ahmed Ratan, *et al*.
January 1, 2021
https://www.biomolther.org/journal/view.html?volume=29&number=1&spage=1&year=2021

"[E]xtreme caution must be taken to scrutinize backfire-effects i.e. the undesirable adverse effects (Table 2). One such dangerous backfire is vaccine-induced enhancement, which has been a major bottleneck in the development of certain corona-, flavi-, lenti-, and paramyxovirus vaccines. Here, antibody-dependent enhancement (ADE) performs a key role (Huisman et al., 2009)."

[312] ***FDA Briefing Document - Moderna COVID-19 Vaccine***
Food and Drug Administration (FDA)
December 17, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_2b26a980a8d44de89cd21c42af406565.pdf

"**Vaccine-enhanced disease**. Available data do not indicate a risk of vaccine-enhanced

disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, **risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown** and needs to be evaluated further in ongoing clinical trials and in observational studies [*emphasis added*] that could be conducted following authorization and/or licensure."

[313] **FDA Briefing Document: *Vaccines and Related Biological Products Advisory Committee Meeting***
Food and Drug Administration (FDA)
December 10, 2020
https://www.fda.gov/media/144245/download

"**8.4. Unknown Risks/Data Gaps... Vaccine-enhanced disease** - Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure."

[314] ***Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease***
International Journal of Clinical Practice
Timothy Cardazo and Ronald Veazey
December 4, 2020
https://pubmed.ncbi.nlm.nih.gov/33113270/

"**Results of the study**: COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE). This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.

Conclusions drawn from the study and clinical implications: The **specific and significant COVID-19 risk of ADE** should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval [*emphasis added*], in order to meet the medical ethics standard of patient comprehension for informed consent."

[315] ***Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies***
Nature Microbiology
Wen Shi Lee, Adam K. Wheatley, Stephen J. Kent, and Brandon J. DeKosky
September 9, 2020
https://www.nature.com/articles/s41564-020-00789-5

> "**Abstract**: … Data from the study of SARS-CoV and other respiratory viruses suggest that anti-SARS-CoV-2 antibodies could exacerbate COVID-19 through antibody-dependent enhancement (ADE). Previous respiratory syncytial virus and dengue virus vaccine studies revealed human clinical safety risks related to ADE, resulting in failed vaccine trials…
>
> **Risk of ERD for SARS-CoV-2 vaccines**: Safety concerns for SARS-CoV-2 vaccines were initially fuelled (sic) by mouse studies that showed enhanced immunopathology, or ERD, in animals vaccinated with SARS-CoV following viral challenge…
>
> Should it occur, ERD caused by human vaccines will first be observed in larger phase II and/or phase III efficacy trials that have sufficient infection events for statistical comparisons between the immunized and placebo control study arms…
>
> **Conclusion**: ADE has been observed in SARS, MERS and other human respiratory virus infections including RSV and measles, which suggests a real risk of ADE for SARS-CoV-2 vaccines and antibody-based interventions… Going forwards, it will be crucial to evaluate animal and clinical datasets for signs of ADE, and to balance ADE-related safety risks against intervention efficacy if clinical ADE is observed."

[316] **Correspondence: *Implications of antibody-dependent enhancement of infection for SARS-CoV-2 countermeasures***
Nature Biotechnology
Nikolai Eroshenko, Taylor Gill, Marianna K. Keaveney, George M. Church, Jose M. Trevejo, and Hannu Rajaniemi
June 5, 2020
https://www.nature.com/articles/s41587-020-0577-1

> "ADE has been observed with dengue virus, Zika virus, Ebola virus and, importantly in the context of COVID-19, coronaviruses (CoVs)… We believe that it is important to consider ADE in the context of efforts to develop countermeasures against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Indeed, data from previous CoV research strongly suggest that ADE may play a role in the virus's pathology…
>
> Although efficacy data on human CoV vaccines are lacking, results from preclinical models suggest that certain vaccine designs are more likely to induce ADE immune responses than others…
>
> In fact, preclinical studies employing various animals, including mice, hamsters, ferrets and macaques, provided evidence that SARS-CoV vaccines are capable of causing an ADE response…
>
> Although the development of vaccines and therapeutics for SARS-CoV-2 remains urgent, we must proceed with caution, using the full armory of vaccine and protein design tools at our disposal to rationally minimize the risk of ADE."

[317] **Science Committee hearing: Testimony of Dr. Peter Hotez**
US House of Representatives
March 5, 2020
https://www.c-span.org/video/?c4873497/user-clip-hotez-coronavirus-vaccine-safety-testimony

> Hotez: "One of the things we're not hearing a lot about is the unique, potential safety problem of coronavirus vaccines. This was first found in the early 1960s with the respiratory syncytial virus vaccines in children, and it was done here in Washington at NIH and the Children's National Medical Center, that some of those kids who got the vaccine actually did worse, and I believe there were two deaths as a consequence of that study. Because what happens with certain types of respiratory-virus vaccines, you get immunized and then when you get actually exposed to the virus, you get this kind of paradoxical, immune enhancement phenomenon… When we started developing coronavirus vaccines and our colleagues, we noticed in laboratory animals that they started to show some of the same immune pathology that resembled what had happened 50 years earlier. It was, 'Oh my god, this is going to be problematic.'… The clinical trials are not going to go quickly because of that immune enhancement."

[318] ***Viral-Induced Enhanced Disease Illness***
Frontiers in Microbiology
Maria K. Smatti, Asmaa A. Al Thani, and Hadi M. Yassine
December 5, 2018
Includes an overview of clinical studies for past SARS-CoV vaccines.
https://www.frontiersin.org/articles/10.3389/fmicb.2018.02991/full

> "**Abstract**: … Considering that antibody dependent enhancement (ADE) is a major obstacle in vaccine development, there are continued efforts to understand the underlying mechanisms through identification of the epitopes and antibodies responsible for disease enhancement or protection. This review discusses the recent findings on virally induced ADE, and highlights the potential mechanisms leading to this condition…
>
> **Coronaviruses**: … Several studies have investigated the mechanisms underlying SARS-CoV mediated ADE."

[319] ***Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus***
PLOS One
Chien-Te Tseng, Elena Sbrana, *et al*.
April 20, 2012
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0035421

> "**Results**: … All mice exhibited histopathologic changes in lungs two days after challenge including all animals vaccinated (Balb/C and C57BL/6) or given live virus, influenza vaccine, or PBS suggesting infection occurred in all. Histopathology seen in animals given one of the SARS-CoV vaccines was uniformly a Th2-type immunopathology with prominent eosinophil infiltration, confirmed with special eosinophil stains…
>
> **Conclusions**: These SARS-CoV vaccines all induced antibody and protection against infection with SARS-CoV. However, challenge of mice given any of the vaccines led to occurrence of Th2-type immunopathology suggesting hypersensitivity to SARS-CoV components was induced. Caution in proceeding to application of a SARS-CoV vaccine in humans is indicated…

Experiments: … Representative photo micrographs of lung sections from mice in this experiment two days after challenge with SARS-CoV are shown in figure 5. The pathologic changes were extensive and similar in all challenged groups (H & E stains). Perivascular and peribronchial inflammatory infiltrates were observed in most fields along with desquamation of the bronchial epithelium, collections of edema fluid, sloughed epithelial cells, inflammatory cells and cellular debris in the bronchial lumen. Large macrophages and swollen epithelial cells were seen near lobar and segmental bronchi, small bronchioles and alveolar ducts. Necrotizing vasculitis was prominent in medium and large blood vessels, involving vascular endothelial cells as well as the tunica media, and included lymphocytes, neutrophils, and eosinophils in cellular collections. Occasional multinucleated giant cells were also seen."

[320] ***A Double-Inactivated Severe Acute Respiratory Syndrome Coronavirus Vaccine Provides Incomplete Protection in Mice and Induces Increased Eosinophilic Proinflammatory Pulmonary Response upon Challenge***
Journal of Virology
Meagan Bolles, Damon Deming, *et al*.
November 3, 2011
https://journals.asm.org/doi/10.1128/JVI.06048-11

"**Discussion**: ... The development of vaccines or therapeutics for SARS-CoV is complicated by several challenges: the presence of a large heterogeneous zoonotic reservoir of related strains, the resistance of highly susceptible aged populations to vaccination, and potential **disease-enhancing complications** of the vaccine formulations [*emphasis added*]…

As shown here, a vaccine that appears protective in young animals is much less protective, and potentially pathogenic, in an aged-animal model…

In each of the experiments conducted here, immunization with the whole inactivated SARS vaccine induced increased inflammatory infiltrates and pulmonary eosinophilia upon subsequent challenge, demonstrating the potential for dangerous clinical complications. This is consistent with two prior studies of vaccine formulations incorporating SARS N, where N-specific immune responses resulted in enhanced eosinophilic immune pathology. This pathological signature is reminiscent of the two known human examples of vaccine-induced immunopathology, atypical measles and enhanced RSV. For both of these vaccine-induced immunopathologies, infection subsequent to vaccination resulted in failure to control viral replication, enhanced clinical disease, and a pathology characterized by increased complement deposition and inflammation, skewing toward Th2 responses, and eosinophilic influx…

The major conclusion that can be drawn from these studies is that although DIV SARS vaccines do elicit protection under optimal conditions (homologous challenge in immunocompetent individuals), more stringent challenges reveal likely failures. If DIV vaccine approaches are to be used for SARS in the future, efforts must be made to improve the quality and magnitude of the vaccine-induced immune response while limiting the vaccine's capacity to induce immune pathology."

[321] ***Anti-Severe Acute Respiratory Syndrome Coronavirus Spike Antibodies Trigger Infection of Human Immune Cells via a pH- and Cysteine Protease-Independent FcγR Pathway***
Journal of Virology
Martial Jaume, Ming S. Yip, *et al*.
October 2011
https://journals.asm.org/doi/10.1128/JVI.00671-11

> "**Abstract**: Public health measures successfully contained outbreaks of the severe acute respiratory syndrome coronavirus (SARS-CoV) infection. However, the precursor of the SARS-CoV remains in its natural bat reservoir, and reemergence of a human-adapted SARS-like coronavirus remains a plausible public health concern. Vaccination is a major strategy for containing resurgence of SARS in humans, and a number of vaccine candidates have been tested in experimental animal models. We previously reported that antibody elicited by a SARS-CoV vaccine candidate based on recombinant full-length Spike-protein trimers potentiated infection of human B cell lines despite eliciting *in vivo* a neutralizing and protective immune response in rodents. These observations prompted us to investigate the mechanisms underlying antibody-dependent enhancement (ADE) of SARS-CoV infection *in vitro*. We demonstrate here that anti-Spike immune serum, while inhibiting viral entry in a permissive cell line, potentiated infection of immune cells by SARS-CoV Spike-pseudotyped lentiviral particles, as well as replication-competent SARS coronavirus. Antibody-mediated infection was dependent on Fcγ receptor II but did not use the endosomal/lysosomal pathway utilized by angiotensin I converting enzyme 2 (ACE2), the accepted receptor for SARS-CoV. This suggests that **ADE of SARS-CoV utilizes a novel cell entry mechanism into immune cells**. Different SARS vaccine candidates elicit sera that differ in their capacity to induce ADE in immune cells despite their comparable potency to neutralize infection in ACE2-bearing cells. **Our results** suggest a novel mechanism by which SARS-CoV can enter target cells and **illustrate the potential pitfalls associated with immunization against it** [*emphasis added*]. These findings should prompt further investigations into SARS pathogenesis."

Viral Immune Escape (VIE)

Note: The citations below are presented in reverse, chronological order.

[322] **ADDED since 10/14/2021**
The spike protein of SARS-CoV-2 variant A.30 is heavily mutated and evades vaccine-induced antibodies with high efficiency
Cellular & Molecular Immunology (Nature)
Prerna Arora, Cheila Rocha, *et al*.
October 25, 2021
https://www.nature.com/articles/s41423-021-00779-5

> "In summary, A.30 exhibits a cell line preference not observed for other viral variants and efficiently evades neutralization by antibodies elicited by ChAdOx1 nCoV-19 [*Astrazeneca*] or BNT162b2 vaccination [*Pfizer*]… Notably, **robust entry into cell lines** was combined with **high resistance against antibodies** induced upon ChAdOx1 nCoV-19 or BNT162b2 vaccination [*emphasis added*]... Collectively, our results suggest that the SARS-CoV-2 variant A.30 can evade control by vaccine-induced antibodies and might show an increased capacity to enter cells in a cathepsin L-dependent manner, which might particularly aid in the extrapulmonary

spread. As a consequence, the potential spread of the A.30 variant warrants close monitoring."

[323] **Virtual meeting (video): *Vaccines and Related Biological Products Advisory Committee*, *remarks by Dr. Jessica Rose***
Food and Drug Administration (FDA)
September 17, 2021
https://youtu.be/WFph7-6t34M?t=14985

Rose (starting at 4:09:45): "Israel's one of the most injected countries, and it appears from this data that this represents a clear failure of these products to provide protective immunity against emerging variants and to prevent transmission, regardless of how many additional shots administered.

And this begs the question as to whether **these injection rollouts are driving the emergence of the new variants**. There's a clear and present danger of the emergence of variants of concern if we continue with these alleged booster shots [*emphasis added*]."

[324] ***Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California***
University of California, San Francisco
Venice Servellita, Mary-Kate Morris, *et al*.
August 25, 2021
https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v1.full-text

"**Abstract**: Associations between vaccine breakthrough cases and infection by SARS coronavirus 2 (SARS-CoV-2) variants have remained largely unexplored. Here we analyzed SARS-CoV-2 whole-genome sequences and viral loads from 1,373 persons with COVID-19 from the San Francisco Bay Area from February 1 to June 30, 2021, of which 125 (9.1%) were vaccine breakthrough infections. Fully vaccinated were more likely than unvaccinated persons to be infected by variants carrying mutations associated with decreased antibody neutralization (L452R, L452Q, E484K, and/or F490S) (78% versus 48%, p = 1.96e-08), but not by those associated with increased infectivity (L452R and/or N501Y) (85% versus 77%, p = 0.092). Differences in viral loads were non-significant between unvaccinated and fully vaccinated persons overall (p = 0.99) and according to lineage (p = 0.09 – 0.78)… In 5 cases with available longitudinal samples for serologic analyses, vaccine breakthrough infections were found to be associated with **low or undetectable neutralizing antibody levels** attributable to immunocompromised state or infection by an antibody-resistant lineage [*emphasis added*]. These findings suggest that vaccine breakthrough cases are preferentially caused by circulating antibody-resistant SARS-CoV-2 variants, and that symptomatic breakthrough infections may potentially transmit COVID-19 as efficiently as unvaccinated infections, regardless of the infecting lineage…

Discussion: … [W]e found that vaccine breakthrough infections are more likely to be caused by immunity-evading variants as compared to unvaccinated infections. These findings are largely attributed to the observed decreased proportion of vaccine breakthrough infections from the alpha variant, despite its documented higher infectivity relative to all VOCs except delta and gamma. Decreased alpha infections are consistent with the higher effectiveness of available SARS-CoV-2 vaccines against alpha relative to other VOCs, most of which exhibit higher resistance to neutralizing antibodies than alpha. **The predominance of immune-evading variants among breakthrough cases indicates selective pressure for immune-resistant**

variants locally over time in the vaccinated population concurrent with ongoing viral circulation in the community [*emphasis added*]. In particular, the delta variant, which is the predominant circulating lineage in the United States as of July 2021, has been shown to be resistant to vaccine-induced immunity as well as being more infectious than alpha"

[325] **ADDED since 10/14/2021**

The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines

Osaka University (Japan)
Yafei Liu, Noriko Arase, *et al*.
August 23, 2021
https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1.full

"**Discussion**: … SARS-CoV-2 has acquired a number of mutations to date, which have arisen within infected individuals. Therefore, new variants are likely to emerge more frequently in situations where many people are infected. Because the Delta variant is spreading so explosively, it has already acquired numerous additional mutations in the spike protein coding region, suggesting that the Delta variant will continue to acquire further mutations. Some mutations observed in the RBD [*receptor binding domain*] of the Delta variant have been reported to be epitopes for anti-RBD neutralizing antibodies (Greaney et al., 2021a; Greaney et al., 2021b; Wang et al., 2021b). **Newly emerged variants** that adapt to the environment of their host's immune system **will be selected** and **expand**. The Delta variant with 4 additional mutations in the RBD were not neutralized by most BNT162b2-immune sera because of unique mutations in the NTD. More importantly, **infectivity of the Delta 4+ was enhanced** by some BNT162b2-immune sera [*emphasis added*]. Furthermore, of the four additional mutations, a Delta variant with three mutations has already been registered in the GISAID database; it is likely that a Delta variant that has acquired five mutations in the RBD in total will acquire additional mutations in the near future. Although we have selected K417N, N439K, E484K, and N501Y as additional mutations for the Delta variant, **other combinations** of anti-RBD neutralizing epitopes can be expected to have similar or **stronger effects** than the Delta 4+ variant [*emphasis added*]. Indeed, the Delta 4+ still possess R346, one of major epitope residues for anti-RBD neutralizing antibodies such as C135...

A third round of booster immunization with the SARS-CoV-2 vaccine is currently under consideration. Our data suggest that repeated immunization with the wild-type spike may not be effective in controlling the newly emerging Delta variants."

[326] **Video (2m): Interview excerpt with Luc Montagnier (2008 Nobel Prize in Medicine)**
August 18, 2021
https://rumble.com/vldilx-nobel-prize-winner-professor-luc-montagnier-says-vaccine-is-creating-varian.html

"[I]t is the vaccinations that are causing the variants… The **new variants are a production and result from the vaccination** [*emphasis added*]… You see it in each country, it's the same: The curve of vaccination is followed by the curve of deaths… I'm following this closely and I am doing experiments at the institute with patients who become sick with Corona after being vaccinated. I will show you that they are creating the variants that are resistant to the vaccine."

[327] ***Ninety-third SAGE meeting on COVID-19***

Scientific Advisory Group for Emergencies (SAGE)
July 7, 2021
https://www.gov.uk/government/publications/sage-93-minutes-coronavirus-covid-19-response-7-july-2021/sage-93-minutes-coronavirus-covid-19-response-7-july-2021

> "9. There are four major risks associated with high numbers of infections. These are an increase in hospitalisations and deaths, more 'Long-COVID'; workforce absences (including in the NHS); and the increased risk of new variants emerging. The combination of high prevalence and high levels of vaccination **creates the conditions in which an immune escape variant is most likely to emerge** [*emphasis added*]. The likelihood of this happening is unknown, but such a variant would present a significant risk both in the UK and internationally."

[328] ***Antigenic minimalism of SARS-CoV-2 is linked to surges in COVID-19 community transmission and vaccine breakthrough infections***
Mayo Clinic
A.J. Venkatakrishnan, Praveen Anand, *et al*.
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.23.21257668v1.full-text

> "**Abstract**: The raging COVID-19 pandemic in India and reports of 'vaccine breakthrough infections' globally have raised alarm mandating the characterization of the immuno-evasive features of SARS-CoV-2. Here, we systematically analyzed over 1.3 million SARS-CoV-2 genomes from 178 countries and performed whole-genome viral sequencing from 53 COVID-19 patients, including 20 vaccine breakthrough infections. We identified 116 Spike protein mutations that increased in prevalence during at least one surge in SARS-CoV-2 test positivity in any country over a three-month window. Deletions in the Spike protein N-terminal domain (NTD) are highly enriched for these 'surge-associated mutations'… Overall, the expanding repertoire of NTD deletions throughout the pandemic and their association with case surges and vaccine breakthrough infections point to antigenic minimalism as an emerging evolutionary strategy for SARS-CoV-2 to evade immune responses. This study highlights the urgent need to sequence viral genomes at a larger scale globally and to mandate that sequences are deposited with more granular and transparent clinical annotations to ensure that therapeutic development keeps pace with the evolution of SARS-CoV-2.
>
> **Introduction**: The ongoing COVID-19 pandemic has infected around 160 million people and killed more than 3 million people worldwide, as of May 20211. The **continual emergence of SARS-CoV-2 variants** with increased transmissibility and **capacity for immune escape**, such as B.1.1.7 ('UK variant') and P.1 ('Brazilian variant'), threatens to prolong the pandemic through **devastating outbreaks** such as the one currently being witnessed in India [*emphasis added*]…
>
> **Results**: … This suggests that the surging SARS-CoV-2 variants in India and Chile may have acquired NTD deletions in the antigenic supersite in order to evade neutralizing antibodies and achieve immune escape. From a viral evolution standpoint, these observations raise the question of whether SARS-CoV-2 is expanding its repertoire of deletable regions in the Spike protein as the pandemic progresses.
>
> **Discussion**: The worldwide mass vaccination campaign has had a profound impact on COVID-19 transmission. However, certain variants are less susceptible to neutralization by sera from vaccinated individuals and convalescent COVID-19 patients. Such findings motivate the need to vigilantly track the emergence of new variants and to determine whether they are likely to cause

surges or vaccine breakthrough infections… Thus, a concerted evolution of strategically placed deletions and substitutions appear to be conferring SARS-CoV-2 with the fitness to evade immunity and achieve efficient transmission between hosts."

[329] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Authorea
Roxana Bruno, Peter A. Mccullough, et al.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

"**Unanticipated adverse reactions to SARS-CoV-2 vaccines**: … 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 some of which affect the antigenic domain of Spike glycoprotein. 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, a phenomenon known as "original antigenic sin" or antigenic priming. It is unknown to what extent mutations that affect SARS-CoV-2 antigenicity will become fixed during viral evolution, 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 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 [*emphasis added*]."

[330] **Open Letter to the World Health Organization**
Dr. Geert Vanden Bossche, DVM, PhD
March 6, 2021
https://37b32f5a-6ed9-4d6d-b3e1-5ec648ad9ed9.filesusr.com/ugd/28d8fe_266039aeb27a4465988c37adec9cd1dc.pdf

"I am all but an antivaxxer. As a scientist, I do not usually appeal to any platform of this kind to make a stand on vaccine-related topics. As a dedicated virologist and vaccine expert, I only make an exception when health authorities allow vaccines to be administered in ways that threaten public health, most certainly when scientific evidence is being ignored. The present extremely critical situation forces me to spread this emergency call. As the unprecedented extent of human intervention in the Covid-19-pandemic is now at risk of resulting in a global catastrophe without equal, this call cannot sound loudly and strongly enough."

Video (2m): Urgent call to WHO: Time to switch gears
https://www.youtube.com/watch?v=mUlDeCRDLnU

[331] ***Will Delaying Vaccine Doses Cause a Coronavirus Escape Mutant?***
The Scientist
Chris Baraniuk
February 4, 2021
https://www.the-scientist.com/news-opinion/will-delaying-vaccine-doses-cause-a-coronavirus-escape-mutant--68424

> "Among those concerned is Paul Bieniasz, a virologist at the Rockefeller University. 'Rolling out a partially effective vaccine regime in the peak of a highly prevalent viral epidemic is just not a great idea if one of your goals is to avoid vaccine resistance,' he says.
>
> There's a chance, Bieniasz explains, that people waiting for their second dose may have a sub-optimal level of immunity that places selective pressure on the virus. If someone were to become infected during the interval between jabs, that pressure could allow for the emergence of a mutant version of SARS-CoV-2 able to shake off a person's immune response—a so-called escape variant. Any such variant that also proved capable of causing severe disease could potentially spark a whole new, devastating wave of infections and deaths."

[332] ***Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens***
PLOS Biology
Andrew F. Read, Susan J. Baigent, *et al*.
July 27, 2015
https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002198

> "**Author Summary**: There is a theoretical expectation that some types of vaccines could prompt the evolution of more virulent ('hotter') pathogens. This idea follows from the notion that natural selection removes pathogen strains that are so 'hot' that they kill their hosts and, therefore, themselves. Vaccines that let the hosts survive but do not prevent the spread of the pathogen relax this selection, allowing the evolution of hotter pathogens to occur. This type of vaccine is often called a leaky vaccine. When vaccines prevent transmission, as is the case for nearly all vaccines used in humans, this type of evolution towards increased virulence is blocked. But when vaccines leak, allowing at least some pathogen transmission, **they could create the ecological conditions that would allow hot strains to emerge and persist** [*emphasis added*]. This theory proved highly controversial when it was first proposed over a decade ago, but here we report experiments with Marek's disease virus in poultry that show that modern commercial leaky vaccines can have precisely this effect: they allow the onward transmission of strains otherwise too lethal to persist. Thus, the use of leaky vaccines can facilitate the evolution of pathogen strains that put unvaccinated hosts at greater risk of severe disease."

SARS-CoV-2 Spike Protein

Note: The citations below are presented in reverse, chronological order.

[333] **ADDED since 10/14/2021**
New VAERS analysis reveals hundreds of serious adverse events that the CDC and FDA never told us about
Steve Kirsch and Albert Benavides
November 9, 2021
https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds
Team of Vaccine Safety Experts: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

For excerpts, see [231]

[334] **ADDED since 10/14/2021**
SARS–CoV–2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro
Viruses journal
Hui Jiang and Ya-Fang Mei
October 13, 2021
https://www.mdpi.com/1999-4915/13/10/2056/htm

"**Abstract**: Here, by using an in vitro cell line, we report that the SARS–CoV–2 spike protein significantly inhibits DNA damage repair, which is required for effective V(D)J recombination in adaptive immunity. Mechanistically, we found that the spike protein **localizes in the nucleus** and **inhibits DNA damage repair by impeding key DNA repair protein BRCA1 and 53BP1 recruitment to the damage site**. Our findings reveal a potential molecular mechanism by which the spike protein might impede adaptive immunity and **underscore the potential side effects of full-length spike-based vaccines** [*emphasis added*]…

3. Results … NHEJ repair and homologous recombination (HR) repair are two major DNA repair pathways that not only continuously monitor and ensure genome integrity but are also vital for adaptive immune cell functions."

3.3. Spike Proteins Impede the Recruitment of DNA Damage Repair Checkpoint Proteins…

To determine how the spike protein inhibits both NHEJ and HR repair pathways, we analyzed the recruitment of BRCA1 and 53BP1, which are the key checkpoint proteins for HR and NHEJ repair, respectively. We found that the spike protein markedly inhibited both BRCA1 and 53BP1 foci formation (Figure 3D–G). Together, these data show that the SARS–CoV–2 full–length spike protein inhibits DNA damage repair by hindering DNA repair protein recruitment."

Notes:

- From this comparative study, Comparison of nonhomologous end joining and homologous recombination in human cells:
  "[W]e conclude that in proliferating cells **NHEJ repairs 75% of DSBs** [*DNA double-strand breaks*] while **HR repairs the remaining 25%** [*emphasis added*]."
- From this study, 53BP1: A key player of DNA damage response with critical functions in

cancer:
"It has been extensively demonstrated that **aberrant expression of 53BP1 contributes to tumor occurrence** and **development**. 53BP1 loss of function in tumor tissues is **also related to tumor progression** and poor prognosis in human malignancies [*emphasis added*]."

[335] ***Why are we vaccinating children against COVID-19?***
Toxicology Reports
Ronald N. Kostoff, Daniela Calina, *et al*.
October 7, 2021
https://www.sciencedirect.com/science/article/pii/S221475002100161X

"**3.1.3.1. Intrinsic inoculant toxicity**: We believe that mid-or long-term adverse effects are possible based on the recent emergence of evidence that would support the probability of mid- and long-term adverse effects from the COVID-19 inoculants, such as:

1) The spike protein itself can be a toxin/pathogenic protein:

2) S protein alone can damage vascular endothelial cells (ECs) by downregulating ACE2 and consequently inhibiting mitochondrial function.

3) it is concluded that ACE2 and endothelial damage is a central part of SARS-CoV2 pathology and may be induced by the spike protein alone.

4) the spike protein of SARS-CoV-1 (without the rest of the virus) reduces ACE2 expression, increases angiotensin II levels, exacerbates lung injury, and triggers cell signaling events that may promote pulmonary vascular remodeling and Pulmonary Arterial Hypertension (PAH) as well as possibly other cardiovascular complications.

5) the recombinant S protein alone elicits functional alterations in cardiac vascular pericytes (PCs)…

12) The spike protein has been found in the plasma of post-inoculation individuals, implying that it could circulate to, and impact adversely, any part of the body.

13) The spike protein of SARS-CoV-2 crosses the blood-brain barrier in mice, and "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".

14) The spike proteins manufactured in vivo by the present COVID-19 inoculations could potentially "precipitate the onset of autoimmunity in susceptible subgroups, and potentially exacerbate autoimmunity in subjects that have pre-existing autoimmune diseases", based on the finding that anti-SARS-CoV-2 protein antibodies cross-reacted with 28 of 55 diverse human tissue antigens…

3.2. Novel best-case scenario cost-benefit analysis of COVID-19 inoculations for most vulnerable …

The results show ***conservatively*** that there are **five times the number of deaths *truly* attributable to each inoculation vs those *truly* attributable to COVID-19 in the 65+ demographic**. As age decreases, and the risk for COVID-19 decreases, the cost-benefit increases [*emphasis added*]. Thus, if the best-case scenario looks ***poor*** for benefits from the inoculations, any realistic scenario will look ***very poor***. For children the chances of death from

COVID-19 are negligible, but the chances of serious damage over their lifetime from the toxic inoculations are not negligible."

[336] ***Open Letter and Notice of Liability from Doctors and Scientists to the EMA and the Members of the European Parliament Regarding COVID-19 Vaccination***
Doctors for COVID Ethics
September 13, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Letter-and-Notice-of-Liability-to-EMA-and-MEPs.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"Perhaps the most pertinent finding is that, due to the discovery of a widespread memory-type antibody response to SARS-CoV-2, the antibodies induced by the COVID-19 vaccines can be expected to activate the so-called complement system. This can bring about the destruction of any cell that manufactures the SARS-CoV-2 spike protein, particularly in the circulation. If that happens to the endothelia, that is, the cell layer that lines the inner surfaces of our blood vessels, then those vessels may begin to leak and clots will form. Given that 2021 research showed the spike protein to enter the bloodstream shortly after vaccination, this dangerous endothelial involvement in spike-production is highly likely, and should be expected to occur…

COVID-19 vaccines, on the other hand, are not protein antigens but the genetic blueprint for the SARS-CoV-2 spike protein antigen. That blueprint comes in the form of mRNA or DNA, which, after vaccination, enters our body's cells and instructs those cells to manufacture the spike protein. The spike protein then protrudes from the cell and induces antibody formation. In response, the immune system will react not only with the spike protein, but will attack and try to destroy the entire cell…

As well as damage from leakage and clotting alone, it is additionally possible that the vaccine itself may leak into surrounding organs and tissues. Should this take place, the cells of those organs will themselves begin to produce spike protein, and will come under attack in the same way as the vessel walls. Damage to major organs such as the lungs, ovaries, placenta and heart can be expected [*to*] ensue, with increasing severity and frequency as booster shots are rolled out."

[337] ***The SARS-CoV-2 spike protein subunit S1 induces COVID-19-like acute lung injury in K18-hACE2 transgenic mice and barrier dysfunction in human endothelial cells***
American Journal of Physiology
Ruben M.L. Biancatelli, Pavel A. Solopov, *et al*.
August 10, 2021
Note: Figure 3 presents images comparing the lungs of mice injected with SARS-CoV-2 spike proteins and a control group.
https://journals.physiology.org/doi/full/10.1152/ajplung.00223.2021

"**Results - Spike Protein Elicits "Cytokine Storm" in BALF and Serum**: Mice instilled with S1SP [SARS-CoV-2 spike protein] displayed a cytokine storm in BALF (Fig. 2A) and serum (Fig. 2B), in agreement with the observed neutrophil, monocyte, and macrophage recruitment (Fig. 1D). Minimal cytokine levels were observed in mice exposed to either saline or SP.

Spike Protein Induces Morphologically Evident ALI and Activates the NF-κB and STAT3 Pathways in the Lungs: … Figure 3. The S1 subunit of the SARS-CoV-2 spike protein (S1SP)

causes acute lung injury and the activation of the STAT3 and NF-κB inflammatory pathways 72 h after exposure."

[338] ***The SARS-CoV-2 Spike protein disrupts human cardiac pericytes function through CD147-receptor-mediated signalling: a potential non-infective mechanism of COVID-19 microvascular disease***
University of Bristol Medical School
Elisa Avolio, Michele Carrabba, *et al*.
July 20, 2021
https://www.biorxiv.org/content/10.1101/2020.12.21.423721v2.full

"**Abstract**: … The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) uses the Spike (S) protein to engage with its receptors and infect host cells. To date, it is still not known whether heart vascular pericytes (PCs) are infected by SARS-CoV-2, and if the S protein alone provokes PC dysfunction. Here, we aimed to investigate the effects of the S protein on primary human cardiac PC signalling and function… In conclusion, our findings suggest that circulating S protein prompts vascular PC dysfunction, potentially contributing to establishing microvascular injury in organs distant from the site of infection…

We provide evidence that cardiac PCs are not infected by SARS-CoV-2. Importantly, we show that the recombinant S protein alone elicits cellular signalling through the CD147 receptor in cardiac PCs, thereby inducing cell dysfunction and microvascular disruption in vitro…

Discussion: Our study provides novel proof-of-concept evidence for S protein to cause molecular and functional changes in human vascular PCs…

In conclusion, although more investigation being needed to definitively prove the harmful effects of the S protein on the heart PCs and associated microvasculature in vivo, this work suggests that fragments of the S protein may elicit vascular cell dysfunction through CD147, independently from the infection. This mechanism has the **potential to spread cellular and organ injury beyond the infection sites** and may have important clinical implications [*emphasis added*]. For instance, in patients with disrupted endothelial barrier and increased vascular permeability due to underlying diseases, such as hypertension, diabetes, and severe obesity, S protein molecules could easily spread to the PC compartment and cause, or exacerbate, microvascular injury."

[339] **Audio interview (8m): *Dr. Byram Bridle Professor of Viral Immunology on Spike Protein***
May 31, 2021
https://odysee.com/@Jay:46/dr-byram-bridle-professor-of-viral:e
Video (13m): Dr Byram Bridle at press conference held by Derek Sloan (Canadian Member of Parliament), June 17, 2021
https://odysee.com/@stonemonkey:c/byram:e

"I'm going to walk you through this… Everything I'm stating here is completely backed up by peer-reviewed, scientific publications in well-known, well-respected scientific journals… What has been discovered by the scientific community is the spike protein, on its own, is almost entirely responsible for the damage to the cardio-vascular system, if it gets into circulation. Indeed, if you inject the purified spike protein into the blood of research animals, they get all kinds of damage to the cardio-vascular system, it can cross the blood-brain barrier and cause damage to the brain... The assumption, all up until now, is that these vaccines behave like all of

our traditional vaccines, that they don't go anywhere other than the injection site. So they stay in our shoulder. Some of the protein will go to the local draining lymph node, in order to activate the immune system. However, this is where the cutting-edge science is coming in. This is where it gets scary.

Through a request for information from the Japanese regulatory agency, myself and several international collaborators have been able to get access to what's called a bio-distribution study. It's the first time ever that scientists have been privy to seeing where these messenger mRNA vaccines go after vaccination. In other words, is it a safe assumption that it stays in the shoulder muscle? The short answer is, absolutely not. It's very disconcerting. The spike protein gets into the blood, circulates through the blood in individuals, over several days post-vaccination. Once it gets in the blood, it accumulates in a number of tissues, such as the spleen, the bone marrow, the liver, the adrenal glands... One that's of particular concern for me is it accumulates in quite high concentrations in the ovaries. And then also a (scientific paper) that was just accepted for publication that backs this up looked at 13 young healthcare workers that had received the Moderna vaccine… (and) they found the spike protein in circulation, so in the blood of 11 of those 13 healthcare workers who had received the vaccine…

Now we have clear-cut evidence that the vaccines that make our bodies… manufacture this protein, the vaccine itself plus the protein gets into blood circulation. When in circulation, the spike protein combined to the receptors that are on our platelets and the cells that line our blood vessels. When that happens, it can do one of two things – It can either cause platelets to clump, and that can lead to clotting, and that's exactly why we've been seeing clotting disorders associated with these vaccines. It can also lead to bleeding and, of course, the heart's involved… That's why we're seeing heart problems. The protein can also cross the blood-brain barrier and cause neurological damage. That's why also in fatal cases of blood clots, many times it's seen in the brain…

In short, the conclusion is, we made a big mistake, we didn't realize it until now. We thought the spike protein was a great target antigen. We never knew the spike protein itself was a toxin and a pathogenic protein. **So by vaccinating people, we are inadvertently inoculating them with a toxin** [*emphasis added*]."

[340] ***SARS-COV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 - Overview of Pharmacokinetic Test***
Pfizer, Inc.
Note: Allegedly, this is the Pfizer animal study acquired by Dr. Byram Bridle and colleagues (see [339]) from a Japanese regulatory agency that appears to show Pfizer knew their COVID-19 vaccine 1) circulates in the bloodstream following intravenous administration, and 2) deposits constituent lipids in the liver, ovaries, and other organs. Authors and date unknown.
https://archive.org/details/pfizer-confidential-translated/page/n2/mode/1up

"**4. Distribution**: … Total recoveries of radioactivity relative to the dose outside of the dose site were highest in the liver (up to 18%) and were significantly lower in the spleen (<1.0%), adrenal glands (<0.11%), and ovaries (<0.095%) than in the liver."

[341] ***Circulating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients***
Clinical Infectious Diseases
Alana F. Ogata, Chi-An Cheng, *et al*.
May 10, 2021
Note: This Harvard study is the first to show evidence that the SARS-CoV-2 spike protein is present systemically in the bloodstream following vaccination, and does not remain localized at the injection site.
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab465/6279075

"**Abstract**: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) proteins were measured in longitudinal plasma samples collected from 13 participants who received two doses of mRNA-1273 vaccine. Eleven of 13 participants showed detectable levels of SARS-CoV-2 protein as early as day 1 after first vaccine injection.

Introduction: … Here we provide evidence that circulating SARS-CoV-2 proteins are present in the plasma of participants vaccinated with the mRNA-1273 vaccine…

Discussion: In this study, 11 participants exhibit S1 antigen in plasma after the first injection, whereas nucleocapsid concentrations are insignificant in all participants, confirming that the detected S1 originates from vaccination and not natural infection…

Nonetheless, evidence of systemic detection of spike and S1 protein production from the mRNA-1273 vaccine is significant and has not yet been described in any vaccine study, likely due to limitations in assay sensitivity and timing assessment. The clinical relevance of this finding is unknown and should be further explored. These data show that **S1 antigen production after the initial vaccination can be detected by day 1 and is present beyond the site of injection** and the associated regional lymph nodes [*emphasis added*]."

[342] ***Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19***
International Journal of Vaccine Theory, Practice, and Research
Stephanie Seneff and Greg Nigh
May 10, 2021
https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF~1.PDF

"**Spike Protein Toxicity**: … The spike protein generated endogenously by the vaccine could also negatively impact the male testes, as the ACE2 receptor is highly expressed in Leydig cells in the testes (Verma et al., 2020). Several studies have now shown that the **coronavirus spike protein is able to gain access to cells in the testes via the ACE2 receptor,** and **disrupt male reproduction** [*emphasis added*] (Navarra et al., 2020; Wang and Xu, 2020). A paper involving postmortem examination of testicles of six male COVID-19 patients found microscopic evidence of spike protein in interstitial cells in the testes of patients with damaged testicles (Achua et al., 2021)."

[343] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Authorea
Roxana Bruno, Peter A. Mccullough, *et al*.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

> "**Abstract**: … The recently identified role of SARS-CoV-2 Spike glycoprotein for inducing endothelial damage characteristic of COVID-19, even in absence of infection, is extremely relevant given that most of the authorized vaccines induce endogenous production of Spike…
>
> **Will serious adverse effects from the SARS-CoV-2 vaccines go unnoticed?** ... [E]ven 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 increases 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."

[344] ***The novel coronavirus' spike protein plays additional key role in illness. Salk researchers and collaborators show how the protein damages cells, confirming COVID-19 as a primarily vascular disease***
Salk Institute
April 30, 2021
https://www.salk.edu/news-release/the-novel-coronavirus-spike-protein-plays-additional-key-role-in-illness/

> "While the findings themselves aren't entirely a surprise, the paper provides clear confirmation and a detailed explanation of the mechanism through which the protein damages vascular cells for the first time. There's been a growing consensus that SARS-CoV-2 affects the vascular system, but exactly how it did so was not understood. Similarly, scientists studying other coronaviruses have long suspected that the spike protein contributed to damaging vascular endothelial cells, but this is the first time the process has been documented.

In the new study, the researchers created a 'pseudovirus' that was surrounded by SARS-CoV-2 classic crown of spike proteins, but did not contain any actual virus. Exposure to this pseudovirus resulted in damage to the lungs and arteries of an animal model—**proving that the spike protein alone was enough to cause disease**. Tissue samples showed inflammation in endothelial cells lining the pulmonary artery walls [*emphasis added*]."

[345] ***SARS-CoV-2 spike protein alone may cause lung damage***
Medical Xpress
Experimental Biology
April 27, 2021
https://medicalxpress.com/news/2021-04-sars-cov-spike-protein-lung.html

"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…

"Our findings show that the SARS-CoV2 spike protein causes lung injury even without the presence of intact virus," said Pavel Solopov, Ph.D., DVM, research assistant professor at the Frank Reidy Research Center for Bioelectrics at Old Dominion University…

The researchers found that the genetically modified mice injected with the spike protein exhibited COVID-19-like symptoms that included severe inflammation, an influx of white blood cells into their lungs and evidence of a cytokine storm—an immune response in which the body starts to attack its own cells and tissues rather than just fighting off the virus."

[346] ***First case of postmortem study in a patient vaccinated against SARS-CoV-2***
International Journal of Infectious Diseases
Torsten Hansen, Ulf Titze, *et al*.
April 16, 2021
https://www.ijidonline.com/article/S1201-9712(21)00364-7/fulltext

"**Highlights**:

- We report on a patient with a single dose of vaccine against SARS-CoV-2.
- He developed relevant serum titer levels but died 4 weeks later.
- By postmortem molecular mapping, **we found viral RNA in nearly all organs examined**.
- However, we did not observe any characteristic morphological features of COVID-19. [*emphasis added*]
- Immunogenicity might be elicited, while sterile immunity was not established."

[347] ***SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2***
Circulation Research (Salk Institute)
Yuyang Lei, Jiao Zhang, *et al*.
March 31, 2021
https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.121.318902

Includes images of "[r]epresentative images of vascular endothelial control cells (left) and cells treated with the SARS-CoV-2 Spike protein (right) [which] show that the spike protein causes increased mitochondrial fragmentation in vascular cells."

"SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) infection relies on the binding of S protein (Spike glycoprotein) to ACE (angiotensin-converting enzyme) 2 in the host cells. Vascular endothelium can be infected by SARS-CoV-2, which triggers mitochondrial reactive oxygen species production and glycolytic shift. Paradoxically, ACE2 is protective in the cardiovascular system, and SARS-CoV-1 S protein promotes lung injury by decreasing the level of ACE2 in the infected lungs. In the current study, we show that **S protein alone can damage vascular endothelial cells** (ECs) by downregulating ACE2 and consequently inhibiting mitochondrial function [*emphasis added*]."

[348] ***Review of COVID-19 Vaccines and the Risk of Chronic Adverse Events Including Neurological Degeneration***
Journal of Medical-Clinical Research & Reviews
J. Bart Classen
March 24, 2021
https://scivisionpub.com/pdfs/review-of-covid19-vaccines-and-the-risk-of-chronic-adverse-events-including-neurological-degeneration-1616.pdf

"**Abstract**: Many have argued that the outbreak of COVID-19 is the result of the release of a viral based bioweapon. Vaccines to COVID-19 have been developed and a policy of universal immunization has been initiated with total disregard to the fact that the virus may be a bioweapon. The potential risk of a catastrophe exists in part because all the vaccines contain the spike protein and or the mRNA/DNA encoding for the COVID-19 associated spike protein. These vaccines were designed and placed on the market with little knowledge of how the spike protein or its nucleic acid causes disease and without knowledge of long-term adverse effects of the vaccines. This paper reviews many of the potential long-term risks that could result from receiving one of the COVID-19 vaccines. The potential for the spike protein and its mRNA to cause prion disease is reviewed as well as reasons why the vaccine could be much more dangerous than the natural infection. Adenoviral derived COVID-19 vaccines are particularly risky because of their potential to recombine with human DNA or viruses already in the human recipient. The result could be new infectious adenoviral species containing spike proteins that could infect humans and farm animals used for food. Some of the COVID-19 vaccines utilize novel technology including nanotechnology and novel adjuvants that increase intracellular penetration of cells and can potentially exacerbate chronic toxicity from the spike protein. Governments should consider suspending sale of the COVID-19 vaccines until they have a better understanding of their risks."

[349] **ADDED since 10/14/2021**

SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines

Vaccines journal
Yuichiro J. Suzuki and Sergiy G. Gychka
January 11, 2021
https://www.mdpi.com/2076-393X/9/1/36/htm

"**3. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Cells**

It was found that the treatment of cultured primary human pulmonary artery smooth muscle cells (SMCs) or human pulmonary artery endothelial cells with the recombinant SARS-CoV-2 spike protein S1 subunit is sufficient to promote cell signaling without the rest of the viral components. Furthermore, our analysis of the postmortem lung tissues of patients who died of COVID-19 has determined that these patients exhibited pulmonary vascular wall thickening, a hallmark of pulmonary arterial hypertension (PAH). Based on these results, we proposed that the SARS-CoV-2 spike protein (without the rest of the viral components) **triggers cell signaling events that may promote pulmonary vascular remodeling and PAH as well as possibly other cardiovascular complications** [*emphasis added*]…

These results collectively reinforce the idea that human cells are sensitively affected by the extracellular and/or intracellular spike proteins though the activation of cell signal transduction…

6. Discussion…

[I]t is important to consider the possibility that the SARS-CoV-2 spike protein produced by the new COVID-19 vaccines triggers cell signaling events that promote PAH, other cardiovascular complications, and/or complications in other tissues/organs in certain individuals (Figure 3). We will need to monitor carefully the long-term consequences of COVID-19 vaccines that introduce the spike protein into the human body. Furthermore, while **human data on the possible long-term consequences of spike protein-based COVID-19 vaccines will not be available soon** [*emphasis added*], it is imperative that appropriate experimental animal models are employed as soon as possible to ensure that the SARS-CoV-2 spike protein does not elicit any signs of the pathogenesis of PAH or any other chronic pathological conditions."

[350] ***Docked severe acute respiratory syndrome coronavirus 2 proteins within the cutaneous and subcutaneous microvasculature and their role in the pathogenesis of severe coronavirus disease 2019***

Human Pathology
Cynthia M. Magro, J. Justin Mulvey, *et al*.
December 2020
https://www.sciencedirect.com/science/article/abs/pii/S0046817720302008?via%3Dihub

"**Summary**: The purpose of this study was to examine the deltoid skin biopsy in twenty-three patients with coronavirus disease 2019 (COVID-19), most severely ill, for vascular complement deposition and correlate this with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA and protein localization and ACE2 expression… The dominant microvascular complement immunoreactant identified was the terminal membranolytic attack complex C5b-9. Microvascular complement deposition strongly colocalized *in situ* with the SARS-CoV-2 viral proteins including spike glycoproteins in the endothelial cells…"

[351] ***The SARS-CoV-2 spike protein alters barrier function in 2D static and 3D microfluidic in-vitro models of the human blood–brain barrier***
Neurobiology of Disease
Tetyana P. Buzhdygan, Brandon J. DeOre, *et al*.
December 2020
https://www.sciencedirect.com/science/article/pii/S096999612030406X?via%3Dihub

"**Abstract**: [T]he results presented in this report explored whether deleterious outcomes from the SARS-CoV-2 viral spike protein on primary human brain microvascular endothelial cells (hBMVECs) could be observed… Evidence 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 [*blood-brain barrier*] 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."

[352] **ADDED since 10/14/2021**
SARS-CoV-2 Spike Protein and Lung Vascular Cells
Journal of Respiration (Georgetown University Medical Center)
Sri Jayalakshmi Suresh and Yuichiro Justin Suzuki
December 31, 2020
https://www.mdpi.com/2673-527X/1/1/4/htm

"**3. Pathology of PAH**

PAH [*pulmonary arterial hypertension*] is a fatal disease without a cure that can affect both males and females of any age, including children. It is a progressive disease, and by the time patients are diagnosed, the thickening of the pulmonary vascular walls has often already occurred. Increased resistance in the pulmonary circulation places strain on the right ventricle, which leads to right heart failure and death. The median overall survival for patients with PAH is 2.8 years from the time of diagnosis (three-year survival: 48%) without treatment. Even with currently available therapies, the prognosis remains poor, with a three-year survival of PAH patients reported to be only 58–75%...

7. COVID-19 Vaccines and PAH

COVID-19 vaccines currently under consideration, including RNA vaccines (BNT162b2 and mRNA-1273), viral vector-based vaccines (AZD1222 and Ad26.COV2.S), and recombinant protein (NVX-CoV2373), all introduce the SARS-CoV-2 spike protein into the human body. Whether the spike protein elicits cell signaling in host cells and exerts adverse events such as promoting PAH is a question raised in response to the experimental results in cultured cells. RNA and viral vector-based vaccines use human host cells to produce the spike protein; thus, the intracellular spike protein will be produced. **The intracellular effects of this foreign molecule on human cells have not been defined** [*emphasis added*]…

8. Conclusions

This analysis suggests that the SARS-CoV-2 spike protein and HIV gp120 have the capacity to trigger cell biological events that may lead to the development of pulmonary vascular remodeling and, perhaps, clinically significant PAH, a fatal condition. Given the observations that cells sensitively respond to the spike protein at pM concentrations in cultured cells, **it is**

likely that the SARS-CoV-2 spike protein not only facilitates the viral entry and serves to acquire immunity as an antigen for vaccines but, also, **targets host cells and may exert adverse effects** (Figure 4). Further experiments should be performed to address the possible effects of the SARS-CoV-2 spike protein on developing PAH. The effects of the SARS-CoV-2 spike protein on the cells of other tissues/organs, such as those of the systemic vasculature, heart, and brain, should also be investigated. Given that this protein will be administered as vaccines to millions and possibly billions of people, it is critical to understand the extracellular and intracellular effects of the SARS-CoV-2 spike protein on human cells that **may promote long-term adverse health consequences** [*emphasis added*]."

[353] ***The S1 protein of SARS-CoV-2 crosses the blood–brain barrier in mice***
Nature magazine
Elizabeth M. Rhea, Aric F. Logsdon, *et al*.
December 16, 2020
https://www.nature.com/articles/s41593-020-00771-8

"**Abstract**: It is unclear whether severe acute respiratory syndrome coronavirus 2, which causes coronavirus disease 2019, can enter the brain. Severe acute respiratory syndrome coronavirus 2 binds to cells via the S1 subunit of its spike protein. We show that **intravenously injected radioiodinated S1 (I-S1) readily crossed the blood–brain barrier** in male mice, was taken up by brain regions and entered the parenchymal brain space [*emphasis added*]. I-S1 was also taken up by the lung, spleen, kidney and liver."

[354] ***A Multibasic Cleavage Site in the Spike Protein of SARS-CoV-2 Is Essential for Infection of Human Lung Cells***
Molecular Cell
Markus Hoffman, Hanna Kliene-Weber, and Stefan Pohlmann
May 1, 2020
https://www.cell.com/molecular-cell/fulltext/S1097-2765(20)30264-1

"**Summary**: The pandemic coronavirus SARS-CoV-2 threatens public health worldwide. The viral spike protein mediates SARS-CoV-2 entry into host cells and harbors a S1/S2 cleavage site containing multiple arginine residues (multibasic) not found in closely related animal coronaviruses. However, the role of this multibasic cleavage site in SARS-CoV-2 infection is unknown. Here, we report that the cellular protease furin cleaves the spike protein at the S1/S2 site and that **cleavage is essential for S-protein-mediated cell-cell fusion** and **entry into human lung cells** [*emphasis added*]… Our results suggest that acquisition of a S1/S2 multibasic cleavage site was essential for SARS-CoV-2 infection of humans and identify furin as a potential target for therapeutic intervention."

[355] ***Two Mutations Were Critical for Bat-to-Human Transmission of Middle East Respiratory Syndrome Coronavirus***
Journal of Virology
Yang Yang, Chang Liu, Lanying Du, Shibo Jiang, Zhengli Shi, Ralph S. Baric, and Fang Li
September 2015
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_dd79a86de7064bb29f9b3d2165063af8.pdf

"To understand how Middle East respiratory syndrome coronavirus (MERS-CoV) transmitted

from bats to humans, we compared the virus surface spikes of MERS-CoV and a related bat coronavirus, HKU4. Although HKU4 spike cannot mediate viral entry into human cells, two mutations enabled it to do so by allowing it to be activated by human proteases...

To evaluate the potential genetic changes required for HKU4 to infect human cells, we **reengineered HKU4 spike**, aiming to build its capacity to mediate viral entry into human cells [*emphasis added*]. To this end, we introduced two single mutations, S746R and N762A, into HKU4 spike. The S746R mutation was expected to restore the hPPC motif in HKU4 spike, whereas the N762A mutation likely disrupted the potential N-linked glycosylation site in the hECP motif in HKU4 spike. To confirm that the S746R mutation restored the hPPC motif, we produced retroviruses pseudotyped with HKU4 spike (referred to as HKU4 pseudoviruses) in human cells… Moreover, mutations in these motifs in coronavirus spikes have demonstrated dramatic effects on viral entry into human cells."

Autoimmunity and Autoimmune Diseases

Note: The citations below are presented in reverse, chronological order.

[356] ***Reactivation of Varicella Zoster Virus after Vaccination for SARS-CoV-2***
Multidisciplinary Digital Publishing Institute (MDPI)
Mina Psichogiou, Michael Samarkos, Nikolaos Mikos, and Angelos Hatzakis
June 1, 2021
https://www.mdpi.com/2076-393X/9/6/572/htm

"**Abstract**: Seven immunocompetent patients aged > 50 years old presented with herpes zoster (HZ) infection in a median of 9 days (range 7–20) after vaccination against SARS-CoV-2. The occurrence of HZ within the time window 1–21 days after vaccination defined for increased risk and the reported T cell-mediated immunity involvement suggest that COVID-19 vaccination is a probable cause of HZ. These cases support the importance of continuing assessment of vaccine safety during the ongoing massive vaccination for the COVID-19 pandemic and encourage reporting and communication of any vaccination-associated adverse event."

[357] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Authorea
Roxana Bruno, Peter A. Mccullough, et al.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

"**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 [*emphasis added*]."

[358] ***Herpes zoster following BNT162b2 mRNA COVID-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series***
Rheumatology
Victoria Furer, Devy Zisman, Adi Kibari, Doron Rimar, Yael Paran, and Ori Elkayam
April 13, 2021
https://academic.oup.com/rheumatology/advance-article/doi/10.1093/rheumatology/keab345/6225015

"**Objectives**: As global vaccination campaigns against COVID-19 disease commence, vaccine safety needs to be closely assessed. The safety profile of mRNA-based vaccines in patients with autoimmune inflammatory rheumatic diseases (AIIRD) is unknown. The objective of this report is to raise awareness of reactivation of herpes zoster (HZ) following the BNT162b2 mRNA vaccination in patients with AIIRD (autoimmune inflammatory rheumatic diseases)…

Conclusion: Epidemiologic studies on the safety of the mRNA-based COVID-19 vaccines in patients with AIIRD are needed to clarify the association between the BNT162b2 mRNA vaccination and reactivation of zoster."

[359] ***Reaction of Human Monoclonal Antibodies to SARS-CoV-2 Proteins With Tissue Antigens: Implications for Autoimmune Diseases***
Frontiers in Immunology
Aristo Vojdani, Elroy Vojdani, and Datis Kharrazian
January 19, 2021
https://www.frontiersin.org/articles/10.3389/fimmu.2020.617089/full

"**Discussion**: … Our study also identified several cross-reactive interactions that may lead to specific autoimmune patterns. For example, we found that SARS-CoV-2 spike protein, nucleoprotein, and membrane protein all cross-reacted with TPO [thyroid peroxidase]…

In a very recent publication in JAMA, Trogen et al. said, 'What cannot and must not be allowed is for desperation to result in the suspension of scientific principles and ethical research values.' We ourselves would apply these principles and ethical values towards investigating whether SARS-CoV-2 peptides contained in a future vaccine may cross-react with human tissue antigens and possibly result in autoimmunity. But while the possibility of future autoimmune disease is daunting and very real, it must be remembered that without vaccinations the SARS-CoV-2 pandemic will spread unchecked, bringing with it a slew of multiple system disorders including autoimmunities both in the present and the future."

[360] **Correspondence:** ***Implications of antibody-dependent enhancement of infection for SARS-CoV-2 countermeasures***
Nature Biotechnology
Nikolai Eroshenko, Taylor Gill, Marianna K. Keaveney, George M. Church, Jose M. Trevejo, and Hannu Rajaniemi
June 5, 2020
https://www.nature.com/articles/s41587-020-0577-1

> "When four different SARS-CoV vaccines developed for human use were tested in mice (two different whole virus vaccines, a recombinant spike protein, and a virus-like particle), they all triggered pulmonary immunopathology upon viral challenge."

[361] ***Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity***
Journal of Translational Autoimmunity
James Lyons-Weiler
April 9, 2020
https://www.sciencedirect.com/science/article/pii/S2589090203001 86?via%3Dihub

> "**Highlights**: The list of viral/human protein matches… indicates which epitopes might be responsible for autoimmunological pathogenic priming due to prior infection or following exposure to SARS-CoV-2 or relatives following vaccination. These epitopes should be excluded from vaccines under development to minimize autoimmunity due to risk of pathogenic priming…
>
> **Discussion**: … The fact that pathogenic priming may be occurring involving autoimmunity against multiple proteins following CoV vaccination is consistent with other observations observed during autoimmunity, including the release of proinflammatory cytokines and cytokine storm. Similar to the SARS-CoV animal studies [6], found that mice vaccinated against MERS-CoV (Middle East Respiratory Syndrome) development exaggerated pulmonary immunopathology when challenged with the MERS virus following vaccination."

COVID-19 and Natural Immunity

[362] ***#Estimated COVID-19 Burden***
Centers for Disease Control and Prevention (CDC)
Note: On September 17, 2021, this page stated 120.2 million 'Estimated Total Infections' as of May 29, 2021.
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

[363] **ADDED since 10/14/2021**
128 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted
Brownstone Institute
Paul Elias Alexander, Harvey Risch, Howard Tenenbaum, Ramin Oskoui, Peter McCullough, and Parvez Dara
October 17, 2021
https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

> Provides links to and key excerpts from "128 of the highest-quality, complete, most robust scientific studies and evidence reports/position statements on natural immunity as compared to COVID-19 vaccine-induced immunity."

Note: The citations below are presented in reverse, chronological order.

[364] **ADDED since 10/14/2021**
Protective immunity after recovery from SARS-CoV-2 infection
Infectious Diseases – The Lancet
Noah Kojima and Jeffrey D. Klausner
November 8, 2021
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00676-9/fulltext

> "We reviewed studies published in PubMed from inception to Sept 28, 2021, and found well conducted biological studies showing protective immunity after infection (panel). Furthermore, multiple epidemiological and clinical studies, including studies during the recent period of predominantly delta (B.1.617.2) variant transmission, found that the risk of repeat SARS-CoV-2 infection decreased by 80.5–100% among those who had had COVID-19 previously (panel). The reported studies were large and conducted throughout the world. Another laboratory-based study that analysed the test results of 9119 people with previous COVID-19 from Dec 1, 2019, to Nov 13, 2020, found that only 0.7% became reinfected. In a study conducted at the Cleveland Clinic in Cleveland, OH, USA, those who had not previously been infected had a COVID-19 incidence rate of 4.3 per 100 people, whereas those who had previously been infected had a COVID-19 incidence rate of 0 per 100 people. Furthermore, a study conducted in Austria found that the frequency of hospitalisation due to a repeated infection was five per 14,840 (0·03%) people and the frequency of death due to a repeated infection was one per 14,840 (0·01%) people… Due to the strong association and biological basis for protection, clinicians should consider counselling recovered patients on their risk for reinfection and document previous infection status in medical records.
>
> [T]hose studies show that **protection from reinfection is strong** and **persists for more than**

10 months of follow-up [*emphasis added*], it is unknown how long protective immunity will truly last. Many systemic viral infections, such as measles, confer long-term, if not lifelong, immunity, whereas others, such as influenza, do not (due to changes in viral genetics). We are limited by the length of current reported follow-up data to know with certainty the expected duration that previous infection will protect against COVID-19. Encouragingly, authors of a study conducted among recovered individuals who had experienced mild SARS-CoV-2 infection reported that mild infection induced a robust antigen-specific, long-lived humoral immune memory in humans…

Some people who have recovered from COVID-19 might not benefit from COVID-19 vaccination. In fact, one study found that previous COVID-19 was **associated with increased adverse events** following vaccination with the Comirnaty BNT162b2 mRNA vaccine (Pfizer–BioNTech) [*emphasis added*]…

Given the evidence of immunity from previous SARS-CoV-2 infection, however, policy makers should consider recovery from previous SARS-CoV-2 infection equal to immunity from vaccination for purposes related to entry to public events, businesses, and the workplace, or travel requirements."

[365] **ADDED since 10/14/2021**

CDC response to Freedom of Information Act Request re. COVID-19 Reinfection and Transmission

Submitted by Siri & Glimstad LLP (attorneys) to Centers for Disease Control and Prevention (CDC)
November 5, 2021
https://www.sirillp.com/wp-content/uploads/2021/11/21-02152-Final-Response-Letter-Brehm-1.pdf

"Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 02, 2021, Freedom of Information Act (FOIA) request on September 02, 2021, seeking:

> 'Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected.'

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that **this information is not collected** [*emphasis added*]…

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer"

[366] **ADDED since 10/14/2021**

Video (6m): Testimony of Dr. Aditi Bhargava
November 3, 2021
https://odysee.com/@Anon:96/aditibhargava:f

> **Bhargava**: "My name is Aditi Bhargava and I'm a professor at UCSF and a microbiologist with 33 years of research experience. These are my scientific views…
>
> Natural immunity is the gold standard.
>
> CDC estimates that nearly 43% of the country has already been infected with SARS-CoV-2 and thus naturally immune. And that was all before the more transmissible delta variant took hold.
>
> Living in a bubble of sterile conditions is counterproductive to everything we know about strengthening the immune system. It's Immunology 101. To downplay the beneficial and protective powers of our immune system goes against the founding principles of immunology. Several studies about SARS-CoV-2 are validating that knowledge.
>
> There is **no documented case of a naturally immune person getting re-infected with severe disease or hospitalisation**, despite the first case reported nearly two years ago. In sharp contrast, **there are thousands of cases of severe COVID hospitalisations and deaths in fully vaccinated people** [*emphasis added*].
>
> CDC now estimates 90% of Americans over the age of 16 have antibodies against SARS-CoV-2. But vaccine induced antibodies are only a small fraction of our immune responses.
>
> Immune studies from the British Health Ministry suggests that Covid vaccines might interfere with the ability of our immune system to produce antibodies against other parts of the virus, [a] crucial aspect for developing cross protection. The spike antibodies are incomplete and cherry-picked stories.
>
> Vaccine induced protection fell through **33 to 42% within 3 months** [*emphasis added*]. That is no different than the protection the unvaccinated have. Hence mandates to prevent spread by using spike antibody levels as the gold standard is gross misrepresentation of data."

[367] **ADDED since 10/14/2021**

A Review and Autopsy of Two COVID Immunity Studies
Brownstone Institute
Martin Kulldorff
November 2, 2021
https://brownstone.org/articles/a-review-and-autopsy-of-two-covid-immunity-studies/

> "How effective is immunity after Covid recovery relative to vaccination? An Israeli study by Gazit et al. found that the vaccinated have a 27 times higher risk of symptomatic infection than the Covid recovered. At the same time, the vaccinated were nine times more likely to be hospitalized for Covid. In contrast, a CDC study by Bozio et al. claims that the Covid recovered are five times more likely to be hospitalized for Covid than the vaccinated. Both studies cannot be right.
>
> I have worked on vaccine epidemiology since I joined the Harvard faculty almost two decades ago as a biostatistician. I have never before seen such a large discrepancy between studies that are supposed to answer the same question. In this article, I carefully dissect both studies,

describe how the analyses differ, and explain why the Israeli study is more reliable…

Conclusion: … Based on the solid evidence from the Israeli study, the Covid recovered have stronger and longer-lasting immunity against Covid disease than the vaccinated. Hence, there is no reason to prevent them from activities that are permitted to the vaccinated. In fact, it is discriminatory."

[368] **ADDED since 10/14/2021**

Physicians Declaration II

International Alliance of Physicians and Medical Scientists (Global Covid Summit)
October 29, 2021
https://doctorsandscientistsdeclaration.org/
Note: Signed by "thousands [*of*] physicians, medical scientists and researchers from around the globe."
About: "Global Covid Summit is the product of an international alliance of doctors and scientists, committed to speaking truth to power about Covid pandemic research and treatment. Thousands have died from Covid as a result of being denied life-saving early treatment. The Declaration is a battle cry from physicians who are daily fighting for the right to treat their patients, and the right of patients to receive those treatments - without fear of interference, retribution or censorship by government, pharmacies, pharmaceutical corporations, and big tech. We demand that these groups step aside and honor the sanctity and integrity of the patient-physician relationship, the fundamental maxim 'First Do No Harm', and the freedom of patients and physicians to make informed medical decisions. Lives depend on it."
https://globalcovidsummit.org/page/about

"WE, THE PHYSICIANS OF THE WORLD, united and loyal to the Hippocratic Oath, recognizing the imminent threat to humanity brought forth by current Covid-19 policies, are compelled to declare the following:

WHEREAS, after 20 months of research, millions of patients treated, hundreds of clinical trials performed and scientific data shared, we have demonstrated and documented our success and understanding in combating COVID-19;

WHEREAS, in considering the risks vs. benefits of major policy decisions, thousands of physicians and medical scientists worldwide have reached consensus on three foundational principles;

NOW THEREFORE, IT IS:

RESOLVED, THAT HEALTHY CHILDREN SHALL NOT BE SUBJECT TO FORCED VACCINATION

- Negligible clinical risks from SARS-CoV-2 infection exist for healthy children under eighteen…
- **Children risk severe, adverse events** from receiving the vaccine…

RESOLVED, THAT NATURALLY IMMUNE PERSONS RECOVERED FROM SARS-CoV-2 SHALL NOT BE SUBJECT TO ANY RESTRICTIONS OR VACCINE MANDATES

- Natural immunity is the **most protective**, and **longest-lasting solution** against the development of COVID-19 disease and its more serious outcomes.

- Naturally immune persons are at the lowest risk of transmission, thus should not be subject to travel, professional, medical or social restrictions.
- Natural immunity provides the best source of herd immunity, a condition necessary for eradicating the Covid virus.

RESOLVED, THAT ALL HEALTH AGENCIES AND INSTITUTIONS SHALL CEASE INTERFERING WITH PHYSICIANS TREATING INDIVIDUAL PATIENTS (view supporting evidence)

- Early intervention with numerous, available agents has proven to be safe and effective, and has **saved hundreds of thousands of lives**.
- No medicine already given regulatory approval shall be restricted from "off-label" use, particularly during this global humanitarian crisis caused by a rapidly mutating virus, which requires quick to adopt treatment strategies.
- Health agencies shall be prohibited from interfering with physicians prescribing evidence-based treatments they deem necessary, and insurance companies must cease blocking payments for life-saving medicine prescribed by doctors.

RECOMMENDED LEGISLATIVE OR EXECUTIVE ACTION:

We believe that **violating any of these three principles unnecessarily** and **directly risks death to our citizens**. We hereby recommend the leaders of states, provinces and nations legislate or take executive action to prohibit the three practices described above [*emphasis added*]."

[369] ***One-year sustained cellular and humoral immunities of COVID-19 convalescents***
Clinical Infectious Diseases
Jie Zhang, Hao Lin, *et al*.
October 5, 2021
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561

"**Results**: SARS-CoV-2-specific IgG antibodies, and also NAb can persist among over 95% COVID-19 convalescents from 6 months to 12 months after disease onset."

[370] ***Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans***
European Journal of Immunology
Anu Haveri, Nina Ekstron, *et al*.
September 27, 2021
https://onlinelibrary.wiley.com/doi/10.1002/eji.202149535

"**Abstract**: Most subjects develop antibodies to SARS-CoV-2 following infection. In order to estimate the duration of immunity induced by SARS-CoV-2 it is important to understand for how long antibodies persist after infection in humans. Here, we assessed the persistence of serum antibodies following wild-type SARS-CoV-2 infection at 8 and 13 months after diagnosis in 367 individuals… We found that **NAb [*neutralizing antibodies*] against the wild-type virus persisted in 89%** and S-IgG in 97% **of subjects for at least 13 months** after infection [*emphasis added*]."

[371] ***The prevalence of adaptive immunity to COVID-19 and reinfection after recovery – a***

comprehensive systematic review and meta-analysis of 12,011,447 individuals
Qatar University
Tawanda Chivese, Joshua T. Matizanadzo, *et al*.
September 17, 2021
https://www.medrxiv.org/content/10.1101/2021.09.03.21263103v3.full-text

"**Methods and analyses**: A synthesis of existing research was conducted. The Cochrane Library for COVID-19 resources, the China Academic Journals Full Text Database, PubMed, and Scopus as well as preprint servers were searched for studies conducted between 1 January 2020 to 1 April 2021. We included studies with the relevant outcomes of interest. All included studies were assessed for methodological quality and pooled estimates of relevant outcomes were obtained in a meta-analysis using a bias adjusted synthesis method…

Results: Fifty-four studies, from 18 countries, with a total of 12 011 447 individuals, followed up to 8 months after recovery, were included. At 6-8 months after recovery, the **prevalence of detectable SARS-CoV-2 specific immunological memory remained high**; IgG – 90.4% …, CD4+ - 91.7%..., and memory B cells 80.6%... and the **pooled prevalence of reinfection was 0.2%** [*emphasis added*]. Individuals who recovered from COVID-19 had an 81% reduction in odds of a reinfection.

Conclusion: Around 90% of people previously infected with SARS-CoV-2 had evidence of immunological memory to SARS-CoV-2, which was sustained for at least 6-8 months after recovery, and had a low risk of reinfection."

[372] ***Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?***
British Medical Journal
Jennifer Block
September 13, 2021
https://www.bmj.com/content/374/bmj.n2101

"The US CDC estimates that SARS-CoV-2 has infected more than 100 million Americans, and evidence is mounting that natural immunity is at least as protective as vaccination. Yet public health leadership says everyone needs the vaccine…

The evidence: 'Starting from back in November, we've had a lot of really important studies that showed us that memory B cells and memory T cells were forming in response to natural infection,' says Gandhi [*an infectious disease specialist at University of California San Francisco*]. Studies are also showing, she says, that these memory cells will respond by producing antibodies to the variants at hand.

Gandhi included a list of some 20 references on natural immunity to covid in a long Twitter thread supporting the durability of both vaccine and infection induced immunity. 'I stopped adding papers to it in December because it was getting so long,' she tells The BMJ.

But the studies kept coming. A National Institutes of Health (NIH) funded study from La Jolla Institute for Immunology found 'durable immune responses' in 95% of the 200 participants up to eight months after infection. One of the largest studies to date, published in Science in February 2021, found that although antibodies declined over 8 months, memory B cells increased over time, and the half life of memory CD8+ and CD4+ T cells suggests a steady presence.

Real world data have also been supportive. Several studies (in Qatar, England, Israel, and the

US) have found infection rates at equally low levels among people who are fully vaccinated and those who have previously had covid-19. Cleveland Clinic surveyed its more than 50 000 employees to compare four groups based on history of SARS-CoV-2 infection and vaccination status. Not one of over 1300 unvaccinated employees who had been previously infected tested positive during the five months of the study. Researchers concluded that that cohort 'are unlikely to benefit from covid-19 vaccination.' In Israel, researchers accessed a database of the entire population to compare the efficacy of vaccination with previous infection and found nearly identical numbers. 'Our results question the need to vaccinate previously infected individuals,' they concluded' …

Different risk-benefit analysis? … A large study in the UK and another that surveyed people internationally found that people with a history of SARS-CoV-2 infection experienced greater rates of side effects after vaccination. Among 2000 people who completed an online survey after vaccination, those with a history of covid-19 were **56% more likely to experience a severe side effect that required hospital care** [*emphasis added*].

Patrick Whelan, of UCLA, says the 'sky high' antibodies after vaccination in people who were previously infected may have contributed to these systemic side effects. 'Most people who were previously ill with covid-19 have antibodies against the spike protein. If they are subsequently vaccinated, those antibodies and the products of the vaccine can form what are called immune complexes,' he explains, which may get deposited in places like the joints, meninges, and even kidneys, creating symptoms."

[373] ***Open Letter and Notice of Liability from Doctors and Scientists to the EMA and the Members of the European Parliament Regarding COVID-19 Vaccination***
Doctors for COVID Ethics
September 13, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Letter-and-Notice-of-Liability-to-EMA-and-MEPs.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"Until recently, the immune profile of COVID-19 and COVID-19 vaccines was not fully characterised. While we have known since mid-2020 that robust and lasting memory T-cell immunity to SARS-CoV-2 exists, the antibody picture has been less clear. Now, however, a convergence of evidence from **peer reviewed studies published in 2021** reveals that **pre-existing immunity to SARS-CoV-2 involves not only T-cells but also memory antibodies**, in 99% of people studied [*emphasis added*]."

[374] ***Protracted yet Coordinated Differentiation of Long-Lived SARS-CoV-2-Specific CD8+ T Cells during Convalescence***
Journal of Immunology (University of California, San Franscisco)
Toncui Ma, Heeju Ryu, *et al*.
September 1, 2021
https://www.jimmunol.org/content/207/5/1344

"**Abstract**: … These results suggest that following a typical case of mild COVID-19, SARS-CoV-2–specific CD8+ T cells not only persist but continuously differentiate in a coordinated fashion well into convalescence into a state characteristic of long-lived, self-renewing memory."

[375] ***Anti- SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA Vaccination***

The Rockefeller University (New York)
Alice Cho, Frauke Muecksch, *et al*.
August 30, 2021
https://www.biorxiv.org/content/10.1101/2021.07.29.454333v2.full

"**Summary**: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection produces B-cell responses that continue to evolve for at least one year. During that time, memory B cells express increasingly broad and potent antibodies that are **resistant to mutations found in variants of concern** [*emphasis added*]…"

[376] ***A Systematic Review of the Protective Effect of Prior SARS-CoV-2 Infection on Repeat Infection***
medRxiv
N. Kojima, N.K. Shrestha, and J.D. Klausner
August 29, 2021
https://www.medrxiv.org/content/10.1101/2021.08.27.21262741v1

"**Methods**: For this systematic review, we searched scientific publications on PubMed and, the pre-print server, MedRxiv through August 18, 2021… To identify relevant studies with appropriate control groups, we developed the following criteria for studies to be included in the systematic analysis: (1) baseline polymerase chain reaction (PCR) testing, (2) a negative comparison group, (3) longitudinal follow-up, (4) a cohort of human participants, i.e., not a case report or case series, and (5) outcome determined by PCR. The review was conducted following PRISMA guidelines. We assessed for selection, information, and analysis bias, per PRISMA guidelines.

Results: We identified 1,392 reports. Of those, 10 studies were eligible for our systematic review. The **weighted average risk reduction against reinfection was 90.4%** with a standard deviation of 7.7%. Protection against SARS-CoV-2 reinfection was observed for up to 10 months [*emphasis added*]."

[377] ***Having SARS-CoV-2 once confers much greater immunity than a vaccine—but vaccination remains vital***
Science Insider
Meredity Wadman
August 26, 2021
https://www.science.org/news/2021/08/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital

"The natural immune protection that develops after a SARS-CoV-2 infection offers considerably more of a shield against the Delta variant of the pandemic coronavirus than two doses of the Pfizer-BioNTech vaccine, according to a large Israeli study... The newly released data show people who once had a SARS-CoV-2 infection were much less likely than never-infected, vaccinated people to get Delta, develop symptoms from it, or become hospitalized with serious COVID-19…

The new analysis relies on the database of Maccabi Healthcare Services, which enrolls about 2.5 million Israelis. The study, led by Tal Patalon and Sivan Gazit at KSM, the system's research and innovation arm, found in two analyses that never-infected people who were vaccinated in January and February were, in June, July, and the first half of August, six to 13 times more likely

to get infected than unvaccinated people who were previously infected with the coronavirus. In one analysis, comparing more than 32,000 people in the health system, the risk of developing symptomatic COVID-19 was **27 times higher** among the vaccinated, and the risk of hospitalization **eight times higher** [*emphasis added*]."

[378] ***Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection***
Tel-Aviv University (Israel)
Ariel Israel, Yotam Shenhar, *et al*.
August 22, 2021
https://www.medrxiv.org/content/10.1101/2021.08.19.21262111v1.full-text

"**Objective**: To determine the kinetics of SARS-CoV-2 IgG antibodies following administration of two doses of BNT162b2 vaccine, or SARS-CoV-2 infection in unvaccinated individuals.

Results: A total of 2,653 individuals fully vaccinated by two doses of vaccine during the study period and 4,361 convalescent patients were included. Higher SARS-CoV-2 IgG antibody titers were observed in vaccinated individuals (median 1581 AU/mL IQR [533.8-5644.6]) after the second vaccination, than in convalescent individuals (median 355.3 AU/mL IQR [141.2-998.7]; p<0.001). In vaccinated subjects, **antibody titers** decreased by up to **40%** each subsequent month while in convalescents they decreased by less than **5%** per month…

Conclusions: This study demonstrates individuals who received the Pfizer-BioNTech mRNA vaccine have different kinetics of antibody levels compared to patients who had been infected with the SARS-CoV-2 virus, with higher initial levels but a much faster exponential decrease in the first group."

[379] ***Pre-activated antiviral innate immunity in the upper airways controls early SARS-CoV-2 infection in children***
Nature Biotechnology
J. Loske, J. Rohmel, *et al*.
August 18, 2021
https://www.nature.com/articles/s41587-021-01037-9

"**Abstract**: … Children displayed higher basal expression of relevant pattern recognition receptors such as MDA5 (IFIH1) and RIG-I (DDX58) in upper airway epithelial cells, macrophages and dendritic cells, resulting in stronger innate antiviral responses upon SARS-CoV-2 infection than in adults. We further detected distinct immune cell subpopulations including KLRC1 (NKG2A)+ cytotoxic T cells and a CD8+ T cell population with a memory phenotype occurring predominantly in children. Our study provides evidence that the airway immune cells of children are primed for virus sensing, resulting in a stronger early innate antiviral response to SARS-CoV-2 infection than in adults."

[380] ***Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections***
KSM Research and Innovation Center, Maccabitech Institute for Research and Innovation (Israel)
Sivan Gazit, Roei Shlezinger, *et al*.
August 13, 2021
https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1

"**Results**: SARS-CoV-2-naïve vaccinees [*vaccine recipients with no prior SARS-CoV-2 infection*] had a **13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection** with the Delta variant compared to those previously infected [*emphasis added*], when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant (P<0.001) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a 5.96-fold (95% CI, 4.85 to 7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

Conclusions: This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity."

[381] ***Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants***
Science magazine
Lingshu Wang, Tongqing Zhou, *et al*.
August 13, 2021
https://science.sciencemag.org/content/373/6556/eabh1766

"**Introduction**: Worldwide appearance of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOCs) with increased transmissibility and resistance to therapeutic antibodies necessitates the discovery of broadly reactive antibodies. We isolated receptor binding domain (RBD) targeting antibodies that potently neutralize 23 variants…

Conclusion: Our study demonstrates that convalescent subjects previously infected with ancestral variant SARS-CoV-2 produce antibodies that cross-neutralize emerging VOCs with high potency."

[382] ***Seven-month kinetics of SARS-CoV-2 antibodies and role of pre-existing antibodies to human coronaviruses***
Nature Communications
Natalia Ortega, Marta Ribes, *et al*.
August 6, 2021
https://www.nature.com/articles/s41467-021-24979-9

"**Abstract**: Unraveling the long-term kinetics of antibodies to SARS-CoV-2 and the individual characteristics influencing it, including the impact of pre-existing antibodies to human coronaviruses causing common cold (HCoVs), is essential to understand protective immunity to COVID-19 and devise effective surveillance strategies. IgM, IgA and IgG levels against six SARS-CoV-2 antigens and the nucleocapsid antigen of the four HCoV (229E, NL63, OC43 and HKU1) were quantified by Luminex, and antibody neutralization capacity was assessed by flow

cytometry, in a cohort of health care workers followed up to 7 months (N = 578). **Seroprevalence increases over time** from 13.5% (month 0) and 15.6% (month 1) to 16.4% (month 6) [*emphasis added*]. Levels of antibodies, including those with neutralizing capacity, are stable over time, except IgG to nucleocapsid antigen and IgM levels that wane. After the peak response, anti-spike antibody levels increase from ~150 days post-symptom onset in all individuals (73% for IgG), in the absence of any evidence of re-exposure. IgG and IgA to HCoV are significantly higher in asymptomatic than symptomatic seropositive individuals. Thus, pre-existing cross-reactive HCoVs antibodies could have a protective effect against SARS-CoV-2 infection and COVID-19 disease."

[383] ***One Year after Mild COVID-19: The Majority of Patients Maintain Specific Immunity, But One in Four Still Suffer from Long-Term Symptoms***
Journal of Clinical Medicine (University of Augsburg, Germany)
Andreas Rank, Athanasia Tzortzini, *et al*.
July 27, 2021
https://www.mdpi.com/2077-0383/10/15/3305

"**Abstract**: … This study focused on mild COVID-19 and investigated correlations of immunity with persistent symptoms and immune longevity… Activation-induced marker assays identified specific T-helper cells and central memory T-cells in 80% of participants at a 12-month follow-up."

[384] ***Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells***
Cell Reports Medicine
Kristen W. Cohen, Susanne L. Linderman, *et al*.
July 20, 2021
https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00203-2?_return

"**Summary**: Ending the COVID-19 pandemic will require long-lived immunity to SARS-CoV-2. Here, we evaluate 254 COVID-19 patients longitudinally up to eight months and find durable broad-based immune responses… Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients…

Discussion: … Our findings show that most COVID-19 patients induce a wide-ranging immune defense against SARS-CoV-2 infection, encompassing antibodies and memory B cells recognizing both the RBD and other regions of the spike, broadly-specific and polyfunctional CD4+ T cells, and polyfunctional CD8+ T cells. The immune response to natural infection is likely to provide some degree of protective immunity even against SARS-CoV-2 variants because the CD4+ and CD8+ T cell epitopes will likely be conserved."

[385] ***CDC/IDSA COVID-19 Clinician Call***
Centers for Disease Control and Prevention (CDC) and Infectious Diseases Society of America (IDSA)
July 17, 2021
https://www.idsociety.org/globalassets/idsa/media/clinician-call-slides--qa/07-17-21-clinician-call-slides-1.pdf

Slide 1: "70th in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19"

Slide 39: "Immune responses to SARS-CoV-2 following natural infection can persist for at least 11 months"

[386] ***Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine***
University of California, Irvine
Suhas Sureshchandra, Sloan A. Lewis, et al.
July 15, 2021
https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1.full

"**Abstract**: … We used single-cell RNA sequencing and functional assays to compare humoral and cellular responses to two doses of mRNA vaccine with responses observed in convalescent individuals with asymptomatic disease. Our analyses revealed enrichment of spike-specific B cells, activated CD4 T cells, and robust antigen-specific polyfunctional CD4 T cell responses in all vaccinees. On the other hand, CD8 T cell responses were both weak and variable… Natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due to the recognition of a broader set of viral epitopes presented by the virus not seen in the mRNA vaccine."

[387] **ADDED since 10/14/2021**
Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees
Curative, Inc.
N Kojima, A Roshani, M Brobeck, A Baca, and JD Klausner
July 8, 2021
https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2.full-text

"**Introduction**: … Among a clinical laboratory that has been conducting routine workforce screening since the beginning of the pandemic, we aimed to assess the relative risk of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) infection among individuals who were SARS-CoV-2 naïve, previously infected, or vaccinated…

Conclusion: Previous SARS-CoV-2 infection and vaccination for SARS-CoV-2 were associated with decreased risk for infection or re-infection with SARS-CoV-2 in a routinely screened workforce. There was **no difference in the infection incidence** between vaccinated individuals and individuals with previous infection [*emphasis added*]."

[388] **ADDED since 10/14/2021**

Temporal maturation of neutralizing antibodies in COVID-19 convalescent individuals improves potency and breadth to circulating SARS-CoV-2 variants

Immunity (National Institute of Infectious Diseases, Tokyo, Japan)
Saya Moriyama, Yu Adachi, *et al*.
July 2, 2021
https://www.cell.com/immunity/fulltext/S1074-7613(21)00259-4

> "**Summary**: Antibody titers against SARS-CoV-2 slowly wane over time. Here, we examined how time affects antibody potency. To assess the impact of antibody maturation on durable neutralizing activity against original SARS-CoV-2 and emerging variants of concern (VOCs), we analyzed receptor binding domain (RBD)-specific IgG antibodies in convalescent plasma taken 1–10 months after SARS-CoV-2 infection. Longitudinal evaluation of total RBD IgG and neutralizing antibody revealed declining total antibody titers but improved neutralization potency per antibody to original SARS-CoV-2, indicative of antibody response maturation. Neutralization assays with authentic viruses revealed that early antibodies capable of neutralizing original SARS-CoV-2 had limited reactivity toward B.1.351 (501Y.V2) and P.1 (501Y.V3) variants. **Antibodies from late convalescents exhibited increased neutralization potency to VOCs**, suggesting persistence of cross-neutralizing antibodies in plasma. Thus, maturation of the antibody response to SARS-CoV-2 potentiates cross-neutralizing ability to circulating variants, suggesting that declining antibody titers may not be indicative of declining protection [*emphasis added*]."

[389] ***Impact of SARS-CoV-2 variants on the total CD4+ and CD8+ T cell reactivity in infected or vaccinated individuals***

Cell Reports Medicine
Alison Tarke, John Sidney, *et al*.
July 1, 2021
https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00204-4?

> "**Highlights**: T cells of exposed donors or vaccinees effectively recognize SARS-CoV-2 variants
>
> **Summary**: … [T]he SARS-CoV-2 variants analyzed here do not significantly disrupt the total SARS-CoV-2 T cell reactivity"

[390] **ADDED since 10/14/2021**

SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells

Nature Communications (Korea Advanced Institute of Science and Technology)
Jae Hyung Jung, Min-Seok Rha, *et al*.
June 30, 2021
https://www.nature.com/articles/s41467-021-24377-1

"**Abstract**: Memory T cells contribute to rapid viral clearance during re-infection, but the longevity and differentiation of SARS-CoV-2-specific memory T cells remain unclear. Here we conduct ex vivo assays to evaluate SARS-CoV-2-specific CD4+ and CD8+ T cell responses in COVID-19 convalescent patients **up to 317 days post-symptom onset (DPSO)**, and find that **memory T cell responses are maintained during the study period** regardless of the severity of COVID-19 [*emphasis added*]. In particular, we observe sustained polyfunctionality and proliferation capacity of SARS-CoV-2-specific T cells."

[391] ***Immunodominant T-cell epitopes from the SARS-CoV-2 spike antigen reveal robust pre-existing T-cell immunity in unexposed individuals***
Scientific Reports (Nature)
Swapnil Mahajan, Vasumathi Kode, *et al*.
June 23, 2021
https://www.nature.com/articles/s41598-021-92521-4

"**Abstract**: … In this study, we identified immunodominant CD8 T-cell epitopes in the spike antigen using a novel TCR-binding algorithm. The predicted epitopes induced robust T-cell activation in unexposed donors demonstrating pre-existing CD4 and CD8 T-cell immunity to SARS-CoV-2 antigen… [O]ur findings suggest that SARS-CoV-2 reactive T-cells are likely to be present in many individuals because of prior exposure to flu and CMV viruses."

[392] ***Necessity of COVID-19 vaccination in previously infected individuals***
Cleveland Clinic
Nabin K. Shrestha, Patrick C. Burke, *et al*.
June 19, 2021
https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.full-text

"**Conclusions**: Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.

Summary: Cumulative incidence of COVID-19 was examined among 52238 employees in an American healthcare system [*Cleveland Clinic Health System*]. COVID-19 did not occur in anyone over the five months of the study among 2579 individuals previously infected with COVID-19, **including 1359 who did not take the vaccine** [*emphasis added*]."

[393] ***SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity***
The Lancet
Stine SF Nielsen, Line K Vibholm, *et al*.
June 4, 2021
https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00203-6/fulltext

"**Added value of this study**: In this context, we investigated, the adaptive immune response developed during SARS-CoV-2 infections in 203 recovered patients experiencing a full spectrum of disease severity, from asymptomatic infections to severe cases requiring hospitalization. The analysis of both binding and neutralization capacity of participant antibodies, alongside CD8+ T-cell responses, towards multiple SARS-CoV-2 epitopes, provides a broad characterization of the adapted response during primary virus infection. We found that the vast majority of recovered individuals have clearly detectable and functional SARS-CoV-2 spike specific adaptive immune responses, despite diverse disease severities…

Discussion: … Overall, our results show that the majority of patients developed a **robust and broad both humoral and cellular immune response** to SARS-CoV-2 [*emphasis added*]."

[394] **Research Letter: *Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy***
JAMA Internal Medicine (Magenta Hospital and Legnano Hospital, Italy)
Jose Vitale, Nicola Murnoli, *et al*.
May 28, 2021
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2780557

"**Methods**: We investigated the incidence of SARS-CoV-2 primary infection and reinfection among individuals who, during the first wave of the pandemic in Italy (February to July 2020), underwent diagnostic reverse-transcriptase–polymerase chain reaction (PCR)…

Results: … During the follow-up (mean [SD], 280 days) 5 reinfections … were confirmed in the cohort of 1579 positive patients…

Discussion: The study results suggest that reinfections are rare events and patients who have recovered from COVID-19 have a lower risk of reinfection. Natural immunity to SARS-CoV-2 appears to confer a protective effect for at least a year."

[395] **ADDED since 10/14/2021**
Email and FedEx to Rochelle P. Walensky, Director of the CDC: *re. CDC recommendations regarding the fully vaccinated*
Siri & Glimstad LLP (attorneys)
Aaron Siri, Elizabeth A. Brehm, Caroline Tucker, and Jessica Wallace
May 28, 2021
https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-July-6-petition.pdf

"We write on behalf of our client and its members with regard to certain recently announced updates in CDC recommendations, reflected on the CDC's *When You've Been Fully Vaccinated* and *Interim Public Health Recommendations for Fully Vaccinated People* webpages. These recommendations apply to only fully vaccinated individuals. We write to request clarification that the additional 'freedoms' afforded to those that have been immunized will also be afforded to those that have had COVID-19 (the 'convalescent'). As outlined below and in the attached Declaration of Peter A. McCullough, MD, MPH, **restrictions on the rights and civil liberties of the convalescent** beyond the restrictions placed on the vaccinated **are not supported by the existing science** *[emphasis added]*."

[396] ***Quantifying the risk of SARS-CoV-2 reinfection over time***
Reviews in Medical Virology
Patricial Harrington and Mairin Ryan
May 27, 2021
https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260

"**Summary**: … To our knowledge, this is the first systematic review to synthesise the evidence on the risk of SARS-CoV-2 reinfection over time… Across studies, the total number of PCR-positive or antibody-positive participants at baseline was 615,777, and the maximum duration of follow-up was more than 10 months in three studies. **Reinfection was an uncommon event (absolute rate 0%–1.1%)**, with no study reporting an increase in the risk of reinfection over

time… These data suggest that **naturally acquired SARS-CoV-2 immunity does not wane for at least 10 months post-infection** [*emphasis added*]."

[397] ***Had COVID? You'll probably make antibodies for a lifetime***
Nature magazine
Ewen Callaway
May 26, 2021
https://www.nature.com/articles/d41586-021-01442-9

"Many people who have been infected with SARS-CoV-2 will probably make antibodies against the virus for most of their lives. So suggest researchers who have identified long-lived antibody-producing cells in the bone marrow of people who have recovered from COVID-19.

The study provides evidence that immunity triggered by SARS-CoV-2 infection will be **extraordinarily long-lasting** [*emphasis added*]."

[398] ***SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans***
Nature magazine – Washington University School of Medicine
Jackson S. Turner, Wooseob Kim, *et al*.
May 24, 2021:
https://www.nature.com/articles/s41586-021-03647-4

"**Abstract**: … Consistently, circulating resting memory B cells directed against SARS-CoV-2 S were detected in the convalescent individuals. Overall, our results indicate that **mild infection with SARS-CoV-2 induces robust antigen-specific, long-lived humoral immune memory** in humans [*emphasis added*]."

[399] ***Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2***
Hospices Civils de Lyon (France)
Claudia Gonzalez, Carla Saade, *et al*.
May 11, 2021
https://www.medrxiv.org/content/10.1101/2021.05.11.21256578v1.full-text

"**Background**: … SARS-CoV-2 mutations appeared recently and can lead to conformational changes in the spike protein and probably induce modifications in antigenicity. In this study, we wanted to assess the neutralizing capacity of antibodies to prevent cell infection, using a live virus neutralisation test.

Methods: Sera samples were collected from different populations: two-dose vaccinated COVID-19-naïve healthcare workers (HCWs; Pfizer-BioNTech BNT161b2), 6-months post mild COVID-19 HCWs, and critical COVID-19 patients. We tested various clades such as 19A (initial one), 20B (B.1.1.241 lineage), 20I/501Y.V1 (B.1.1.7 lineage), and 20H/501Y.V2 (B.1.351 lineage).

Conclusion: Neutralisation capacity was slightly reduced for critical patients and HCWs 6-months post infection. No neutralisation escape could be feared concerning the two variants of concern in both populations. The **reduced neutralising response observed** towards the 20H/501Y.V2 in comparison with the 19A and 20I/501Y.V1 isolates **in fully immunized subjects with the BNT162b2 vaccine** is a striking finding of the study [*emphasis added*]."

[400] ***WHO scientific brief: COVID-19 natural immunity***
World Health Organization (WHO)
May 10, 2021
https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y

"**Key Messages**:

- Within 4 weeks following infection, 90-99% of individuals infected with the SARS-CoV-2 virus develop detectable neutralizing antibodies.
- The strength and duration of the immune responses to SARS-CoV-2 are not completely understood and currently available data suggests that it varies by age and the severity of symptoms. Available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months)."

[401] ***The BNT162b2 mRNA vaccine against SARS-CoV-2 reprograms both adaptive and innate immune responses***
Radhoud University Medical Center (Netherlands)
F. Konstantin Fohse, Busranur Geckin, *et al*.
May 6, 2021
https://www.medrxiv.org/content/10.1101/2021.05.03.21256520v1.full-text

"In conclusion, our data show that the BNT162b2 vaccine [*Pfizer/BioNTech*] induces effects on both the adaptive and the innate branch of immunity and that these effects are different for various SARS-CoV-2 strains. Intriguingly, the BNT162b2 vaccine induces reprogramming of innate immune responses as well, and this needs to be taken into account: in combination with strong adaptive immune responses, this could contribute to a more balanced inflammatory reaction during COVID-19 infection, or it may contribute to a **diminished innate immune response** towards the virus [*emphasis added*]."

[402] ***Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection***
New York University
Ellie Ivanova, Joseph Devlin, *et al*.
May 3, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3838993

"**Abstract**: Both SARS-CoV-2 infection and vaccination elicit potent immune responses… While both infection and vaccination induced robust innate and adaptive immune responses, our analysis revealed significant qualitative differences between the two types of immune challenges."

[403] ***SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy***
EClinical Medicine published by the Lancet (Cornell University, Doha, Qatar)
Laith J. Abu-Raddad, Hiam Chemaitelly, *et al*.
April 27, 2021
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00141-3/fulltext

> "**Interpretation**: Reinfection is rare in the young and international population of Qatar. Natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months."

[404] ***Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel***
Sheba Medical Center (Israel)
Yair Goldberg, Micha Mandel, *et al*.
April 24, 2021
https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full-text

> "**Abstract**: … Vaccination was highly effective with overall estimated efficacy for documented infection of 92·8% (CI:[92·6, 93·0]); hospitalization 94·2% (CI:[93·6, 94·7]); severe illness 94·4% (CI:[93·6, 95·0]); and death 93·7% (CI:[92·5, 94·7]). Similarly, the overall estimated level of protection from prior SARS-CoV-2 infection for documented infection is 94·8% (CI:[94·4, 95·1]); hospitalization 94·1% (CI:[91·9, 95·7]); and severe illness 96·4% (CI:[92·5, 98·3]). Our results question the need to vaccinate previously-infected individuals."

[405] ***Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study***
The Lancet
Christian Holm Hansen, Daniela Michlmayr, Sophie Madeleine Gubbels, Kare Melbak, and Steen Ethelberg
March 27, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00575-4/fulltext

> **Background**: … In 2020, as part of Denmark's extensive, free-of-charge PCR-testing strategy, approximately 4 million individuals (69% of the population) underwent 10·6 million tests. Using these national PCR-test data from 2020, we estimated protection towards repeat infection with SARS-CoV-2….
>
> **Discussion**: We used a large national surveillance dataset of individually referable PCR test results to estimate the degree to which previous infection with SARS-CoV-2 results in protection against repeat infection. We found protection in the population to be **80% or higher in those younger than 65 years**, but to be approximately 47% in those aged 65 years and older. **We did not see signs of waning protection against repeat infection** within the year 2020 [*emphasis added*]."

[406] **ADDED since 10/14/2021**

SARS-CoV-2 infection induces sustained humoral immune responses in convalescent patients following symptomatic COVID-19

Nature Communications
Jun Wu, Boyun Liang, *et al*.
March 22, 2021
https://www.nature.com/articles/s41467-021-22034-1

"**Abstract**: … At late time points, the positivity rates for binding and neutralizing SARS-CoV-2-specific antibodies are still >70%. These data indicate sustained humoral immunity in recovered patients who had symptomatic COVID-19, suggesting prolonged immunity."

[407] ***Reinfection Rates Among Patients Who Previously Tested Positive for Coronavirus Disease 2019: A Retrospective Cohort Study***

Cleveland Clinic
Megan M. Sheehan, Anita J. Reddy, and Michael B. Rothberg
March 15, 2021
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab234/6170939

"**Conclusions**: Prior infection in patients with COVID-19 was highly protective against reinfection and symptomatic disease. **This protection increased over time** [*emphasis added*]...

Discussion: … Protection of prior infection against symptomatic disease was 85%; even when asymptomatic cases were included, protection offered against reinfection was 82%. Few patients were hospitalized following reinfection, and none with COVID-related symptoms required intensive care, suggesting a high level of protection against severe disease. Six months after infection, protection against symptomatic disease exceeded 90%."

[408] ***A majority of uninfected adults show preexisting antibody reactivity against SARS-CoV-2***

JCI Insight
Abdelilah Majdoubi, Christina Michalski, *et al*.
March 15, 2021
https://insight.jci.org/articles/view/146316/pdf

"**Introduction**: … While much attention has focused on defining immune reactivity in individuals after infection, other data indicate that many individuals show preexisting SARS-CoV-2 cross-reactive T and B cells without prior exposure to the virus…

Discussion: … The main finding in this study is that, at a population level, the vast majority of adults show anti-body reactivity against SARS-CoV-2 antigens… [I]t is extremely unlikely that this antibody reactivity results from a direct exposure to SARS-CoV-2. Moreover, findings of similar antibody reactivity in prepandemic adult sera and from sera obtained from infants younger than 1 year of age confirms that we are detecting genuine cross-reactivity rather than reactivity to SARS-CoV-2 from asymptomatic COVID-19 cases…

In conclusion, this study reveals **common preexisting, broadly reactive SARS-CoV-2 antibodies in uninfected adults** [*emphasis added*]."

[409] **ADDED since 10/14/2021**

A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report

Maccabi Healthcare Services (Israel)
Galit Perez, Tamar Banon, *et al*.
March 8, 2021
https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1

> "In this descriptive preliminary report, we conducted a large-scale assessment on the country level of the possible occurrence of COVID-19 reinfection within the members of a large healthcare provider in Israel. Out of 149,735 individuals with a documented positive PCR test between March 2020 and January 2021, 154 had two positive PCR tests at least 100 days apart, **reflecting a reinfection proportion of 1 per 1000** [*emphasis added*]. Given our strict inclusion criteria, we believe these numbers represent true reinfection incidence in MHS and should be clinically regarded as such."

[410] **ADDED since 10/14/2021**

Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection

Nature Immunology (University of Birmingham and National Infection Service, UK)
Jianmin Zuo, Alexander C. Dowell, *et al*.
March 5, 2021
https://www.nature.com/articles/s41590-021-00902-8

> "**Discussion**: The magnitude and quality of the immune memory response to SARS-CoV-2 will be critical in preventing reinfection. Here we undertook an assessment of SARS-CoV-2-specific T cell immune response at 6 months following primary infection in a unique cohort of healthy adults with asymptomatic or mild-to-moderate COVID-19… The major finding was that **virus-specific T cells were detectable in all donors at this extended follow-up period** [*emphasis added*]…
>
> The magnitude of T cell response was heterogeneous and may reflect diversity in the profile of T cell immunity during acute infection. A striking feature was that the magnitude of cellular immunity by ELISPOT was 50% higher in donors who had experienced symptomatic infection. This demonstrates that the initial 'set point' of cellular immunity established following acute infection is maintained for at least 6 months."

[411] ***SARS-CoV-2 re-infection risk in Austria***

European Journal of Clinical Investigation
Stefan Pilz, Ali Chakeri, *et al*.
February 13, 2021
https://onlinelibrary.wiley.com/doi/10.1111/eci.13520

> "**Conclusions**: We observed a relatively low re-infection rate of SARS-CoV-2 in Austria. **Protection** against SARS-CoV-2 **after natural infection is comparable with the highest available estimates on vaccine efficacies** [*emphasis added*].
>
> **Results**: From 15,424 patients with SARS-CoV-2 positive tests in the first wave, 584 were recorded as COVID-19 deaths, so that our COVID-19 survivor group consists of 14 840 patients…

During the observation period from September 1 to November 30, we recorded 40 tentative re-infections in the COVID-19 survivor group (**0.27%**), and 253,581 new infections in the general population group (**2.85%**) [*emphasis added*]…"

[412] ***Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers***
New England Journal of Medicine (Oxford University Hospitals Staff Testing Group)
Sheila F. Lumley, Deise O'Donnell, *et al*.
February 11, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2034545

"**Methods**: We investigated the incidence of SARS-CoV-2 infection confirmed by polymerase chain reaction (PCR) in seropositive and seronegative health care workers attending testing of asymptomatic and symptomatic staff at Oxford University Hospitals in the United Kingdom. Baseline antibody status was determined by anti-spike (primary analysis) and anti-nucleocapsid IgG assays, and staff members were followed for up to 31 weeks…

Results: A total of 12,541 health care workers participated and had anti-spike IgG measured; 11,364 were followed up after negative antibody results and 1265 after positive results... **There were no symptomatic infections in workers with anti-spike antibodies** [*emphasis added*]…

Conclusions: The presence of anti-spike or anti-nucleocapsid IgG antibodies was associated with a substantially reduced risk of SARS-CoV-2 reinfection in the ensuing 6 months."

[413] **ADDED since 10/14/2021**
Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection
Science magazine (La Jolla Institute for Immunology)
Jennifer M. Dan, Jose Mateus, *et al*.
February 5, 2021
https://www.science.org/doi/10.1126/science.abf4063

"**Variable memory**

Immune memory against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) helps to determine protection against reinfection, disease risk, and vaccine efficacy. Using 188 human cases across the range of severity of COVID-19, Dan et al. analyzed cross-sectional data describing the dynamics of SARS-CoV-2 memory B cells, CD8+ T cells, and CD4+ T cells for more than 6 months after infection. The authors found a high degree of heterogeneity in the magnitude of adaptive immune responses that persisted into the immune memory phase to the virus. However, immune memory in three immunological compartments remained measurable in greater than 90% of subjects for more than 5 months after infection. Despite the heterogeneity of immune responses, these results show that **durable immunity** against secondary COVID-19 disease is a possibility for most individuals…

This is the **largest antigen-specific study to date** of the four major types of immune memory for any viral infection [*emphasis added*]."

[414] ***Lasting immunity found after recovery from COVID-19***
National Institutes of Health (NIH)
Sharon Reynolds
January 26, 2021
https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19

> "The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection…
>
> The researchers found **durable immune responses** in the majority of people studied [*emphasis added*]. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset...
>
> Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards…
>
> Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus."

[415] **ADDED since 10/14/2021**
Cellular Immunity in COVID-19 Convalescents with PCR-Confirmed Infection but with Undetectable SARS-CoV-2–Specific IgG
University of Duisburg-Essen
Sina Schwarzkopf, Adalbert Krawczyk, *et al*.
January 2021
https://wwwnc.cdc.gov/eid/article/27/1/20-3772_article

> "**Abstract**: We investigated immune responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) among a group of convalescent, potential blood donors in Germany who had PCR-confirmed SARS-CoV-2 infection… Using interferon-γ ELISpot, we observed that 78% of PCR-positive volunteers with undetectable antibodies showed T cell immunity against SARS-CoV-2. We observed a similar frequency (80%) of T-cell immunity in convalescent donors with strong antibody responses but did not detect immunity in negative controls. We concluded that, in convalescent patients with undetectable SARS-CoV-2 IgG, immunity may be mediated through T cells."

[416] ***Intrafamilial Exposure to SARS-CoV-2 Associated with Cellular Immune Response without Seroconversion, France***
Emerging Infectious Diseases
Floriane Gallais, Aurelie Velay, *et al*.
January 2021
https://wwwnc.cdc.gov/eid/article/27/1/20-3611_article

> "**Abstract**: We investigated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)–specific antibodies and T-cell responses against SARS-CoV-2…
>
> **Discussion**: In this study, we demonstrate that intrafamilial contacts can display a SARS-CoV-2–specific T-cell response in the absence of seroconversion, especially when they have been symptomatic. This T-cell response provides evidence that transient or anatomically contained SARS-CoV-2 infection, or both, may have occurred and that T-cell responses would be more

sensitive indicators of SARS-Co-V-2 exposure than antibodies…

Overall, our results indicate that persons exposed to SARS-CoV-2 may develop virus-specific T-cell responses without detectable circulating antibodies. This aspect of the immune response against SARS-CoV-2 contributes substantially to the understanding of the natural history of COVID-19. Furthermore, our data indicate that epidemiologic data relying solely on the detection of SARS-CoV-2 antibodies may lead to a **substantial underestimation of prior exposure to the virus** [*emphasis added*]."

[417] ***Cellular immunity to SARS-CoV-2 found at six months in non-hospitalised individuals***
UK Coronavirus Immunology Consortium (UK-CIC), Public Health England and Manchester University NHS Foundation Trust
November 2, 2020
https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals

"[R]esearchers… collected serum and blood samples from a cohort of more than 2,000 clinical and non-clinical healthcare workers including 100 individuals who tested sero-positive for SARS-CoV-2 in March/April 2020… [T] this study of 100 individuals is one of the largest in the world to date in this field…

T cell responses were present in all individuals at six months after SARS-CoV-2 infection. The cellular immune response was directed against a range of proteins from the virus, including the Spike protein that is being used in most vaccine studies. However, comparable immunity was present against additional proteins, such as nucleoprotein, which suggests that these may be of value for incorporation in future vaccine protocols. This indicates that **a robust cellular memory against the virus persists for at least six months** [*emphasis added*]…"

[418] ***Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans***
Science magazine
Jose Mateus, Alba Grifoni, *et al*.
October 2, 2020
https://www.science.org/lookup/doi/10.1126/science.abd3871

"**Abstract**: Many unknowns exist about human immune responses to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. SARS-CoV-2–reactive CD4+ T cells have been reported in unexposed individuals, suggesting **preexisting cross-reactive T cell memory in 20 to 50% of people** [*emphasis added*]. However, the source of those T cells has been speculative. Using human blood samples derived before the SARS-CoV-2 virus was discovered in 2019, we mapped 142 T cell epitopes across the SARS-CoV-2 genome to facilitate precise interrogation of the SARS-CoV-2–specific CD4+ T cell repertoire. We demonstrate a range of preexisting memory CD4+ T cells that are cross-reactive with comparable affinity to SARS-CoV-2 and the common cold coronaviruses human coronavirus (HCoV)-OC43, HCoV-229E, HCoV-NL63, and HCoV-HKU1. Thus, variegated T cell memory to coronaviruses that cause the common cold may underlie at least some of the extensive heterogeneity observed in coronavirus disease 2019 (COVID-19) disease."

[419] **ADDED since 10/14/2021**

Immune cells for common cold may recognize SARS-CoV-2

National Institutes of Health (NIH)
Tianna Hicklin
August 18, 2020
https://www.nih.gov/news-events/nih-research-matters/immune-cells-common-cold-may-recognize-sars-cov-2

> "Previous studies have reported that 20–50% of people who hadn't been exposed to SARS-CoV-2 showed T cell responses against different parts of the SARS-CoV-2 virus. To investigate further, a research team led by Drs. Alessandro Sette and Daniela Weiskopf at the La Jolla Institute for Immunology tested blood samples collected between March 2015 and March 2018 for T-cell responses against different pieces of SARS-CoV-2…
>
> [The researchers] found that of the SARS-CoV-2 and 'common cold' coronavirus fragments that were most similar (at least 67% genetic similarity) 57% showed cross-reactivity by memory T cells.
>
> 'We have now proven that, in some people, **pre-existing T cell memory against common cold coronaviruses can cross-recognize SARS-CoV-2**, down to the exact molecular structures [*emphasis added*],' Weiskopf says. 'This could help explain why some people show milder symptoms of disease while others get severely sick.'"

[420] ***Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19***

Cell
Takuya Sekine, Andre Perez-Potti, *et al*.
August 14, 2020
https://www.cell.com/cell/fulltext/S0092-8674(20)31008-4

> "**Summary**: SARS-CoV-2-specific memory T cells will likely prove critical for long-term immune protection against COVID-19. Here, we systematically mapped the functional and phenotypic landscape of SARS-CoV-2-specific T cell responses in unexposed individuals, exposed family members, and individuals with acute or convalescent COVID-19… Our collective dataset shows that SARS-CoV-2 elicits broadly directed and functionally replete memory T cell responses, suggesting that natural exposure or infection may prevent recurrent episodes of severe COVID-19."

[421] **ADDED since 10/14/2021**

Primary exposure to SARS-CoV-2 protects against reinfection in rhesus macaques

Science (Beijing Union Medical College)
Wei Deng, Linlin Bao, *et al*.
August 14, 2020
https://www.science.org/doi/10.1126/science.abc5343

> "**Abstract**: … Rhesus macaques reinfected with the identical SARS-CoV-2 strain during the early recovery phase of the initial SARS-CoV-2 infection did not show detectable viral dissemination, clinical manifestations of viral disease, or histopathological changes. Comparing the humoral and cellular immunity between primary infection and rechallenge revealed notably enhanced neutralizing antibody and immune responses. Our results suggest that primary SARS-CoV-2 exposure protects against subsequent reinfection in rhesus macaques."

[422] ***SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls***
Nature magazine
Nina Le Bert, Anthony T. Tan, *et al*.
July 15, 2020
https://www.nature.com/articles/s41586-020-2550-z

"**Abstract**: Memory T cells induced by previous pathogens can shape susceptibility to, and the clinical severity of, subsequent infections. Little is known about the presence in humans of pre-existing memory T cells that have the potential to recognize severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Here we studied T cell responses against the structural (nucleocapsid (N) protein) and non-structural (NSP7 and NSP13 of ORF1) regions of SARS-CoV-2 in individuals convalescing from coronavirus disease 2019 (COVID-19) (n = 36). In all of these individuals, we found CD4 and CD8 T cells that recognized multiple regions of the N protein. Next, we showed that patients (n = 23) who recovered from SARS (the disease associated with SARS-CoV infection) possess long-lasting memory T cells that are reactive to the N protein of SARS-CoV **17 years after** the outbreak of SARS in 2003; **these T cells displayed robust cross-reactivity to the N protein of SARS-CoV-2** [*emphasis added*]. We also detected SARS-CoV-2-specific T cells in individuals with no history of SARS, COVID-19 or contact with individuals who had SARS and/or COVID-19 (n = 37)… Thus, infection with betacoronaviruses induces multi-specific and long-lasting T cell immunity against the structural N protein."

Cross-neutralization of SARS-CoV-2 by a human monoclonal SARS-CoV antibody
Nature magazine
Dora Pinto, Young-Jun Park, *et al*.
May 18, 2020
https://www.nature.com/articles/s41586-020-2349-y

"**Abstract**: … The SARS-CoV-2 spike (S) glycoprotein promotes entry into host cells and is the main target of neutralizing antibodies. Here we describe **several monoclonal antibodies that target the S glycoprotein of SARS-CoV-2**, which we identified from memory B cells of an individual who was infected with severe acute respiratory syndrome coronavirus (SARS-CoV) in 2003 [*emphasis added*]. One antibody (named S309) potently neutralizes SARS-CoV-2 and SARS-CoV pseudoviruses as well as authentic SARS-CoV-2, by engaging the receptor-binding domain of the S glycoprotein."

[423] ***Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals***
Cell
Alba Grifoni, Daniela Weiskopf, *et al*.
May 14, 2020
https://www.cell.com/cell/fulltext/S0092-8674(20)30610-3

"**Highlights**:

- Epitope pools detect CD4+ and CD8+ T cells in 100% and 70% of convalescent COVID patients
- T cell responses are focused not only on spike but also on M, N, and other ORFs

- T cell reactivity to SARS-CoV-2 epitopes is also detected in non-exposed individuals

Summary: … Importantly, we detected SARS-CoV-2-reactive CD4+ T cells in ~40%–60% of **unexposed individuals**, suggesting cross-reactive T cell recognition between circulating 'common cold' coronaviruses and SARS-CoV-2 [*emphasis added*]."

COVID-19 Prophylactics, Treatments, and Protocols

Vitamin D

Note: The citations below are presented in reverse, chronological order.

[424] **ADDED since 10/14/2021**
COVID-19 Mortality Risk Correlates Inversely with Vitamin D3 Status, and a Mortality Rate Close to Zero Could Theoretically Be Achieved at 50 ng/mL 25(OH)D3: Results of a Systematic Review and Meta-Analysis
Nutrients journal
Lorenz Borsche, Bernd Glauner, and Julian von Mendel
October 14, 2021
https://www.mdpi.com/2072-6643/13/10/3596/htm

> "**Results**: One population study and seven clinical studies were identified, which reported D3 blood levels preinfection or on the day of hospital admission. The two independent datasets showed a negative Pearson correlation of D3 levels and mortality risk... For the combined data, median (IQR) D3 levels were 23.2 ng/mL.. Regression suggested a **theoretical point of zero mortality at approximately 50 ng/mL D3** [*emphasis added*].
>
> **Conclusions**: The datasets provide strong evidence that low D3 is a predictor rather than just a side effect of the infection. Despite ongoing vaccinations, we recommend raising serum 25(OH)D levels to above 50 ng/mL to prevent or mitigate new outbreaks due to escape mutations or decreasing antibody activity."

[425] **ADDED since 10/14/2021**
Seasonal UV exposure and vitamin D: Association with the dynamics of COVID-19 transmission in Europe
FEBS Open Bio (Bar-Ilan University, Israel)
Sunanda Biswas Mukherjee, Alessandaro Gorohovski, *et al*.
October 5, 2021
https://febs.onlinelibrary.wiley.com/doi/10.1002/2211-5463.13309

> "**Abstract**: Several recent studies have demonstrated that low plasma 25(OH) vitamin D levels are associated with the risk of COVID-19 infection. The primary source of vitamin D production in humans is environmental UV radiation… [W]e first performed a comprehensive meta-analysis of all related published literature based on the association of vitamin D and COVID-19, which supported the hypothesis that the low vitamin D level is a critical risk factor for COVID-19 infection. Next, to understand the potential impact of seasonal UV and temperature levels on COVID-19 cases, we analyzed meteorological data and daily COVID-19 cases per million in the populations of 26 European countries. We observed that low temperature, UV index, and cloud-free vitamin D UV dose (UVDVF) levels are negatively correlated with COVID-19 prevalence in Europe. Furthermore, a distributed lag non-linear model was used to assess the non-linear delayed effects of individual seasonal factors on COVID-19 cases. Such analysis highlighted the significantly delayed impact of UVDVF on the cumulative relative risk of COVID-19 infection. The findings of this study suggest that low UV exposure can affect the required production of vitamin D in the body, which **substantially influences the dynamics of COVID-19**

transmission and severity [*emphasis added*]."

[426] ***An observational and Mendelian randomisation study on vitamin D and COVID-19 risk in UK Biobank***
Scientific Reports
Xue Li, Jos van Geffen, *et al*.
September 14, 2021
https://www.nature.com/articles/s41598-021-97679-5

"**Abstract**: A growing body of evidence suggests that vitamin D deficiency has been associated with an increased susceptibility to viral and bacterial respiratory infections. In this study, we aimed to examine the association between vitamin D and COVID-19 risk and outcomes. We used logistic regression to identify associations between vitamin D variables and COVID-19 (risk of infection, hospitalisation and death) in 417,342 participants from UK Biobank… **Ambient UVB was strongly and inversely associated with COVID-19 hospitalization and death overall** and consistently after stratification by BMI and ethnicity [*emphasis added*]. We also observed an interaction that suggested greater protective effect of genetically-predicted vitamin D levels when ambient UVB radiation is stronger.

Introduction: [E]vidence suggests that COVID-19 disproportionately affects black and minority ethnic individuals, with one potential explanation being the higher prevalence of vitamin D deficiency, in addition to other risk factors. It is thus hypothesised that having adequate vitamin D levels may help reduce the risk of contracting the SARS-CoV-2 virus or reduce the risk of severe or lethal COVID-19 disease.

[427] **ADDED since 10/14/2021**
Vitamin D3 and its hydroxyderivatives as promising drugs against COVID-19: a computational study
Journal of Biomolecular Structure and Dynamics
Yuwei Song, Shariq Qayyum, *et al*.
August 20, 2021
https://www.tandfonline.com/doi/full/10.1080/07391102.2021.1964601

"**Abstract**: … In this study, we used combined molecular docking, molecular dynamics simulations and binding free energy analyses to investigate the potentials of vitamin D3 and its hydroxyderivatives as TMPRSS2 inhibitor and to inhibit the SARS-CoV-2 receptor binding domain (RBD) binding to angiotensin-converting enzyme 2 (ACE2), as well as to unveil molecular and structural basis of 1,25(OH)2D3 capability to inhibit ACE2 and SARS-CoV-2 RBD interactions. The results show that vitamin D3 and its hydroxyderivatives are favorable to bind active site of TMPRSS2 and the binding site(s) between ACE2 and SARS-CoV2-RBD, which indicate that vitamin D3 and its biologically active hydroxyderivatives can serve as TMPRSS2 inhibitor and can inhibit ACE2 binding of SARS-CoV-2 RBD to **prevent SARS-CoV-2 entry** [*emphasis added*]."

[428] ***The sufficient vitamin D and albumin level have a protective effect on COVID-19 infection***
Archives of Microbiology
Somaieh Matin, Nasrin Fouladi, *et al*.
July 30, 2021
https://link.springer.com/article/10.1007/s00203-021-02482-5

"**Abstract**: There is limited information regarding the protective factors of SARS-CoV-2 infection. This research is focused on analyzing the role of vitamin D and albumin in the severity, progression, or possible prevention of COVID-19 infection. In this case–control study, 191 patients and 203 healthy individuals were enrolled. Blood samples were taken to test the albumin and vitamin D levels of both groups. Our results show a direct association of vitamin D deficiency with the infection of COVID-19 and severity. According to our findings, **84.4% of patients with COVID-19 in this study had vitamin D deficiency** [*emphasis added*]. Moreover, the average level of albumin was significantly decreased in those infected patients who had respiratory symptoms. In the present study, a considerable negative correlation was established between the levels of vitamin D and the severity of COVID-19 infection. This reflects on the immunomodulatory and inhibitory nature of vitamin D to the viral replication."

[429] **ADDED since 10/14/2021**
Pre-infection 25-hydroxyvitamin D3 levels and association with severity of COVID-19 illness
Galilee Medical Center (Israel)
Amiel A. Dror, Nicole g. Morozov, *et al*.
June 7, 2021
https://www.medrxiv.org/content/10.1101/2021.06.04.21258358v1.full-text

"**Objective**: Studies have demonstrated a potential link between low vitamin D levels and both an increased risk of infection with SARS-CoV-2 and poorer clinical outcomes but have not established temporality. This retrospective study examined if, and to what degree, a relationship exists between pre-infection serum vitamin D levels and disease severity and mortality of SARS-CoV-19…

Results: Of 1176 patients admitted, 253 had VitD levels prior to COVID-19 infection. Compared with mildly or moderately diseased patients, those with severe or critical COVID-19 disease were more likely to have **pre-infection vitamin D deficiency of less than 20 ng/mL** [*emphasis added*]...

Conclusions: Among hospitalized COVID-19 patients, pre-infection deficiency of vitamin D was associated with increased disease severity and mortality."

[430] **ADDED since 10/14/2021**
Analysis of vitamin D level among asymptomatic and critically ill COVID-19 patients and its correlation with infammatory markers
Scientific Reports – Nature (M.L.B. Medical College, India)
Anshul Jain, Rachna Chaurasia, *et al*.
November 19, 2020
https://www.nature.com/articles/s41598-020-77093-z.pdf

"Study included either asymptomatic COVID-19 patients (Group A) or severely ill patients requiring ICU admission (Group B)… The mean level of vitamin D (in ng/mL) was 27.89 ± 6.21 in Group A and 14.35 ± 5.79 in Group B, the difference was highly significant. The prevalence

of vitamin D deficiency was 32.96% and 96.82% respectively in Group A and Group B…The **fatality rate was high in vitamin D deficient** (**21% vs 3.1%**) [*emphasis added*]. Vitamin D level is markedly low in severe COVID-19 patients. Infammatory response is high in vitamin D defcient COVID-19 patients. This all translates into increased mortality in vitamin D deficient COVID-19 patients. As per the flexible approach in the current COVID-19 pandemic, authors recommend mass administration of vitamin D supplements to population at risk for COVID-19…

Conclusion: Vitamin D deficiency markedly increases the chance of having severe disease after infection with SARS-Cov-2. The intensity of inflammatory response is also higher in vitamin D deficient COVID-19 patients. This all translates to increased morbidity and mortality in COVID-19 patients who are deficient in vitamin D. Keeping the current COVID-19 pandemic in view, authors recommend administration of vitamin D supplements to population at risk for COVID-19."

[431] **ADDED since 10/14/2021**
Short term, high-dose vitamin D supplementation for COVID-19 disease: a randomised, placebo-controlled, study (SHADE study)
British Medical Journal (Institute of Medical Education and Research, Chandigarh, India)
Ashu Rastogi, Anil Bhansali, *et al*.
November 12, 2020
https://pmj.bmj.com/content/postgradmedj/early/2020/11/12/postgradmedj-2020-139065.full.pdf

"**Participants**: Asymptomatic or mildly symptomatic SARS-CoV-2 RNA positive vitamin D deficient (25(OH) D<20 ng/ml) individuals.

Intervention: Participants were randomised to receive daily 60 000 IU of cholecalciferol (oral nano-liquid droplets) for 7 days with therapeutic target 25(OH) D>50 ng/ml (intervention group) or placebo (control group)…

Results: Forty SARS-CoV-2 RNA positive individuals were randomised to intervention (n=16) or control (n=24) group.… 10 (**62.5%**) participants in the intervention group and 5 (**20.8%**) participants in the control arm (p<0.018) became SARS-CoV-2 RNA negative [*emphasis added*].

Conclusion: Greater proportion of vitamin D-deficient individuals with SARS-CoV-2 infection turned SARS-CoV-2 RNA negative with a significant decrease in fibrinogen on high-dose cholecalciferol supplementation."

[432] ***Evidence Regarding Vitamin D and Risk of COVID-19 and Its Severity***
Nutrients journal
Joseph Mercola, William B. Grant. and Carol L. Wagner
October 31, 2020
https://www.mdpi.com/2072-6643/12/11/3361/htm

"**2.14. Other Nutrients That May Augment the Effectiveness of Vitamin D Supplementation**: … Although vitamin D is likely to be the most important nutrient to optimize COVID-19 prevention, other nutrients, such as magnesium, vitamin K2 and other micronutrients, are also known to impact the immune system and infection risk…

3. Conclusions: As discussed here, there is emerging evidence that higher serum 25(OH)D concentrations are associated with the reduced risk and severity of COVID-19…

The strongest evidence to date comes from **14 observational studies** that report inverse correlations between serum 25(OH)D concentrations and SARS-CoV-2 positivity and/or COVID-19 incidence, severity and/or death [*emphasis added*]."

[433] ***Vitamin D Status in Hospitalized Patients with SARS-CoV-2 Infection***
Journal of Clinical Endocrinology & Metabolism
Jose L. Hernandez, Daniel Nan, *et al*.
October 27, 2020
https://academic.oup.com/jcem/article/106/3/e1343/5934827

"**Results**: … Vitamin D deficiency was found in **82.2% of COVID-19 cases** [*emphasis added*] and 47.2% of the population-based controls… Vitamin D-deficient COVID-19 patients had a greater prevalence of hypertension and cardiovascular diseases, raised serum ferritin and troponin levels, as well as a longer length of hospital stay than those with serum 25OHD levels ≥20 ng/m."

[434] **ADDED since 10/14/2021**
Vitamin D and survival in COVID-19 patients: A quasi-experimental study
The Journal of Steroid Biochemistry and Molecular Biology
Cedric Annweiler, Berangere Hanotte, *et al.*
October 13, 2020
https://www.sciencedirect.com/science/article/pii/S096007602030296X

"**Abstract**: Vitamin D may be a central biological determinant of COVID-19 outcomes. The objective of this quasi-experimental study was to determine whether bolus vitamin D3 supplementation taken during or just before COVID-19 was effective in improving survival among frail elderly nursing-home residents with COVID-19. Sixty-six residents with COVID-19 from a French nursing-home were included in this quasi-experimental study… In conclusion, bolus vitamin D3 supplementation during or just before COVID-19 was associated in **frail elderly** with **less severe COVID-19** and **better survival rate**."

[435] ***Effect of calcifediol treatment and best available therapy versus best available therapy on intensive care unit admission and mortality among patients hospitalized for COVID-19: A pilot randomized clinical study***
Journal of Steroid Biochemistry and Molecular Biology
Marta Entrenas Castillo, Luis Manuel Entrenas Costa, *et al*.
October 2020
https://www.sciencedirect.com/science/article/abs/pii/S0960076020302764

"**Highlights**:

- The vitamin D endocrine system have a variety of actions on cells and tissues involved in COVID-19 progression.
- Early calcifediol (25-hydroxyvitamin D) treatment to hospitalized COVID-19 patients significantly reduced intensive care unit admissions-Calcifediol seems to be able to reduce severity of the COVID-19…

Conclusion: Our pilot study demonstrated that administration of a high dose of Calcifediol or 25-hydroxyvitamin D, a main metabolite of vitamin D endocrine system, **significantly reduced**

the need for ICU treatment of patients requiring hospitalization due to proven COVID-19 [*emphasis added*]."

[436] ***SARS-CoV-2 positivity rates associated with circulating 25-hydroxyvitamin D levels***
PLOS One
Harvey W. Kaufman, Justin K. Niles, Martin H. Kroll, Caixia Bi, and Michael F. Holick
September 17, 2020
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239252

"**Discussion**: … In conclusion, SARS-CoV-2 NAAT positivity is strongly and inversely associated with circulating 25(OH)D levels, a relationship that persists across latitudes, races/ethnicities, sexes, and age ranges. Our findings provide further rationale to explore the role of vitamin D supplementation in reducing the risk for SARS-CoV-2 infection and COVID-19 disease."

[437] ***Vitamin D deficiency as a predictor of poor prognosis in patients with acute respiratory failure due to COVID-19***
Journal of Endocrinological Investigation
G.E. Carpagnano, V. Di Lecce, *et al*.
August 9, 2020
https://link.springer.com/article/10.1007/s40618-020-01370-x

"**Results**: … A survival analysis highlighted that, after 10 days of hospitalization, **severe vitamin D deficiency patients had a 50% mortality probability**, while those with vitamin D ≥ 10 ng/mL had a 5% mortality risk (p = 0.019) [*emphasis added*]…

Conclusions: High prevalence of hypovitaminosis D was found in COVID-19 patients with acute respiratory failure, treated in a RICU. Patients with severe vitamin D deficiency had a significantly higher mortality risk. Severe vitamin D deficiency may be a marker of poor prognosis in these patients, suggesting that adjunctive treatment might improve disease outcomes."

[438] ***Strong Correlation Between Prevalence of Severe Vitamin D Deficiency and Population Mortality Rate from COVID-19 in Europe***
Wiener klinische Wochenschrift
Isaac Z. Pugach and Sofya Pugach
July 1, 2020
https://www.medrxiv.org/content/10.1101/2020.06.24.20138644v1

"**Results**: There were 10 countries data sets that fit the criteria and were analyzed. Severe Vitamin D deficiency was defined as 25(OH)D less than 25 nmol/L (10 ng/dL). Pearson correlation analysis between death rate per million from COVID-19 and prevalence of severe Vitamin D deficiency shows a strong correlation with r = 0.76, p = 0.01, indicating significant correlation. Correlation remained significant, even after adjusting for age structure of the population. Additionally, over time, correlation strengthened, and r coefficient asymptoticaly increased."

[439] ***The role of Vitamin D in the prevention of Coronavirus Disease 2019 infection and mortality***
Aging Clinical and Experimental Research
Petre Cristian Ilie, Simina Stefanescu, and Lee Smith
May 6, 2020
https://link.springer.com/article/10.1007%2Fs40520-020-01570-8

> "**Discussions**: … In conclusion, we found significant relationships between vitamin D levels and the number COVID–19 cases and **especially the mortality caused by this infection** [*emphasis added*]. The most vulnerable group of population for COVID–19 is also the one that has the most deficit in Vitamin D.
>
> Vitamin D has already been shown to protect against acute respiratory infections and it was shown to be safe. We believe, that we can advise Vitamin D supplementation to protect against COVID–19 infection."

[440] ***Vitamin D supplementation to prevent acute respiratory tract infections: systematic review and meta-analysis of individual participant data***
British Medical Journal
Adrian R. Martineau, David A. Jolliffe, *et al*.
February 15, 2017

> "**Results**: 25 eligible randomised controlled trials (total 11 321 participants, aged 0 to 95 years) were identified. IPD were obtained for 10 933 (96.6%) participants. Vitamin D supplementation reduced the risk of acute respiratory tract infection among all participants… The body of evidence contributing to these analyses was assessed as being of high quality…
>
> **Conclusions and policy implications**: Our study reports a major new indication for vitamin D supplementation: the prevention of acute respiratory tract infection. We also show that people who are very deficient in vitamin D and those receiving daily or weekly supplementation without additional bolus doses experienced particular benefit. Our results add to the body of evidence supporting the introduction of public health measures such as food fortification to improve vitamin D status, particularly in settings where profound vitamin D deficiency is common."

[441] **Vitamin D and the Immune System**
Journal of Investigative Medicine
Cynthia Aranow
March 2, 2011
https://jim.bmj.com/content/59/6/881

> "**Abstract**: … Vitamin D can modulate the innate and adaptive immune responses. Deficiency in vitamin D is associated with increased autoimmunity and an increased susceptibility to infection. …
>
> The immune system defends the body from foreign, invading organisms, promoting protective immunity while maintaining tolerance to self. The implications of vitamin D deficiency on the immune system have become clearer in recent years and in the context of vitamin D deficiency, there appears to be an increased susceptibility to infection and a diathesis, in a genetically susceptible host to autoimmunity."

Vitamin C

Note: The citations below are presented in reverse, chronological order.

[442] ***Vitamin C and COVID-19***
Frontiers in Medicine
Harri Hemila and Angelique M.E. de Man
January 18, 2021
https://www.frontiersin.org/articles/10.3389/fmed.2020.559811/full

> "In numerous animal studies, vitamin C has prevented and alleviated viral and bacterial infections. In a few dozen placebo-controlled trials with humans, vitamin C has shortened infections caused by respiratory viruses, which indicates that the vitamin can also influence viral infections in humans. In critically ill patients, plasma vitamin C levels are commonly very low. Gram doses of vitamin C are needed to increase the plasma vitamin C levels of critically ill patients to the levels of ordinary healthy people. A meta-analysis of 12 trials with 1,766 patients calculated that vitamin C reduced the length of ICU stay on average by 8%. Another meta-analysis found that vitamin C shortened the duration of mechanical ventilation in ICU patients. Two randomized placebo-controlled trials found statistically significant reduction in the mortality of sepsis patients. The effects of vitamin C on acute respiratory distress syndrome (ARDS) frequently complicating COVID-19 pneumonia should be considered. Vitamin C is a safe and inexpensive essential nutrient."

[443] ***Serum Levels of Vitamin C and Vitamin D in a Cohort of Critically Ill COVID-19 Patients of a North American Community Hospital Intensive Care Unit in May 2020: A Pilot Study***
Medicine in Drug Discovery
Cristian Arvinte, Maharaj Singh, and Paul E. Marik
September 18, 2020
https://www.sciencedirect.com/science/article/pii/S2590098620300518

> "**Objective**: The objective of this pilot study was to measure serum vitamin C and vitamin D levels in a cohort of patients with critical COVID-19 illness in our community hospital ICU…
>
> **Results**: …
>
> Serum levels of vitamin C and vitamin D were low in most of our critically ill COVID-19 ICU patients.
>
> Older age and low vitamin C level appeared co-dependent risk factors for mortality from COVID-19 in our sample…
>
> **Conclusion**: Our pilot study found low serum levels of vitamin C and vitamin D in most of our critically ill COVID-19 ICU patients. Older age and low vitamin C level appeared co-dependent risk factors for mortality. Many were also insulin-resistant or diabetic, overweight or obese, known as independent risk factors for low vitamin C and vitamin D levels, and for COVID-19.
>
> These findings suggest the need to further explore whether caring for COVID-19 patients ought to routinely include measuring and correcting serum vitamin C and vitamin D levels, and whether treating critically ill COVID-19 warrants acute parenteral vitamin C and vitamin D replacement."

[444] ***Vitamin C levels in patients with SARS-CoV-2-associated acute respiratory distress syndrome***
Critical Care – BioMed Central (BMC)
Luis Chiscano-Camon, Juan Carlos Ruiz-Rodriguez, Adolf Ruiz-Sanmartin, Oriol Roca, and Ricard Ferrer
August 26, 2020
https://ccforum.biomedcentral.com/articles/10.1186/s13054-020-03249-y

> "Vitamin C is an antioxidant with anti-inflammatory and immune-supportive properties. Its levels are decreased in patients with sepsis-related acute respiratory distress syndrome (ARDS). Moreover, a significant number of patients with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) disease developed ARDS [1]. Therefore, we hypothesized that ARDS coronavirus disease 2019 (COVID-19) patients may present vitamin C deficiency.
>
> Plasma vitamin C levels in a population of adult ICU patients COVID-19 who met ARDS criteria according to the Berlin definition were prospectively measured. The study was approved by the local Clinical Research Ethics Committee (PR (AG)270/2020)… Seventeen patients (94.4%) had **undetectable vitamin C levels** and 1 patient had low levels (2.4 mg/L) [*emphasis added*].
>
> To our knowledge, this is the first study to analyze the levels of vitamin C in patients with SARS-CoV-2-associated ARDS. Our study revealed that vitamin C levels are undetectable in more than 90% of the patients included…
>
> Moreover, vitamin C may have implications for treatment of COVID-19-associated ARDS. Indeed, one preclinical study showed that vitamin C increased resistance to infection caused by coronavirus. Moreover, other clinical studies that included surgical patients and patients with pneumonia showed encouraging results in terms of decreased incidence and severity of lung injury and mortality."

[445] ***Quercetin and Vitamin C: An Experimental, Synergistic Therapy for the Prevention and Treatment of SARS-CoV-2 Related Disease (COVID-19)***
Frontiers in Immunology
Ruben Manuel Luciano Colunga Biancatelli, Max Berrill, John D. Catravas, and Paul E. Marik
June 19, 2020
https://www.frontiersin.org/articles/10.3389/fimmu.2020.01451/full

> "**Introduction**: … In this review we collate the evidence of the antiviral properties of quercetin, describe its biologic action and pharmacokinetics profile, expand on our previous review of vitamin C, discuss their synergistic actions, and propose this experimental multi-drug approach for the prevention and treatment of SARS-CoV-2/COVID-19 pandemic.
>
> **Conclusion**: Quercetin displays a broad range of antiviral properties which can interfere at multiple steps of pathogen virulence -virus entry, virus replication, protein assembly- and that these therapeutic effects can be augmented by the co-administration of vitamin C. Furthermore, due to their lack of severe side effects and low-costs, we strongly suggest the combined administration of these two compounds for both the prophylaxis and the early treatment of respiratory tract infections, especially including COVID-19 patients."

[446] ***Intravenous Ascorbic Acid for Supportive Treatment in Hospitalized COVID-19 Patients***
International Society of Orthomolecular Medicine
Paul S. Anderson
March 24, 2020
https://isom.ca/article/intravenous-ascorbic-acid-for-supportive-treatment-in-hospitalized-covid-19-patients/

"**Abstract**: Intravenous ascorbic acid (IVAA) is a well-known intervention in medicine, which currently is rarely used in US hospitals. Due to the unusual and extreme clinical demands of hospitalized COVID-19 patients, IVAA has been implemented in Chinese hospitals, and data published by the 'Expert Group on Clinical Treatment of New Corona Virus Disease in Shanghai' (Shanghai, 2019) details the use of IVAA as safe and effective adjunctive care of hospitalized COVID-19 patients. In the IVAA treated group, there was no mortality, no reported side effects, and shorter hospital stays universally. In addition, the Shanghai Expert Group recommends IVAA use in extremely critical settings within COVID-19 patients. IVAA, as an intervention, is relatively inexpensive and simple for both pharmacy and nursing staff use…

Salient Clinical Data: … The crisis in China, and the presence of an expert in the use of IVAA in the Shanghai Expert Group, facilitated the addition of IVAA to their therapeutic interventions in the hospital treatment of patients with COVID-19. Background data and details are in the references, resources, and information below, but the points critical to use in this current crisis are:

- Chinese facility patient load: 358 total COVID-19 patients as of March 17th, 2020.
- Facility treated approximately 50 cases (of the 358) of moderate to severe COVID-19 infection with IVAA.
- The IVAA dosing was moderate and affordable (detail below) and dose determined by clinical status.
- **All patients who received IVAA improved**.
- There was no mortality in the IVAA group [*emphasis added*]
- There were no side effects reported from any patients in the IVAA group."

[447] ***Vitamin C may reduce the duration of mechanical ventilation in critically ill patients: a meta-regression analysis***
Journal of Intensive Care
Harri Hemila and Elizabeth Chalker
February 7, 2020
https://jintensivecare.biomedcentral.com/articles/10.1186/s40560-020-0432-y

"**Background**: Our recent meta-analysis indicated that vitamin C may shorten the length of ICU stay and the duration of mechanical ventilation. Here we analyze modification of the vitamin C effect on ventilation time, by the control group ventilation time (which we used as a proxy for severity of disease in the patients of each trial)…

Results: We identified nine potentially eligible trials, eight of which were included in the meta-analysis. We pooled the results of the eight trials, including 685 patients in total, and found that vitamin C shortened the length of mechanical ventilation on average by 14% (P = 0.00001)…

Vitamin C was most beneficial for patients with the longest ventilation, corresponding to the most severely ill patients. In five trials including 471 patients requiring ventilation for over 10 h, a dosage of 1–6 g/day of vitamin C shortened ventilation time on average by 25% ($P < 0.0001$)."

[448] ***Vitamin C and Immune Function***
Nutrients - Multidisciplinary Digital Publishing Institute (MDPI)
Anitra C. Carr and Silvia Maggini
November 3, 2017
https://www.mdpi.com/2072-6643/9/11/1211/htm

"**Abstract**: … Vitamin C is an essential micronutrient for humans… It is a potent antioxidant and a cofactor for a family of biosynthetic and gene regulatory enzymes. Vitamin C contributes to immune defense by supporting various cellular functions of both the innate and adaptive immune system. Vitamin C supports epithelial barrier function against pathogens and promotes the oxidant scavenging activity of the skin, thereby potentially protecting against environmental oxidative stress… [I]t has been shown to enhance differentiation and proliferation of B- and T-cells, likely due to its gene regulating effects. Vitamin C deficiency results in impaired immunity and higher susceptibility to infections. In turn, infections significantly impact on vitamin C levels due to enhanced inflammation and metabolic requirements. Furthermore, supplementation with vitamin C appears to be able to both prevent and treat respiratory and systemic infections. Prophylactic prevention of infection requires dietary vitamin C intakes that provide at least adequate, if not saturating plasma levels (i.e., 100–200 mg/day), which optimize cell and tissue levels. In contrast, treatment of established infections requires significantly higher (gram) doses of the vitamin to compensate for the increased inflammatory response and metabolic demand."

Zinc

Note: The citations below are presented in reverse, chronological order.

[449] ***Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection***
The American Journal of Medicine
Peter A. McCullough, Ronan J. Kelly, *et al*.
January 2021
https://www.sciencedirect.com/science/article/pii/S0002934320306732

"**Combination Antiviral Therapy**: … Zinc is a known inhibitor of coronavirus replication. Clinical trials of zinc lozenges in the common cold have demonstrated modest reductions in the duration and or severity of symptoms. By extension, this readily available nontoxic therapy could be deployed at the first signs of COVID-19. Zinc lozenges can be administered 5 times a day for up to 5 days and extended if needed if symptoms persist. The amount of elemental zinc lozenges is <25% of that in a single 220-mg zinc sulfate daily tablet. This dose of zinc sulfate has been effectively used in combination with antimalarials in early treatment of high-risk outpatients with COVID-19."

[450] ***Zinc treatment of outpatient COVID-19: A retrospective review of 28 consecutive patients***
Journal of Medical Virology
Eric Finzi and Allan Harrington
January 21, 2021
https://onlinelibrary.wiley.com/doi/10.1002/jmv.26812

> "All 28 patients were improved after 7 days of zinc… No patients were hospitalized after zinc treatment…
>
> In mild cases of COVID-19 about 80% of patients begin improving after Day 10; 20% worsen the second week. **Zinc treated patients began improvement after 1.6 days on average** [*emphasis added*]."

[451] ***Low zinc levels at clinical admission associates with poor outcomes in COVID-19***
Universitat Pompeu Fabra (Spain)
Marina Vogel-González, Marc Talló-Parra, *et al*.
October 11, 2020
https://www.medrxiv.org/content/10.1101/2020.10.07.20208645v1.full-text

> "**Background**: Biomarkers to predict Coronavirus disease-19 (COVID-19) outcome early at infection are urgently needed to improve prognosis and treatment. Zinc balances immune responses and also has a proven direct antiviral action against some viruses. Importantly, zinc deficiency (ZD) is a common condition in elderly and individuals with chronic diseases, two groups with more severe COVID-19 outcomes. We hypothesize that serum zinc content (SZC) influences COVID-19 disease progression and thus might represent a useful biomarker…
>
> **Findings**: Our study demonstrates a correlation between serum zinc levels and COVID-19 outcome. Serum zinc levels lower than 50 µg/dl at admission correlated with worse clinical presentation, longer time to reach stability and higher mortality. Our in vitro results indicate that **low zinc levels favor viral expansion** in SARS-CoV2 infected cells [*emphasis added*]."

[452] ***Lower zinc levels in the blood are associated with an increased risk of death in patients with COVID-19***
Medical Xpress
European Society of Clinical Microbiology and Infectious Diseases
September 23, 2020
https://medicalxpress.com/news/2020-09-zinc-blood-death-patients-covid-.html

> "New research presented at this week's ESCMID Conference on Coronavirus Disease (ECCVID, held online from 23-25 September) shows that having a lower level of zinc in the blood is associated with a poorer outcome in patients with COVID-19...
>
> Mean baseline zinc levels among the 249 patients were 61 mcg/dl. Among those who died, the zinc levels at baseline were significantly lower at 43mcg/dl vs 63.1mcg/dl in survivors…
>
> After adjusting by age, sex, severity and receiving hydroxychloroquine, statistical analysis showed **each unit increase of plasma zinc** at admission to hospital **was associated with a 7% reduced risk of in-hospital mortality**. Having a plasma zinc level lower than 50mcg/dl at admission was associated with a **2.3 times increased risk of in-hospital death** compared with those patients with a plasma zinc level of 50mcg/dl or higher [*emphasis added*]."

[453] ***COVID-19: Poor outcomes in patients with zinc deficiency***
International Journal of Infectious Diseases
Dinesh Jothimani, Ezhilarasan Kailasam, *et al*.
September 10, 2020
https://www.ijidonline.com/article/S1201-9712(20)30730-X/fulltext

"**Highlights**:

- Patients with coronavirus disease 2019 (COVID-19) had significantly low zinc levels in comparison to healthy controls.
- Zinc deficient patients developed more complications (**70.4% vs 30.0%**, p = 0.009) [*emphasis added*].
- Zinc deficient COVID-19 patients had a prolonged hospital stay (7.9 vs 5.7 days, p = 0.048).
- In vitro studies have shown that reduced zinc levels favour the interaction of angiotensin-converting enzyme 2 (ACE2) with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein and likewise that increased zinc levels inhibit ACE2 expression resulting in reduced viral interaction.

Results: … Amongst the COVID-19 patients, 27 (57.4%) were found to be zinc deficient. These patients were found to have higher rates of complications (p = 0.009), acute respiratory distress syndrome (18.5% vs 0%, p = 0.06), corticosteroid therapy (p = 0.02), prolonged hospital stay (p = 0.05), and increased mortality (18.5% vs 0%, p = 0.06)."

[454] ***The Potential Impact of Zinc Supplementation on COVID-19 Pathogenesis***
Frontiers in Immunology
Inga Wessels, Benjamin Rolles, and Lothar Rink
July 10, 2020
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7365891/

"**Conclusion**: In this perspective, we reviewed the most important literature on the role of zinc homeostasis during viral infections, focusing on the potential benefits of zinc supplementation to prevent and treat SARS-CoV2 infections. Although data specifically on SARS-CoV2 are unfortunately still pending and randomized controlled studies have not been conducted, the enumerated evidence from the literature strongly suggests great benefits of zinc supplementation. **Zinc supplementation** improves the mucociliary clearance, **strengthens the integrity of the epithelium**, **decreases viral replication**, **preserves antiviral immunity**, attenuates the risk of hyper-inflammation, supports anti-oxidative effects and thus **reduces lung damage** and minimized secondary infections [*emphasis added*]. Especially older subjects, patients with chronic diseases and most of the remaining COVID-19 risk groups would most likely benefit. Although studies are needed testing the effect of zinc as therapeutic option for established disease, preventive supplementation of subjects from risk groups should begin now, as zinc is a cost-efficient, globally available and simple to use option with little to no side effects."

[455] ***Hydroxychloroquine and azithromycin plus zinc vs hydroxychloroquine and azithromycin alone: outcomes in hospitalized COVID-19 patients***
Journal of Microbiology
Philip M. Carlucci, Tania Ahuja, Christopher Petrilli, Harish Rajagopalan, Simon Jones, and Joseph Rahimian
May 8, 2020
https://www.medrxiv.org/content/10.1101/2020.05.02.20080036v1.full.pdf

"**Results**: The addition of zinc sulfate did not impact the length of hospitalization, duration of ventilation, or ICU duration. In univariate analyses, **zinc sulfate** increased the frequency of patients being discharged home, and **decreased the need for ventilation, admission to the ICU,** and **mortality or transfer to hospice** for patients who were never admitted to the ICU [*emphasis added*]. After adjusting for the time at which zinc sulfate was added to our protocol, an increased frequency of being discharged home (OR 1.53, 95% CI 1.12-2.09) reduction in mortality or transfer to hospice remained significant (OR 0.449, 95% CI 0.271-0.744)…

Conclusion: This study provides the first in vivo evidence that zinc sulfate in combination with hydroxychloroquine may play a role in therapeutic management for COVID-19."

[456] ***Zinc deficiency enhanced inflammatory response by increasing immune cell activation and inducing IL6 promoter demethylation***
Molecular Nutrition & Food Research
Carment P. Wong, Nicole A. Rinaldi, and Emily Ho
February 5, 2015
https://onlinelibrary.wiley.com/doi/10.1002/mnfr.201400761

"**Scope**: Zinc deficiency results in immune dysfunction and promotes systemic inflammation. The objective of this study was to examine the effects of zinc deficiency on cellular immune activation and epigenetic mechanisms that promote inflammation. This work is potentially relevant to the aging population given that age-related immune defects, including chronic inflammation, coincide with declining zinc status…

Conclusion: Zinc deficiency induced inflammatory response in part by eliciting aberrant immune cell activation and altered promoter methylation. Our results suggested potential interactions between zinc status, epigenetics, and immune function, and how their dysregulation could contribute to chronic inflammation."

[457] ***Zn^{2+} Inhibits Coronavirus and Arterivirus RNA Polymerase Activity In Vitro and Zinc Ionophores Block the Replication of These Viruses in Cell Culture***
PLOS Pathogens
Aartjan J. W. te Velthuis, Sjoerd H. E. van den Worm, *et al*.
November 4, 2010
https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1001176

"**Abstract**: Increasing the intracellular Zn^{2+} concentration with zinc-ionophores like pyrithione (PT) can efficiently impair the replication of a variety of RNA viruses, including poliovirus and influenza virus. For some viruses this effect has been attributed to interference with viral polyprotein processing. In this study we demonstrate that the combination of Zn^{2+} and PT at low concentrations (2 μM Zn^{2+} and 2 μM PT) inhibits the replication of SARS-coronavirus (SARS-CoV) and equine arteritis virus (EAV) in cell culture."

Ivermectin

[458] ***#Ivermectin for COVID-19: Real-time meta-analysis of 63 studies***
October 8, 2021, Version 129
https://ivmmeta.com/

> "Meta analysis using the most serious outcome reported shows **66% [52-76%] and 86% [75-92%] improvement** for early treatment and prophylaxis, **with similar results after** exclusion based sensitivity analysis and **restriction to peer-reviewed studies or Randomized Controlled Trials** [*emphasis added*].
>
> Statistically significant improvements are seen for mortality, ventilation, ICU admission, hospitalization, recovery, cases, and viral clearance. 30 studies show statistically significant improvements in isolation."

	Studies	Prophylaxis	Early treatment	Late treatment	Patients	Authors
All studies	64	**86%** [75-92%]	**66%** [52-76%]	**40%** [24-52%]	47,641	639
Peer-reviewed	44	**86%** [74-93%]	**69%** [51-81%]	**43%** [21-59%]	17,216	474
With GMK/BBC exclusions	47	**84%** [69-91%]	**73%** [63-80%]	**46%** [23-62%]	37,558	518
Randomized Controlled Trials	31	**84%** [25-96%]	**62%** [43-75%]	**30%** [2-50%]	6,548	371

Percentage improvement with ivermectin treatment

[459] ***One Page Summary of the Clinical Trials Evidence for Ivermectin in COVID-19***
Front Line COVID-19 Critical Care (FLCCC) Alliance
January 11, 2021
https://covid19criticalcare.com/wp-content/uploads/2020/12/One-Page-Summary-of-the-Clinical-Trials-Evidence-for-Ivermectin-in-COVID-19.pdf

> "Ivermectin, an anti-parasitic medicine whose discovery won the Nobel Prize in 2015, has proven, highly potent, anti-viral and anti-inflammatory properties in laboratory studies. In the past 4 months, numerous, controlled clinical trials from multiple centers and countries worldwide are reporting consistent, large improvements in COVID-19 patient outcomes when treated with ivermectin. Our comprehensive scientific review of these referenced trials can be found on the Open Science Foundation pre-print server here: https://osf.io/wx3zn/."

Note: The citations below are presented in reverse, chronological order.

[460] **ADDED since 10/14/2021**
Ivermectin as a SARS-CoV-2 Pre-Exposure Prophylaxis Method in Healthcare Workers: A Propensity Score-Matched Retrospective Cohort Study
Cureus
Jose Morgenstern, Jose N. Redondo, *et al*.
August 26, 2021
https://www.cureus.com/articles/63131-ivermectin-as-a-sars-cov-2-pre-exposure-prophylaxis-method-in-healthcare-workers-a-propensity-score-matched-retrospective-cohort-study

"**Background**: Ivermectin is a drug that has been shown to be active against coronavirus disease 19 (COVID-19) in previous studies. Healthcare personnel are highly exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Therefore, we decided to offer them ivermectin as a pre-exposure prophylaxis (PrEP) method…

Results: In 28 days of follow-up, **significant protection of ivermectin** preventing the infection from SARS-CoV-2 was observed: 1.8% compared to those who did not take it (6.6%; p-value = 0.006), with a **risk reduction of 74%** [*emphasis added*]."

[461] **Press conference: *Tokyo Medical Association President recommends #Ivermectin to all doctors***
Tokyo Medical Association
August 26, 2021
https://odysee.com/@snowchindy:f/video_2021-08-27_19-46-39:3

"In Africa, if we compare countries distributing Ivermectin once a year with countries which do not give ivermectin. I mean, they don't give ivermectin to prevent Covid, but to prevent parasitic diseases, but anyway, if we look at Covid numbers in countries that give ivermectin, the number of cases is 134.4 per 100,000, and the number of deaths is 2.2 per 100,000. Now African countries which do not distribute ivermectin – 950.6 cases per 100,000 and 29.3 deaths per 100,000. I believe the difference is clear. Of course, one cannot conclude that ivermectin is effective only on the basis of these figures, but when we have all these elements, we cannot say that ivermectin is absolutely not effective, at least not me. We can do other studies to confirm its efficacy, but we are in a crisis situation. With regard to the use of ivermectin, it is obviously necessary to obtain the informed consent of the patients, and I think we're in a situation where we can afford to give them this treatment."

[462] ***Summary of the Evidence for Ivermectin in COVID-19***
Front Line COVID-19 Critical Care (FLCCC) Alliance
August 4, 2021
https://covid19criticalcare.com/wp-content/uploads/2021/08/SUMMARY-OF-THE-EVIDENCE-BASE.pdf

"Ivermectin is an anti-parasite medicine whose discovery won the Nobel Prize in 2015 for its impacts in ridding large parts of the globe of parasitic diseases via distribution of over 3.7 billion doses within public health campaigns since 1987.

Since 2012, numerous in-vitro studies began to report highly potent anti-viral effects against a diverse array of viruses, including SARS-CoV-2 along with numerous anti-inflammatory and immuno-modulating effects…

Currently, as of August 4, 2021, the totality of the evidence is as follows: …

Conclusion: Based on the totality of the existing evidence above, the FLCCC strongly recommends ivermectin be used in both the prevention and treatment of all phases of COVID-19 in both vaccinated and unvaccinated populations."

[463] ***Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19***
New Microbes and New Infections
A.D. Santin, D.E. Schelm, *et al*.
August 3, 2021
https://www.sciencedirect.com/science/article/pii/S2052297521000883?via%3Dihub

"**Abstract**: In 2015, the Nobel Committee for Physiology or Medicine, in its only award for treatments of infectious diseases since six decades prior, honoured the discovery of ivermectin (IVM), a multifaceted drug deployed against some of the world's most devastating tropical diseases. Since March 2020, when IVM was first used against a new global scourge, COVID-19, more than 20 randomized clinical trials (RCTs) have tracked such inpatient and outpatient treatments. **Six of seven meta-analyses** of IVM treatment RCTs reporting in 2021 **found notable reductions in COVID-19 fatalities,** with a mean 31% relative risk of mortality vs. controls [*emphasis added*]. During mass IVM treatments in Peru, excess deaths fell by a mean of 74% over 30 days in its ten states with the most extensive treatments. Reductions in deaths correlated with the extent of IVM distributions in all 25 states with $p < 0.002$. Sharp reductions in morbidity using IVM were also observed in two animal models, of SARS-CoV-2 and a related betacoronavirus. The indicated biological mechanism of IVM, competitive binding with SARS-CoV-2 spike protein, is likely non-epitope specific, possibly yielding full efficacy against emerging viral mutant strains…

Introduction: … Dr Satoshi Omura, the Nobel co-laureate for the discovery of IVM, and colleagues conducted a comprehensive review of IVM clinical activity against COVID-19, concluding that **the preponderance of the evidence demonstrated major reductions in mortality and morbidity**. Our review of that evidence, updated with consideration of several new studies, supports the same conclusion [*emphasis added*]."

[464] ***Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines***
American Journal of Therapeutics
Andrew Bryant, Theresa A. Lawrie, *et al*.
July/August 2021
https://journals.lww.com/americantherapeutics/Fulltext/2021/08000/Ivermectin_for_Prevention_and_Treatment_of.7.aspx

"**Background**: Repurposed medicines may have a role against the SARS-CoV-2 virus. The antiparasitic ivermectin, with antiviral and anti-inflammatory properties, has now been tested in numerous clinical trials.

Data sources: We searched bibliographic databases up to April 25, 2021. Two review authors sifted for studies, extracted data, and assessed risk of bias. Meta-analyses were conducted and certainty of the evidence was assessed using the GRADE approach and additionally in trial sequential analyses for mortality. Twenty-four randomized controlled trials involving 3406 participants met review inclusion.

Conclusions: Moderate-certainty evidence finds that **large reductions in COVID-19 deaths** are possible using ivermectin [*emphasis added*]. Using ivermectin early in the clinical course may reduce numbers progressing to severe disease. The apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally.

All-cause mortality: Meta-analysis of 15 trials, assessing 2438 participants, found that ivermectin reduced the risk of death by an average of 62% (95% CI 27%–81%) compared with no ivermectin treatment."

[465] ***COVID-19 Treatment Guidelines***
National Institutes of Health (NIH)
Updated July 8, 2021
https://www.covid19treatmentguidelines.nih.gov/tables/table-2e/

"Table 2e. Characteristics of Antiviral Agents That Are Approved or Under Evaluation for the Treatment of COVID-19

Ivermectin

- Dosing Regimens. The dose most commonly used in clinical trials is IVM 0.2–0.6 mg/kg PO given as a single dose or as a once-daily dose for up to 5 days
- Adverse Events. Generally well tolerated"

[466] ***Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection***
Open Forum Infectious Diseases (Oxford)
Andrew Hill, Anna Garratt, *et al*.
July 6, 2021
https://academic.oup.com/ofid/advance-article/doi/10.1093/ofid/ofab358/6316214

"**Abstract**: … This meta-analysis investigated ivermectin in 24 randomized clinical trials (3328 patients) identified through systematic searches of PUBMED, EMBASE, MedRxiv and trial registries. Ivermectin was associated with reduced inflammatory markers (C-Reactive Protein, d-dimer and ferritin) and faster viral clearance by PCR. Viral clearance was treatment dose- and duration-dependent. In 11 randomized trials of moderate/severe infection, there was a **56% reduction in mortality** [*emphasis added*] (Relative Risk 0.44 [95%CI 0.25-0.77]; p=0.004; 35/1064 (3%) deaths on ivermectin; 93/1063 (9%) deaths in controls) with favorable clinical recovery and reduced hospitalization."

[467] ***Antiviral effect of high-dose ivermectin in adults with COVID-19: A proof-of-concept randomized trial***
EClinicalMedicine – The Lancet
Alejandro Krolewiecki, Adrian Lifschitz, *et al*.
June 17, 2021
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00239-X/fulltext

"**Findings**: 45 participants were recruited (30 to IVM and 15 controls) between May 18 and September 9, 2020. There was no difference in viral load reduction between groups but a significant difference was found in patients with higher median plasma IVM levels (72% IQR 59–77) versus untreated controls (42% IQR 31–73) (p = 0·004). Mean ivermectin plasma concentration levels correlated with viral decay rate (r: 0·47, p = 0·02). Adverse events were similar between groups…

Interpretation: A concentration dependent antiviral activity of oral high-dose IVM was identified at a dosing regimen that was well tolerated."

[468] **RETRACTED: *The mechanisms of action of Ivermectin against SARS-CoV-2: An evidence-based clinical review article***
The Journal of Antibiotics
Asiya Kamber Zaidi and Puya Dehgani-Mobaraki
June 15, 2021
https://www.nature.com/articles/s41429-021-00430-5

"**Abstract**: Considering the urgency of the ongoing COVID-19 pandemic, detection of various new mutant strains and future potential re-emergence of novel coronaviruses, repurposing of approved drugs such as Ivermectin could be worthy of attention. This evidence-based review article aims to discuss the mechanism of action of ivermectin against SARS-CoV-2 and summarizing the available literature over the years. A schematic of the key cellular and biomolecular interactions between Ivermectin, host cell, and SARS-CoV-2 in COVID-19 pathogenesis and prevention of complications have been proposed…

Introduction: … Several doctor-initiated clinical trial protocols that aimed to evaluate outcomes, such as reduction in mortality figures, shortened length of intensive care unit stay and/or hospital stay and elimination of the virus with ivermectin use have been registered at the US ClinicalTrials.gov. Real-time data is also available with a meta-analysis of 55 studies to date. As per data available on 16 May 2021, 100% of 36 early treatment and prophylaxis studies report positive effects (96% of all 55 studies). Of these, 26 studies show statistically significant improvements in isolation. Random effects meta-analysis with pooled effects using the most serious outcome reported 79% and 85% improvement for early treatment and prophylaxis respectively… Statistically significant improvements were seen for mortality, ventilation, hospitalization, cases, and viral clearance. **100% of the 17 Randomized Controlled Trials (RCTs) for early treatment and prophylaxis report positive effects**, with an estimated improvement of 73% and 83% respectively… and 93% of all 28 RCTs [*emphasis added*]…

This article aims to discuss the mechanism of action by summarizing the in vitro and in vivo evidence demonstrating the role of Ivermectin in COVID-19 as per the available literature over the years…"

Fig 1. notes: Ivermectin; IVM (red block) inhibits and disrupts binding of the SARS-CoV-2 S protein at the ACE-2 receptors (green)."

[469] ***Good news in La Pampa: Preliminary results of ivermectin treatments in Covid-19 patients are encouraging***
Bichos de campo
Field Bugs
June 9, 2021
https://bichosdecampo.com/buenas-noticias-en-la-pampa-son-alentadores-los-resultados-preliminares-de-tratamientos-con-ivermectina-en-pacientes-con-covid-19/

"Ivermectin, an antiparasitic well known to all livestock producers, was shown to have verifiable results for the treatment of Covid-19 symptoms in a study carried out in the province of La Pampa…

[I]t was evidenced that in people over 40 years of age the frequency of hospitalization in intensive care was close to 40% lower in those who received ivermectin, while the development of severe forms of the disease (defined from admission to intensive care or death of patients)

was 35% less frequent in treated subjects than in those who did not participate in the program."

[470] ***Ivermectin: Provide partial monitoring results in expanded use in positive patients***
Pagina 16
June 2021
http://www.pagina16.com.ar/ivermectina-brindan-resultados-parciales-de-monitoreo-en-el-uso-ampliado-en-pacientes-positivos/

"From January to June of this year, of 4,000 patients who were included in the monitoring, carried out by [*Argentina's*] Ministry of Public Health of Misiones together with scientific institutions, in the expanded use of Ivermectin in positive patients, 2,500 of them are actively monitoring and recording information, according to data from the first partial report of the Ivermis T monitoring…

Efficacy: … [A] 3.5-fold decrease in cases requiring hospitalization and a 1.5-fold decrease in fatal cases is observed in the population treated with Ivermectin."

[471] ***Favorable outcome on viral load and culture viability using Ivermectin in early treatment of non-hospitalized patients with mild COVID-19 – A double-blind, randomized placebo-controlled trial***
Sheba Medical Center and Ministry of Health (Israel)
Asaf Biber, Michal Mandelboim, *et al*.
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.31.21258081v1.full-text

"**Background**: we conducted a double blinded randomized control trial to assess whether Ivermectin can shorten viral shedding, in non-hospitalized patients at the early stage of COVID-19 infection.

Discussion: In this double-blind, randomized trial with mild COVID-19 patients, ivermectin significantly reduced time of viral shedding and affected viral viability when initiated at the first week after evidence of infection. Our primary endpoint was to show the benefit of ivermectin on day six (three days after ending treatment) which was achieved with 72% of samples being non-infectious (Ct>30) in comparison to 50% among the placebo group (OR 2·6)."

[472] ***Uttar Pradesh government says early use of Ivermectin helped to keep positivity, deaths low***
The Indian Express
Maulshree Seth
May 12, 2021
https://indianexpress.com/article/cities/lucknow/uttar-pradesh-government-says-ivermectin-helped-to-keep-deaths-low-7311786/

"A year after the country's first Covid-19 cluster, with 5 cases, was reported in Agra district, the Uttar Pradesh government has claimed that it was the first state to have introduced a large-scale 'prophylactic and therapeutic' use of Ivermectin and added that the drug helped the state to maintain a lower fatality and positivity rate as compared to other states…

'Uttar Pradesh was the first state in the country to introduce large-scale prophylactic and therapeutic use of Ivermectin. In May-June 2020, a team at Agra, led by Dr Anshul Pareek, administered Ivermectin to all RRT team members in the district on an experimental basis. It was observed that none of them developed Covid-19 despite being in daily contact with patients

who had tested positive for the virus,' Uttar Pradesh State Surveillance Officer Vikssendu Agrawal said…

Claiming that timely introduction of Ivermectin since the first wave has helped the state maintain a relatively low positivity rate despite its high population density, he [*Agrawal*] said, 'Despite being the state with the largest population base and a high population density, we have maintained a relatively low positivity rate and cases per million of population.'"

[473] ***Ivermectin and the odds of hospitalization due to COVID-19: evidence from a quasi-experimental analysis based on a public intervention in Mexico City***
SocArXiv Papers
Jose Merino, Victor Hugo Borja, *et al*.
May 3, 2021
https://osf.io/preprints/socarxiv/r93g4/

"**Objective**: To measure the effect of Mexico City's population-level intervention –an ivermectin-based Medical Kit—in hospitalizations during the COVID-19 pandemic…

Results: We found a significant reduction in hospitalizations among patients who received the ivermectin-based medical kit; the **range of the effect is 52%-76%** depending on model specification [*emphasis added*]."

[474] ***Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19***
American Journal of Therapeutics
Pierre Kory, Gianfranco Umberto Meduri, Joseph Varon, Jose Iglesias, and Paul Marik
April 22, 2021
https://journals.lww.com/americantherapeutics/Fulltext/2021/06000/Review_of_the_Emerging_Evidence_Demonstrating_the.4.aspx

"**Conclusions**: Meta-analyses based on 18 randomized controlled treatment trials of ivermectin in COVID-19 have found **large, statistically significant reductions in mortality**, time to clinical recovery, and time to viral clearance [*emphasis added*]. Furthermore, results from numerous controlled prophylaxis trials report significantly reduced risks of contracting COVID-19 with the regular use of ivermectin. Finally, the many examples of ivermectin distribution campaigns leading to rapid population-wide decreases in morbidity and mortality indicate that an oral agent effective in all phases of COVID-19 has been identified."

[475] ***Repurposing Ivermectin for COVID-19: Molecular Aspects and Therapeutic Possibilities***
Frontiers in Immunology
Zena Wehbe, Maya Wehbe, *et al*.
March 30, 2021
https://www.frontiersin.org/articles/10.3389/fimmu.2021.663586/full

"In this review, we delineate the story of how this antiparasitic drug was eventually identified as a potential treatment option for COVID-19. We review SARS-CoV-2 lifecycle, the role of the nucleocapsid protein, the turning points in past research that provided initial 'hints' for IVM's antiviral activity and its molecular mechanism of action- and finally, we culminate with the current clinical findings…

Concluding Remarks and Perspectives: The available data from IVM clinical trials lack

uniformity and have not established the optimal anti-viral dose. However, the evidence does support its safety and efficacy in improving survival rates, especially compared to the other aforementioned drugs. It is important to note that past research has demonstrated the importance of combined, rather than anti-viral monotherapy. Indeed, the use of a single drug does not efficiently suppress long-term replication of the virus. As evident by the ongoing clinical trials for the treatment of COVID-19, the most efficient decrease in mortality (0%) was largely a result of multiple prescribed drugs including IVM, hydroxychloroquine and azithromycin or IVM and doxycyline Table 1."

[476] ***Ivermectin reduces in vivo coronavirus infection in a mouse experimental model***
Scientific Reports
A.P. Arevalo, R. Pagotta, *et al*.
March 30, 2021
https://www.nature.com/articles/s41598-021-86679-0/

"**Abstract**: The objective of this study was to test the effectiveness of ivermectin for the treatment of mouse hepatitis virus (MHV), a type 2 family RNA coronavirus similar to SARS-CoV-2… Overall, the results demonstrated that viral infection induced typical MHV-caused disease, with the livers showing severe hepatocellular necrosis surrounded by a severe lymphoplasmacytic inflammatory infiltration associated with a high hepatic viral load (52,158 AU), while mice treated with ivermectin showed a better health status with a lower viral load (23,192 AU; $p < 0.05$), with only a few having histopathological liver damage ($p < 0.05$)… In conclusion, ivermectin diminished the MHV viral load and disease in the mice, being a useful model for further understanding this therapy against coronavirus diseases."

[477] ***Why COVID-19 is not so spread in Africa: How does Ivermectin affect it?***
Tanioka Clinic & National Institute of Sensory Organs (Japan)
Hisaya Tanioka, Sayaka Tanioka, and Kimitaka Kaga
March 26, 2021
https://www.medrxiv.org/content/10.1101/2021.03.26.21254377v1.full.pdf

"**Background**: Scientists have so far been unable to determine the reason for the low number of COVID-19 cases in Africa.

Objective: To evaluate the impact of ivermectin interventions for onchocerciasis on the morbidity, mortality, recovery, and fatality rates caused by COVID-19.

Conclusions: The morbidity and mortality in the onchocerciasis endemic countries are lesser than those in the non-endemic ones. The community-directed onchocerciasis treatment with ivermectin is the most reasonable explanation for the decrease in morbidity and fatality rate in Africa. In areas where ivermectin is distributed to and used by the entire population, it leads to a significant reduction in mortality."

[478] ***Exploring the binding efficacy of ivermectin against the key proteins of SARS-CoV-2 pathogenesis: an in silico approach***
Future Virology
Abhigyan Choudhury, Nabarun C. Das, *et al*.
March 25, 2021
https://www.futuremedicine.com/doi/10.2217/fvl-2020-0342

> "**Results**: Ivermectin was found as a blocker of viral replicase, protease and human TMPRSS2, which could be the biophysical basis behind its antiviral efficiency. The antiviral action and ADMET profile of ivermectin was on par with the currently used anticorona drugs such as hydroxychloroquine and remdesivir.
>
> **Conclusion**: Our study enlightens the candidature of ivermectin as an effective drug for treating COVID-19."

[479] ***The BIRD Recommendation on the Use of Ivermectin for Covid-19***
British Ivermectin Recommendation Development (BIRD) panel
Tess Lawrie, Fahmida Shaik, *et al*.
March 22, 2021
https://bird-group.org/wp-content/uploads/2021/03/BIRD-Proceedings-22-03-2021-final.pdf
Supporters and endorsements: https://bird-group.org/who-are-bird/

> "**Executive Summary**: The antiparasitic medicine ivermectin, which is widely available in LMICs [*low- and middle-income countries*], has been tested in numerous clinical trials of prevention and treatment of covid-19 with promising results. A large body of evidence on ivermectin use in covid-19 had thus accumulated, which required urgent review by health professionals and other stakeholders to determine whether it could inform clinical practice in the UK and elsewhere. More specifically, answers were needed to the following priority questions: (i) For people with covid-19 infection, does ivermectin compared with placebo or no ivermectin improve health outcomes?, and (ii) for people at higher risk of covid-19 infection, does ivermectin compared with placebo or no ivermectin improve health outcomes?
>
> On the 20th of February 2021, the British Ivermectin Recommendation Development (BIRD) meeting was convened in Bath, United Kingdom, to evaluate the evidence on ivermectin use for the prevention and treatment of covid-19. Evidence to address the priority questions was evaluated by a panel of clinical experts and other stakeholders in the form of a DECIDE evidence-to-decision framework, the gold standard tool for developing clinical practice guidelines…
>
> The British Ivermectin Recommendation Development panel **recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality** associated with covid-19 infection and to prevent covid-19 infection among those at higher risk [*emphasis added*]."

[480] ***Global trends in clinical studies of ivermectin in COVID-19***
Japanese Journal of Antibiotics
Morimasa Yagiswa, Patricck J. Foster, Hideaki Hanaki, and Satoshi Omura
March 10, 2021
https://covid19criticalcare.com/wp-content/uploads/2021/04/Satoshi-Omura-Global-trends-in-clinical-studies-of-ivermectin-in-COVID-19-Japanese-Journal-of-Antibiotics-March-10-2021.pdf

"This review is written with the hope of increasing the understanding and support of all parties, by explaining the current situation in which doctors and researchers all around the world are actively attempting to expand the indication for ivermectin as a therapeutic/preventive drug for COVID-19. It is hoped that ivermectin will be utilized as a countermeasure for COVID-19 as soon as possible…

Although clinical trial results have been and continue to be accumulated showing that ivermectin is effective in the treatment and prevention of COVID-19, basic in vitro findings that can reasonably explain its effectiveness have not yet been obtained…

When the effectiveness of ivermectin for the COVID-19 pandemic is confirmed with the cooperation of researchers around the world and its clinical use is achieved on a global scale, it could prove to be of great benefit to humanity. It may even turn out to be comparable to the benefits achieved from the discovery of penicillin—said to be one of the greatest discoveries of the twentieth century. Here, one more use for ivermectin, which has been described as 'miracle' or 'wonder' drug, is being added."

[481] ***Role of ivermectin in the prevention of SARS-CoV-2 infection among healthcare workers in India: A matched case-control study***
PLOS One
Priyamadhaba Behera, Binod Kumar Patro, *et al*.
February 16, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247163

"**Background**: Ivermectin is one among several potential drugs explored for its therapeutic and preventive role in SARS-CoV-2 infection. The study was aimed to explore the association between ivermectin prophylaxis and the development of SARS-CoV-2 infection among healthcare workers…

Conclusion: Two-dose ivermectin prophylaxis at a dose of 300 μg/kg with a gap of 72 hours was associated with a 73% reduction of SARS-CoV-2 infection among healthcare workers for the following month. Chemoprophylaxis has relevance in the containment of pandemic."

[482] ***#COVID-19 Treatment Guidelines – Ivermectin***
National Institutes of Health (NIH)
Last updated February 11, 2021
https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/

"Reports from *in vitro* studies suggest that ivermectin acts by inhibiting the host importin alpha/beta-1 nuclear transport proteins, which are part of a key intracellular transport process that viruses hijack to enhance infection by suppressing the host's antiviral response. In addition, ivermectin docking may interfere with the attachment of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein to the human cell membrane… Some studies of ivermectin have also reported potential anti-inflammatory properties, which have been postulated to be beneficial in people with COVID-19."

[483] ***The Use of Compassionate Ivermectin in the Management of Symptomatic Outpatients and Hospitalized Patients with Clinical Diagnosis of Covid-19 at the Centro Medico Bournigal and at the Centro Medico Punta Cana, Grupo Rescue, Dominican Republic, from May 1 to August 10, 2020***
Journal of Clinical Trials
Jose Morgenstern, Jose N. Redondo, *et al*.
February 2, 2021
https://www.longdom.org/open-access/the-use-of-compassionate-ivermectin-in-the-management-of-symptomatic-outpatients-and-hospitalized-patients-with-clinical.pdf

> "**Abstract**: … In the present Retrospective observational study, 3,099 patients with a definitive or highly probable diagnosis of infection due to COVID-19 were evaluated… A total of 2,706 (87.3%) were discharged for outpatient treatment, all with mild severity of the infection… In 2,688 (99.33%) with outpatient treatment, **the disease did not progress to warrant further hospitalization** and **there were no deaths** [*emphasis added*]. In 16 (0.59%) with outpatient treatment, it was necessary their subsequent hospitalization to a room without any death. In 2 (0.08%) with outpatient treatment, it was necessary their admission to the Intensive Care Unit (ICU) and 1 (0.04%) patient died. There were 411 (13.3%) patients hospitalized, being admitted at a COVID-19 room with a moderate disease 300 (9.7%) patients of which 3 (1%) died; and with a severe to critical disease were hospitalized in the ICU 111 (3.6%), 34 (30.6%) of whom died. The mortality percentage of patients admitted to the ICU of 30.6% is similar with the percentage found in the literature of 30.9%. Total mortality was 37 (1.2%) patients, which is much lower than that reported in world statistics, which are around 3%, by the time of completion of this study."

[484] ***Sharp Reductions in COVID-19 Case Fatalities and Excess Deaths in Peru in Close Time Conjunction, State-By-State, with Ivermectin Treatments***
Social Science Research Network (SSRN)
Juan J. Chamie-Quintero, Jennifer Hibberd, and David Scheim
January 12, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3765018

> "**Abstract**: On May 8, 2020, Peru's Ministry of Health approved ivermectin (IVM) for the treatment of COVID-19. A drug of Nobel Prize-honored distinction, IVM has been safely distributed in 3.7 billion doses worldwide since 1987. It has exhibited major, statistically significant reductions in case mortality and severity in 11 clinical trials for COVID-19, three with randomized controls. The indicated biological mechanism of IVM is the same as that of antiviral antibodies generated by vaccines—binding to SARS-CoV-2 viral spike protein, blocking viral attachment to host cells…
>
> For the 24 states with early IVM treatment (and Lima), **excess deaths dropped 59% (25%) at +30 days and 75% (25%) at +45 days** after day of peak deaths [*emphasis added*]. Case fatalities likewise dropped sharply in all states but Lima, yet six indices of Google-tracked community mobility rose over the same period. For nine states having mass distributions of IVM in a short timeframe through a national program, Mega-Operación Tayta (MOT), excess deaths at +30 days dropped by a population-weighted mean of 74%... Its safety well established even at high doses, IVM is a compelling option for immediate, large scale national deployments as an interim measure and complement to pandemic control through vaccinations."

[485] ***Ivermectin: an award-winning drug with expected antiviral activity against COVID-19***
Journal of Controlled Release
Fabio Rocha Formiga, Roger Leblanc, *et al*.
January 10, 2021
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7539925/

> "**Abstract**: Ivermectin is an FDA-approved broad-spectrum antiparasitic agent with demonstrated antiviral activity against a number of DNA and RNA viruses, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Despite this promise, the antiviral activity of ivermectin has not been consistently proven in vivo. While ivermectin's activity against SARS-CoV-2 is currently under investigation in patients, insufficient emphasis has been placed on formulation challenges. Here, we discuss challenges surrounding the use of ivermectin in the context of coronavirus disease-19 (COVID-19) and how novel formulations employing micro- and nanotechnologies may address these concerns…"

[486] ***Meta-analysis of clinical trials of ivermectin to treat COVID-19 infection***
Unitaid & University of Liverpool
Dr. Andrew Hill
December 2020
https://swprs.org/wp-content/uploads/2021/01/andrew_hill_ivermectin_slides_december_2020.pdf

> Slide 4: "Search strategy: Systematic review of randomised trials of ivermectin to treat COVID-19 infection"
>
> Slide 5: "Meta-analysis methods: Only the randomised clinical trials were included: in WHO GRADE criteria, systematic review and meta-analysis provides the highest level of evidence"
>
> Slide 23: "Conclusions: In this meta-analysis of 11 randomised trials in 1452 patients, Ivermectin treatment was associated with:
>
> - Faster time to viral clearance
> - Shorter duration of hospitalisation
> - 43% higher rates of clinical recovery (95% C.I. 21-67%)
> - **83% improvement in survival rates** [*emphasis added*] (95% C.I. 65-92%)

[487] ***Ivermectin as Prophylaxis Against COVID-19 Retrospective Cases Evaluation Microbiology & Infectious Diseases***
Roberto R. Hirsch and Hector E. Carvallo
December 2020
https://scivisionpub.com/pdfs/ivermectin-as-prophylaxis-against-covid19-retrospective-cases-evaluation-1458.pdf

> "**Abstract**: … Ivermectin has shown its usefulness against SARS COV2, both in treatment and in prophylaxis.
>
> Therefore, this work compiles the characteristics of the group of Health Agents (and their close contacts) from a Buenos Aires Hospital specialized in Infectious Diseases, who resorted to it, as well as the results that were obtained…

Conclusion: … From the data included in this compilation, it appears that Ivermectin has been an excellent adjuvant method for Personal Protective Equipment, for the prophylaxis of SARS Cov 2 in health personnel and their contacts.

As such, it is not only recommended to extend it to all Health Agents, but also to all vulnerable population groups (geriatric and psychiatric institutes, orphanages, prisons, etc.)."

[488] ***Ivermectin as Pre-exposure Prophylaxis for COVID-19 among Healthcare Providers in a Selected Tertiary Hospital in Dhaka – An Observational Study***
European Journal of Medical & Health Services
Mohammed Tarek Alam, Rubaiul Murshed, *et al*.
December 15, 2020
https://www.ejmed.org/index.php/ejmed/article/view/599/337

"**Abstract**

Introduction: While multiple vaccines are undergoing clinical trial across the globe, we yearn for an FDA approved drug to protect us from the devastating pandemic for the time being. This study aims to determine the effectiveness of Ivermectin when administered as pre-exposure prophylaxis for COVID-19…

Result: 73.3% (44 out of 60) subjects in control group were positive for COVID-19, whereas only 6.9% (4 out of 58) of the experimental group were diagnosed with COVID-19 (p-value < 0.05).

Conclusion: Ivermectin, an FDA-approved, safe, cheap and widely available drug, should be subjected to large-scale trials all over the world to ascertain its effectiveness as pre-exposure prophylaxis for COVID-19."

[489] **Video (28m): Sub-committee hearing on early treatment of COVID-19 - Testimony of Pierre Kory, MD**
US Senate
December 8, 2020
https://odysee.com/@FrontlineCovid19CriticalCareAlliance:c/Dr.-Pierre-Kory-FLCCC-Alliance-testifies-to-senate-committee-about-I-MASK-incl.-the-following-QA-part-490351508:3
Transcript: https://www.hsgac.senate.gov/imo/media/doc/Testimony-Kory-2020-12-08.pdf

"I am speaking today not only as an individual physician, but also on behalf of my non-profit organization, the Front-Line COVID-19 Critical Care Alliance, made up of some of the most highly published and well-known critical care experts in the world with almost 2,000 peer - reviewed publications in the medical literature as well as over 100 years of bedside clinical experience in ICU's around the country…

In the last 3-4 months, emerging publications provide conclusive data on the profound efficacy of the anti-parasite, anti-viral drug, anti-inflammatory agent called ivermectin in all stages of the disease. Our protocol was created only recently, after we identified these data. Nearly all studies are demonstrating the therapeutic potency and safety of ivermectin in preventing transmission and progression of illness in nearly all who take the drug...

We now have data from over 20 well-designed clinical studies, ten of them randomized, controlled trials, with **every study consistently reporting large magnitude and statistically**

significant benefits in decreasing transmission rates, shortening recovery times, decreasing hospitalizations, or large reductions in deaths. This clinical data is also supported by multiple basic science, in-vitro and animal studies [*emphasis added*]…

It should be noted that Merck, the pharmaceutical company whose scientists helped discover ivermectin, has from the first availability of the drug, donated hundreds of millions of doses for free to support the WHO parasite eradication programs. We believe a similar initiative is needed to eradicate the globe from the scourge of COVID-19."

[490] ***A COVID-19 prophylaxis? Lower incidence associated with prophylactic administration of ivermectin***
International Journal of Antimicrobial Agents
Martin D. Hellwig and Anabela Maia
November 28, 2020
https://www.sciencedirect.com/science/article/abs/pii/S0924857920304684

"Highlights

- Mass administration of ivermectin is associated with lower COVID-19 incidence.
- Ivermectin has been shown to inhibit SARS-CoV-2 replication in vitro.
- Ivermectin may have a prophylactic effect against COVID-19.
- COVID-19 prophylaxis could help bridge the time until a vaccine becomes widely available.

Abstract: As COVID-19 (coronavirus disease 2019) continues to rapidly spread throughout the world, the incidence varies greatly among different countries… Here, we show that **countries with routine mass drug administration of prophylactic chemotherapy including ivermectin have a significantly lower incidence of COVID-19**. Prophylactic use of ivermectin against parasitic infections is most common in Africa and we hence show that the reported correlation is highly significant both when compared among African nations as well as in a worldwide context. We surmise that this may be connected to ivermectin's ability to inhibit SARS-CoV-2 replication, which likely leads to lower infection rates."

[491] ***Use of Ivermectin Is Associated With Lower Mortality in Hospitalized Patients With Coronavirus Disease 2019***
Chest Journal
Juliana Cepelowicz Rajter, Michael S. Sherman, *et al*.
October 12, 2020
https://journal.chestnet.org/article/S0012-3692(20)34898-4/fulltext

"**Background**: Ivermectin was shown to inhibit severe acute respiratory syndrome coronavirus 2 replication in vitro, which has led to off-label use, but clinical efficacy has not been described previously…

Results: Two hundred eighty patients, 173 treated with ivermectin and 107 without ivermectin, were reviewed… Univariate analysis showed lower mortality in the ivermectin group… Mortality also was lower among ivermectin-treated patients with severe pulmonary involvement…

Interpretation: Ivermectin treatment was associated with lower mortality during treatment of COVID-19, especially in patients with severe pulmonary involvement. Randomized controlled trials are needed to confirm these findings."

[492] ***Ivermectin Docks to the SARS-CoV-2 Spike Receptor-binding Domain Attached to ACE2***
In Vivo
Steven Lehrer and Peter H. Rheinstein
August 31, 2020
https://iv.iiarjournals.org/content/34/5/3023

"**Abstract**: Background/Aim: Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). One drug that has attracted interest is the antiparasitic compound ivermectin, a macrocyclic lactone derived from the bacterium Streptomyces avermitilis. We carried out a docking study to determine if ivermectin might be able to attach to the SARS-CoV-2 spike receptor-binding domain bound with ACE2…

Conclusion: The ivermectin docking site we identified, between the viral spike and the ACE2 receptor, may interfere with the attachment of the spike to the human cell membrane. Our observation is consistent with the findings of Caly et al. and Patel et al."

[493] ***A Combination of Ivermectin and Doxycycline Possibly Blocks the Viral Entry and Modulate the Innate Immune Response in COVID-19 Patients***
Bhabha Atomic Research Centre (Mumbai)
Dharmendra Kumar Maurya
July 9, 2020
https://chemrxiv.org/engage/chemrxiv/article-details/60c74d85842e655304db34b6

"**Abstract**: … Very recently in Bangladesh, a group of doctors reported astounding success in treating patients suffering from COVID-19 with two commonly used drugs, Ivermectin and Doxycycline. In the current study we have explored the possible mechanism by which these drugs might have worked for the positive response in the COVID-19 patients… Our study shows that both Ivermectin and doxycycline have significantly bind with SARS-CoV-2 proteins but Ivermectin was better binding than doxycycline. Ivermectin showed a perfect binding site to the Spike-RBD and ACE2 interacting region indicating that it might be **interfering in the interaction of spike with ACE2 and preventing the viral entry in to the host cells**. Ivermectin also exhibited significant binding affinity with different SARS-CoV-2 structural and non-structural proteins (NSPs) which have diverse functions in virus life cycle. Significant binding of Ivermectin with RdRp indicate its role in the inhibition of the viral replication and **ultimately impeding the multiplication of the virus** [*emphasis added*]. Ivermectin also possess significant binding affinity with NSP3, NSP10, NSP15 and NSP16 which helps virus in escaping from host immune system. Molecular dynamics simulation study shows that binding of the Ivermectin with Mpro, Spike, NSP3, NSP16 and ACE2 was quiet stable. Thus, our docking and simulation studies reveal that combination of Ivermectin and doxycycline might be executing the effect by inhibition of viral entry and enhance viral load clearance by targeting various viral functional proteins…

In summary, the miraculous effect of combination of Ivermectin and doxycycline in COVID-19 patients is possibly by inhibition of spike-ACE2 interaction and inhibiting RNA dependent RNA polymerase, ADP Ribose Phosphatase, Endoribonuclease and NSP10-NSP16 complex

mediated methyltransferase activities, anti-viral activity and chelation of the zinc & immunomodulatory property. Thus, the usage of Ivermectin and doxycycline combination will be an ideal choice in prevention and management of COVID-19."

[494] ***Ivermectin: a systematic review from antiviral effects to COVID-19 complementary regimen Journal of Antibiotics***
Fatemeh Heidary and Reza Gharebaghi
June 12, 2020
https://www.nature.com/articles/s41429-020-0336-z

"**Abstract**: Ivermectin proposes many potentials effects to treat a range of diseases, with its antimicrobial, antiviral, and anti-cancer properties as a wonder drug. It is highly effective against many microorganisms including some viruses. In this comprehensive systematic review, antiviral effects of ivermectin are summarized including in vitro and in vivo studies over the past 50 years…

Conclusion: In this systematic review, we showed antiviral effects of ivermectin on a broad range of RNA and DNA viruses by reviewing all related evidences since 1970…

Ivermectin, owing to its antiviral activity, may play a pivotal role in several essential biological processes, therefore it could serve as a potential candidate in the treatment of different types of viruses including COVID-19."

[495] ***The broad spectrum antiviral ivermectin targets the host nuclear transport importin α/β1 heterodimer***
Antiviral Research
Sundy N.Y. Yang, Sarah C. Atkinson, *et al*.
May 2020
https://www.sciencedirect.com/science/article/abs/pii/S0166354219307211

"**Abstract**: … Although RNA viruses replicate in the infected host cell cytoplasm, the nucleus is central to key stages of the infectious cycle of HIV-1 and influenza, and an important target of DENV nonstructural protein 5 (NS5) in limiting the host antiviral response. We previously identified the small molecule ivermectin as an inhibitor of HIV-1 integrase nuclear entry, subsequently showing ivermectin could inhibit DENV NS5 nuclear import, as well as limit infection by viruses such as HIV-1 and DENV. We show here that ivermectin's broad spectrum antiviral activity relates to its ability to target the host importin (IMP) α/β1 nuclear transport proteins responsible for nuclear entry of cargoes such as integrase and NS5. We establish for the first time that ivermectin can dissociate the preformed IMPα/β1 heterodimer, as well as prevent its formation, through binding to the IMPα armadillo (ARM) repeat domain to impact IMPα thermal stability and α-helicity. We show that ivermectin inhibits NS5-IMPα interaction in a cell context using quantitative bimolecular fluorescence complementation. Finally, we show for the first time that ivermectin can limit infection by the DENV-related West Nile virus at low (μM) concentrations. Since it is FDA approved for parasitic indications, ivermectin merits closer consideration as a broad spectrum antiviral of interest."

[496] ***The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro***
Antiviral Research
Leon Caly, Julian D. Druce, *et al*.
April 3, 2020
https://www.sciencedirect.com/science/article/pii/S0166354220302011?via%3Dihub

"**Highlights**:

- Ivermectin is an inhibitor of the COVID-19 causative virus (SARS-CoV-2) *in vitro*.
- A single treatment able to effect ~5000-fold reduction in virus at 48 h in cell culture.
- Ivermectin is FDA-approved for parasitic infections, and therefore has a potential for repurposing.
- Ivermectin is widely available, due to its inclusion on the WHO model list of essential medicines.

1. Introduction: Ivermectin is an FDA-approved broad spectrum anti-parasitic agent (Gonzalez Canga et al., 2008) that in recent years we, along with other groups, have shown to have anti-viral activity against a broad range of viruses (Gotz et al., 2016; Lundberg et al., 2013; Tay et al., 2013; Wagstaff et al., 2012) *in vitro*…

Taken together these results demonstrate that **ivermectin has antiviral action against the SARS-CoV-2 clinical isolate *in vitro***, with a single dose able to control viral replication within 24–48 h in our system [*emphasis added*]. We hypothesise that this is likely through inhibiting IMPα/β1-mediated nuclear import of viral proteins (Fig. 1G), as shown for other RNA viruses (Tay et al., 2013; Wagstaff et al., 2012; Yang et al., 2020)... Ultimately, development of an effective anti-viral for SARS-CoV-2, if given to patients early in infection, could help to limit the viral load, prevent severe disease progression and limit person-person transmission…

Ivermectin has an established safety profile for human use [*emphasis added*] (Gonzalez Canga et al., 2008; Jans et al., 2019; Buonfrate et al., 2019), and is FDA-approved for a number of parasitic infections (Gonzalez Canga et al., 2008; Buonfrate et al., 2019). Importantly, recent reviews and meta-analysis indicate that high dose ivermectin has comparable safety as the standard low-dose treatment."

[497] ***Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations***
Journal of Antibiotics (Nature)
Andy Crump
February 15, 2017
https://www.nature.com/articles/ja201711

"**Abstract**: Over the past decade, the global scientific community have begun to recognize the unmatched value of an extraordinary drug, ivermectin, that originates from a single microbe unearthed from soil in Japan. Work on ivermectin has seen its discoverer, Satoshi Ōmura, of Tokyo's prestigious Kitasato Institute, receive the 2014 Gairdner Global Health Award and the 2015 Nobel Prize in Physiology or Medicine, which he shared with a collaborating partner in the discovery and development of the drug, William Campbell of Merck & Co. Incorporated. Today, ivermectin is continuing to surprise and excite scientists, offering more and more promise to

help improve global public health by treating a diverse range of diseases, with its **unexpected potential as an antibacterial, antiviral** and **anti-cancer agent** being particularly extraordinary [*emphasis added*]."

[498] ***Ivermectin: A Drug Worthy of a Nobel Prize, but Inaccessible for Those Who Need It***
Barcelona Institute of Global Health
Jose Munoz
October 22, 2015
https://www.isglobal.org/en/healthisglobal/-/custom-blog-portlet/ivermectina-un-medicamento-de-nobel-pero-poco-accesible/91127/0

"The Japanese scientist Satoshi Omura has recently received the Nobel Prize in Physiology and Medicine for his discovery of ivermectin more than 30 years ago. Invermectin is best known for its extraordinarily broad spectrum of activity against nematodes, the roundworms that cause a large proportion of the most common neglected diseases on our planet. It is used to treat millions of people at risk of contracting devastating diseases, such as onchocerciasis and lymphatic filariasis, and also plays an important role in the control of intestinal helminth infections. Because of its excellent safety profile and broad spectrum of activity, ivermectin is catalogued by the World Health Organisation as an essential medicine and is **regarded by many as a 'magic bullet' for global health** [*emphasis added*]."

[499] ***2015 Nobel Prize in Physiology or Medicine***
Nobel Assembly
2015
https://www.nobelprize.org/uploads/2018/06/press-29.pdf

"Today the Avermectin-derivative Ivermectin is used in all parts of the world that are plagued by parasitic diseases. Ivermectin is highly effective against a range of parasites, has limited side effects and is freely available across the globe. The importance of Ivermectin for improving the health and wellbeing of millions of individuals with River Blindness and Lymphatic Filariasis, primarily in the poorest regions of the world, is immeasurable. Treatment is so successful that these diseases are on the verge of eradication, which would be a major feat in the medical history of humankind."

[500] ***WHO Model List of Essential Medicines, 19th edition***
World Health Organization (WHO)
Amended August 2015
https://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf?ua=1

p. 6: "6. Anti-Infective Medicines… 6.1 Anthelminthics… 6.1.2 Antifilarials… ivermectin"

[501] ***Ivermectin, 'Wonder drug' from Japan: the human use perspective***
Proceedings of the Japan Academy, Series B, Physical and Biological Sciences
Andy Crump and Satoshi Omura
February 10, 2011
https://www.jstage.jst.go.jp/article/pjab/87/2/87_2_13/_article

"**Abstract**: Discovered in the late-1970s, the pioneering drug ivermectin, a dihydro derivative of avermectin—originating solely from a single microorganism isolated at the Kitasato Intitute,

Tokyo, Japan from Japanese soil—has had an immeasurably beneficial impact in improving the lives and welfare of billions of people throughout the world. Originally introduced as a veterinary drug, it kills a wide range of internal and external parasites in commercial livestock and companion animals. It was quickly discovered to be ideal in combating two of the world's most devastating and disfiguring diseases which have plagued the world's poor throughout the tropics for centuries. It is now being used free-of-charge as the sole tool in campaigns to eliminate both diseases globally. It has also been **used to successfully overcome several other human diseases** and **new uses for it are continually being found**. This paper looks in depth at the events surrounding ivermectin's passage from being a huge success in Animal Health into its widespread use in humans, a development which has led many to describe it as a **'wonder' drug** [*emphasis added*]."

Hydroxychloroquine and Azithromycin

[502] **ADDED since 10/14/2021**
HCQ for COVID-19
https://c19hcq.com/

"Database of all HCQ COVID-19 studies. 363 studies, 265 peer reviewed, 297 comparing treatment and control groups. HCQ is not effective when used very late with high dosages over a long period (RECOVERY/SOLIDARITY), effectiveness improves with earlier usage and improved dosing. Early treatment consistently shows positive effects."

[503] **ADDED since 10/14/2021**
HCQ for COVID-19: real-time meta analysis of 297 studies
https://hcqmeta.com/
Introduction: "We analyze all significant studies concerning the use of HCQ (or CQ) for COVID-19. Search methods, inclusion criteria, effect extraction criteria (more serious outcomes have priority), all individual study data, PRISMA answers, and statistical methods are detailed in Appendix 1. We present random-effects meta-analysis results for all studies, for studies within each treatment stage, for mortality results only, after exclusion of studies with critical bias, and for Randomized Controlled Trials (RCTs) only."

- "97% of the 33 early treatment studies report a positive effect (14 statistically significant in isolation).
- Meta analysis using the most serious outcome reported shows 64% [54-72%] improvement for the 33 early treatment studies…
- 83% of Randomized Controlled Trials (RCTs) for early, PrEP, or PEP treatment report positive effects, the probability of this happening for an ineffective treatment is 0.0038."

[504] #***Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media***
Doctors for Open Debate
September 5, 2020
https://docs4opendebate.be/en/open-letter/
Signatories: https://docs4opendebate.be/en/signatories/
Note: As of October 10, 2021, the Signatories page cites a total of 751 medical doctors and 2,831

medically trained health professionals.

"[T]here is an affordable, safe and efficient therapy available for those who do show severe symptoms of disease in the form of HCQ (hydroxychloroquine), zinc and azithromycin. Rapidly applied, this therapy leads to recovery and often prevents hospitalisation. Hardly anyone has to die now.

This effective therapy has been confirmed by the clinical experience of colleagues in the field with impressive results. This contrasts sharply with the theoretical criticism (insufficient substantiation by double-blind studies) which in some countries (e.g. the Netherlands) has even led to a ban on this therapy. **A meta-analysis in The Lancet, which could not demonstrate an effect of HCQ, was withdrawn**. The primary data sources used proved to be unreliable and 2 out of 3 authors were in conflict of interest [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[505] **ADDED since 10/14/2021**
Observational Study on 255 Mechanically Ventilated Covid Patients at the Beginning of the USA Pandemic
Smith Center for Infectious Diseases and Urban Health
Leon G. Smith, Nicolas Mendoza, David Dobesh, and Stephen M. Smith
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1.full-text

"**Introduction**: This observational study looked at 255 COVID19 patients who required invasive mechanical ventilation (IMV) during the first two months of the US pandemic…

Results: By discharge or Day 90, 78.2% of the cohort expired. The most common pre-existing conditions were hypertension, (63.5%), diabetes (59.2%) and obesity (50.4%)… Causal modeling establishes that weight-adjusted **HCQ and AZM therapy improves survival by over 100%** [*emphasis added*]."

[506] ***COVID-19 Outpatients – Early Risk-Stratified Treatment with Zinc Plus Low Dose Hydroxychloroquine and Azithromycin: A Retrospective Case Series Study***
International Journal of Antimicrobial Agents
Roland Derwand, Martin Scholz, and Vladamir Zelenko
October 26, 2020
https://www.sciencedirect.com/science/article/pii/S0924857920304258

"**Abstract**: The aim of this study was to describe the outcomes of patients with coronavirus disease 2019 (COVID-19) in the outpatient setting after early treatment with zinc, low-dose hydroxychloroquine and azithromycin (triple therapy) dependent on risk stratification… Independent public reference data from 377 confirmed COVID-19 patients in the same community were used as untreated controls. Of 141 treated patients, **4 (2.8%) were hospitalised, which was significantly fewer (P < 0.001) compared with 58 (15.4%) of 377 untreated patients** [odds ratio (OR) = 0.16, 95% confidence interval (CI) 0.06–0.5]. One patient (0.7%) in the treatment group died versus 13 patients (3.4%) in the untreated group [*emphasis added*] (OR = 0.2, 95% CI 0.03–1.5; P = 0.12). No cardiac side effects were observed. Risk stratification-based treatment of COVID-19 outpatients as early as possible after symptom onset using triple therapy, including the combination of zinc with low-dose hydroxychloroquine, was associated with significantly fewer hospitalisations."

[507] **ADDED since 10/14/2021**

The Key to Defeating COVID-19 Already Exists. We Need to Start Using It

Newsweek

Harvey Risch, Professor of Epidemiology, Yale School of Public Health

July 23, 2020

https://www.newsweek.com/key-defeating-covid-19-already-exists-we-need-start-using-it-opinion-1519535

> "As professor of epidemiology at Yale School of Public Health, I have authored over 300 peer-reviewed publications and currently hold senior positions on the editorial boards of several leading journals. I am usually accustomed to advocating for positions within the mainstream of medicine, so have been flummoxed to find that, in the midst of a crisis, I am fighting for a treatment that the data fully support but which, for reasons having nothing to do with a correct understanding of the science, has been pushed to the sidelines. As a result, tens of thousands of patients with COVID-19 are dying unnecessarily. Fortunately, the situation can be reversed easily and quickly.
>
> I am referring, of course, to the medication hydroxychloroquine. When this inexpensive oral medication is given very early in the course of illness, before the virus has had time to multiply beyond control, it has shown to be highly effective, especially when given in combination with the antibiotics azithromycin or doxycycline and the nutritional supplement zinc.
>
> On May 27, I published an article in the *American Journal of Epidemiology* (*AJE*) entitled, "Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients that Should be Ramped-Up Immediately as Key to the Pandemic Crisis." That article, published in the world's leading epidemiology journal, **analyzed five studies, demonstrating clear-cut** and **significant benefits to treated patients**, plus other very large studies that showed the medication safety [*emphasis added*]…
>
> Beyond these studies of individual patients, we have seen what happens in large populations when these drugs are used. These have been **'natural experiments'** [*emphasis added*]. In the northern Brazil state of Pará, COVID-19 deaths were increasing exponentially. On April 6, the public hospital network purchased 75,000 doses of azithromycin and 90,000 doses of hydroxychloroquine. Over the next few weeks, authorities began distributing these medications to infected individuals. Even though new cases continued to occur, on May 22 the death rate started to plummet and is now about one-eighth what it was at the peak.
>
> A reverse natural experiment happened in Switzerland. On May 27, the Swiss national government banned outpatient use of hydroxychloroquine for COVID-19. Around June 10, COVID-19 deaths increased four-fold and remained elevated. On June 11, the Swiss government revoked the ban, and on June 23 the death rate reverted to what it had been beforehand. People who die from COVID-19 live about three to five weeks from the start of symptoms, which makes the evidence of a causal relation in these experiments strong. Both episodes suggest that a combination of hydroxychloroquine and its companion medications reduces mortality and should be immediately adopted as the new standard of care in high-risk patients…
>
> In the future, I believe this misbegotten episode regarding hydroxychloroquine will be studied by sociologists of medicine as a **classic example of how extra-scientific factors overrode clear-cut medical evidence** [*emphasis added*]. But for now, reality demands a clear, scientific

eye on the evidence and where it points. For the sake of high-risk patients, for the sake of our parents and grandparents, for the sake of the unemployed, for our economy and for our polity, especially those disproportionally affected, we must start treating immediately."

[508] ***A systematic review on the efficacy and safety of chloroquine for the treatment of COVID-19***
Journal of Critical Care
Andrea Cortegiani, Giulia Ingoglia, *et al*.
June 2020
https://www.sciencedirect.com/science/article/pii/S0883944120303907?via%3Dihub

"**Introduction**: Chloroquine has been used worldwide for more than 70 years, and it is part of the World Health Organization (WHO) model list of essential medicines. It is also cheap and has an established clinical safety profile…

Conclusion: There is sufficient pre-clinical rationale and evidence regarding the effectiveness of chloroquine for treatment of COVID-19 as well as evidence of safety from long-time use in clinical practice for other indications to justify clinical research on the topic."

[509] ***Covid-19 Has Turned Public Health Into a Lethal, Patient-Killing Experimental Endeavor***
Alliance for Human Research Protection
June 20, 2020
https://ahrp.org/covid-19-has-turned-public-health-into-a-lethal-patient-killing-experimental-endeavor/

"On June 14th, Dr. Nass first identified two Covid-19 experiments in which **massive, high toxic doses** – four times higher than usual of hydroxychloroquine – **were being given to severely ill hospitalized patients in intensive care units** [*emphasis added*].

- Solidarity was being conducted by the World Health Organization, on 3500 Covid-19 patients at 400 hospitals, across 35 countries. The hydroxychloroquine arm of the trial was suspended May 25th following the fraudulent Surgisphere report in The Lancet that claimed 35% higher death rates in patients receiving Hydroxychloroquine. But when The Lancet retracted the report, the WHO resumed the Solidarity trial's hydroxychloroquine arm, on June 3rd. More than 100 countries expressed interest in participating in the trial.
- Recovery is a similar experimental trial conducted in the UK, using very similar doses. It was sponsored by the Wellcome Trust (GlaxoSmithKline) and the Bill and Melinda Gates Foundation and the UK government. The experiment was conducted at Oxford University, on 1,542 patients of these 396 patients (25.7%) died.

Update: After Dr. Nass' discovery was publicly disseminated, the WHO suspended the hydroxychloroquine arm of the trial [*Solidarity*] on Wednesday June 17th."

[510] ***Improving the efficacy of Chloroquine and Hydroxychloroquine against SARS-CoV-2 may require Zinc additives - A better synergy for future COVID-19 clinical trials***
Le Infezioni in Medicina
Mujeeb Olushola Shittu and Olufemi Ifeoluwa Afolami
June 1, 2020
https://www.infezmed.it/media/journal/Vol_28_2_2020_9.pdf

"**Conclusion**: Chloroquine can induce the uptake of zinc into the cytosol of the cell which is capable of inhibiting RNA-dependent RNA polymerase and ultimately halting the replication of coronavirus in the host cell. Currently, there are several clinical trials that are currently underway in several countries of the world to assess the efficacy of chloroquine as an anti-coronavirus agent. Since chloroquine has been widely prescribed for use as an anti-malarial, its safety is not in doubt. In view of the foregoing, clinical trials predicated upon a synergistic administration of Zn supplement with CQ or HCQ against the novel SARS-CoV-2 virus should be considered so that better COVID-19 clinical trial outcomes can be obtained going forward."

[511] **RETRACTED: *Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis***
The Lancet
Mandeep Mehra, Sapan S. Desai, Frank Ruschitzka, and Amit N. Patel
May 22, 2020
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext

"**Interpretation**: We were unable to confirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital survival and an increased frequency of ventricular arrhythmias when used for treatment of COVID-19."

[512] ***Does zinc supplementation enhance the clinical efficacy of chloroquine/hydroxychloroquine to win today's battle against COVID-19?***
Medical Hypotheses
R. Derwand and M. Scholz
May 6, 2020
https://www.sciencedirect.com/science/article/pii/S0306987720306435

"**Abstract**: Currently, drug repurposing is an alternative to novel drug development for the treatment of COVID-19 patients. The antimalarial drug chloroquine (CQ) and its metabolite hydroxychloroquine (HCQ) are currently being tested in several clinical studies as potential candidates to limit SARS-CoV-2-mediated morbidity and mortality. CQ and HCQ (CQ/HCQ) inhibit pH-dependent steps of SARS-CoV-2 replication by increasing pH in intracellular vesicles and interfere with virus particle delivery into host cells. Besides direct antiviral effects, **CQ/HCQ specifically target extracellular zinc to intracellular lysosomes where it interferes with RNA-dependent RNA polymerase activity and coronavirus replication** [*emphasis added*]. As zinc deficiency frequently occurs in elderly patients and in those with cardiovascular disease, chronic pulmonary disease, or diabetes, we hypothesize that CQ/HCQ plus zinc supplementation may be more effective in reducing COVID-19 morbidity and mortality than CQ or HCQ in monotherapy. Therefore, CQ/HCQ in combination with zinc should be considered as additional study arm for COVID-19 clinical trials."

[513] ***Early treatment of COVID-19 patients with hydroxychloroquine and azithromycin: A retrospective analysis of 1061 cases in Marseille, France***
Travel Medicine and Infectious Disease
Matthieu Million, Jean-Christophe Lagier, Didier Raoult, *et al*.
May 5, 2020
https://www.sciencedirect.com/science/article/abs/pii/S1477893920302179

"**Background**: In France, the combination hydroxychloroquine (HCQ) and azithromycin (AZ) is used in the treatment of COVID-19…

Results: A total of 1061 patients were included in this analysis (46.4% male, mean age 43.6 years – range 14–95 years). Good clinical outcome and virological cure were obtained in 973 patients within 10 days (91.7%). Prolonged viral carriage was observed in 47 patients (4.4%) and was associated to a higher viral load at diagnosis ($p < .001$) but viral culture was negative at day 10. All but one, were PCR-cleared at day 15. A poor clinical outcome (PClinO) was observed for 46 patients (4.3%) and 8 died (0.75%) (74–95 years old). All deaths resulted from respiratory failure and not from cardiac toxicity. Five patients are still hospitalized **(98.7% of patients cured so far)** [*emphasis added*]…

Conclusion: Administration of the HCQ+AZ combination before COVID-19 complications occur is safe and associated with a very low fatality rate in patients.

Introduction: … In a recent international survey conducted among at least 7500 physicians across 30 countries, most of the questioned physicians considered that HCQ and AZ are the two most effective treatments among available therapies for COVID-19."

[514] ***Clinical and microbiological effect of a combination of hydroxychloroquine and azithromycin in 80 COVID-19 patients with at least a six-day follow up: A pilot observational study***
Travel Medicine and Infectious Disease
Philippe Gautret, Jean-Christophe Lagier, *et al*.
April 11, 2020
https://www.sciencedirect.com/science/article/abs/pii/S1477893920301319

"**Methods**: We conducted an uncontrolled non-comparative observational study in a cohort of 80 relatively mildly infected inpatients treated with a combination of hydroxychloroquine and azithromycin over a period of at least three days, with three main measurements: clinical outcome, contagiousness as assessed by PCR and culture, and length of stay in infectious disease unit (IDU).

Results: **All patients improved clinically** except one 86 year-old patient who died, and one 74 year-old patient still in intensive care. A rapid fall of nasopharyngeal viral load was noted, with 83% negative at Day7, and 93% at Day8 [*emphasis added*]. Virus cultures from patient respiratory samples were negative in 97.5% of patients at Day5. Consequently patients were able to be rapidly discharged from IDU with a mean length of stay of five days…

Introduction: … According to an online survey conducted at the end of March, 33% of an international panel of physicians reported personally prescribing (or seeing colleagues prescribe) hydroxychloroquine (or chloroquine), and 41% reported the same for azithromycin (or similar antibiotics) to fight COVID-19. In addition, of those who have treated COVID-19 patients, **37% believe that hydroxychloroquine** (or chloroquine) **is the most effective**

therapy against the disease, and **32% believe the same for azithromycin** [*emphasis added*] (or similar antibiotics)."

[515] ***Largest Statistically Significant Study by 6,200 Multi-Country Physicians on COVID-19 Uncovers Treatment Patterns and Puts Pandemic in Context***
Sermo
April 2, 2020
https://www.sermo.com/press-releases/largest-statistically-significant-study-by-6200-multi-country-physicians-on-covid-19-uncovers-treatment-patterns-and-puts-pandemic-in-context/

"To create a centralized and dynamic knowledge base, Sermo, the largest healthcare data collection company and global social platform for physicians, leveraged its capabilities to publish results of a COVID-19 study with more than 6,200 physicians in 30 countries…

Treatments & Efficacy

- The three most commonly prescribed treatments amongst COVID-19 treaters are 56% analgesics, 41% Azithromycin, and 33% Hydroxychloroquine…
- **Hydroxychloroquine was overall chosen as the most effective therapy** amongst COVID-19 treaters from a list of 15 options (37% of COVID-19 treaters) [*emphasis added*]"

[516] ***Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial***
International Journal of Antimicrobial Agents
Philippe Gautret, Jean-Christophe Lagier, *et al*.
March 20, 2020
https://www.sciencedirect.com/science/article/abs/pii/S0924857920300996

"**Conclusion**: Despite its small sample size, our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin."

[517] ***In Vitro Antiviral Activity and Projection of Optimized Dosing Design of Hydroxychloroquine for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)***
Clinical Infectious Diseases
Xueting Yao, Fei Ye, *et al*.
March 9, 2020
https://academic.oup.com/cid/article/71/15/732/5801998

"**Background**: … Chloroquine has been sporadically used in treating SARS-CoV-2 infection. Hydroxychloroquine shares the same mechanism of action as chloroquine, but its more tolerable safety profile makes it the preferred drug to treat malaria and autoimmune conditions. We propose that the immunomodulatory effect of hydroxychloroquine also may be useful in controlling the cytokine storm that occurs late phase in critically ill patients with SARS-CoV-2…

Results: Hydroxychloroquine (EC50 = 0.72 μM) was found to be more potent than chloroquine (EC50 = 5.47 μM) in vitro."

[518] ***Chloroquine is a potent inhibitor of SARS coronavirus infection and spread***

Virology Journal
Martin J. Vincent, Eric Bergeron, *et al*.
August 22, 2005
https://virologyj.biomedcentral.com/articles/10.1186/1743-422X-2-69

> "**Background**: Severe acute respiratory syndrome (SARS) is caused by a newly discovered coronavirus (SARS-CoV). No effective prophylactic or post-exposure therapy is currently available.
>
> **Results**: We report, however, that chloroquine has strong antiviral effects on SARS-CoV infection of primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and therapeutic advantage…
>
> **Conclusion**: Chloroquine is effective in preventing the spread of SARS CoV in cell culture. Favorable inhibition of virus spread was observed when the cells were either treated with chloroquine prior to or after SARS CoV infection."

Budesonide

[519] ***Budesonide Works***
Presents "links to peer-reviewed studies, articles in medical journals, or news articles regarding the efficacy of budesonide."
https://budesonideworks.com/validation-2/

Note: The citations below are presented in reverse, chronological order.

[520] ***Antiviral Effect of Budesonide against SARS-CoV-2***
Multidisciplinary Digital Publishing Institute (MDPI)
Natalie Heinen, Toni Luise Meister, Mara Klöhn, Eike Steinmann, Daniel Todt, and Stephanie Pfaender
July 20, 2021
https://www.mdpi.com/1999-4915/13/7/1411/htm

> "**Discussion**: Recent observations by Ramakrishnan et al. suggest that the inhaled corticosteroid budesonide reduces clinical recovery times and prevents progression and clinical deterioration during mild COVID-19 infection… [W]e observed significant reduction of viral titers for all viral variants in vitro when cells were treated with 25 μM budesonide. These results are in accordance with previous studies that demonstrated the suppression of SARS-CoV-2 and MERS-CoV RNA copy number by targeting the viral replication–transcription complex."

[521] ***ProLung™-budesonide Inhibits SARS-CoV-2 Replication and Reduces Lung Inflammation***
bioRxiv
Kameswari S. Konduri, Ram Pattisapu, *et al*.
May 5, 2021
https://www.biorxiv.org/content/10.1101/2021.05.05.442779v1.full

"**Conclusions**: ProLung™-budesonide significantly inhibited viral replication in SARS-CoV-2 infected cells. It localized into type II pneumocytes, decreased lung inflammation, AHR and EPO activity with Mch challenge. This novel drug formulation may offer a potential inhalational treatment for COVID-19."

[522] ***Inhaled budesonide for COVID-19 in people at higher risk of adverse outcomes in the community: interim analyses from the PRINCIPLE trial***
PRINCIPLE Collaborative Group
Ly-Mee Yu, Mona Fafadhel, *et al*.
April 12, 2021
https://www.medrxiv.org/content/10.1101/2021.04.10.21254672v1.full-text

"**Methods**: We performed a multicenter, open-label, multi-arm, adaptive platform randomized controlled trial involving people aged ≥65 years, or ≥50 years with comorbidities, and unwell ≤ 14 days with suspected COVID-19 in the community (PRINCIPLE)…

Results: … Time to first self-reported recovery was shorter in the budesonide group compared to usual care (hazard ratio 1.208 [95% BCI 1.076 – 1.356], probability of superiority 0.999, estimated benefit [95% BCI] of 3.011 [1.134 – 5.41] days). Among those in the interim budesonide primary analysis who had the opportunity to contribute data for 28 days follow up, there were 59/692 (8.5%) COVID-19 related hospitalizations/deaths in the budesonide group vs 100/968 (10.3%) in the usual care group (estimated percentage benefit, 2.1% [95% BCI −0.7% – 4.8%], probability of superiority 0.928)."

[523] ***Inhaled budesonide in the treatment of early COVID-19 (STOIC): a phase 2, open-label, randomised controlled trial***
The Lancet
Sanjay Ramakrishnan, Dan V. Nicolau Jr., *et al*.
April 9, 2021
https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00160-0/fulltext

"**Interpretation**: Early administration of inhaled budesonide reduced the likelihood of needing urgent medical care and reduced time to recovery after early COVID-19 [*emphasis added*]…

Discussion: We have shown that the inhaled glucocorticoid budesonide, given for a short duration, might be an effective treatment of early COVID-19 in adults. This effect, with a relative reduction of 91% of clinical deterioration is equivalent to the efficacy seen after the use of COVID-19 vaccines and greater than that reported in any treatments used in hospitalised patients and patients with severe COVID-19."

Monoclonal Antibodies

Note: The citations below are presented in reverse, chronological order.

[524] **ADDED since 10/14/2021**
Potent neutralization of SARS-CoV-2 variants of concern by an antibody with an uncommon genetic signature and structural mode of spike recognition
Cell Reports (Vanderbilt University Medical Center)
Kevin J. Kramer, Nicole V. Johnson, *et al*.
October 5, 2021
https://www.cell.com/cell-reports/fulltext/S2211-1247(21)01243-2

> "**Summary**: … Here, we report a panel of SARS-CoV-2 antibodies isolated using the linking B cell receptor to antigen specificity through sequencing (LIBRA-seq) technology from an individual who recovered from COVID-19. Of these antibodies, 54042-4 shows **potent neutralization** against authentic SARS-CoV-2 viruses, including variants of concern (VOCs). A cryoelectron microscopy (cryo-EM) structure of 54042-4 in complex with the SARS-CoV-2 spike reveals an epitope composed of residues that are highly conserved in currently circulating SARS-CoV-2 lineages. Further, 54042-4 possesses uncommon genetic and structural characteristics that distinguish it from other potently neutralizing SARS-CoV-2 antibodies. Together, these findings provide motivation for the development of 54042-4 as a **lead candidate to counteract current** and **future SARS-CoV-2 VOCs** [*emphasis added*]."

[525] ***Monoclonal Antibodies vs. Vaccines vs. COVID-19: What to Know***
WebMD Health News
Donavyn Coffey
August 26, 2021
https://www.webmd.com/vaccines/covid-19-vaccine/news/20210826/monoclonal-antibodies-vs-vaccines-vs-covid-19

> "Clinical trials show that Regeneron's monoclonal antibody treatment, a combination of two antibodies called casirivimab and imdevimab, **reduces COVID-19-related hospitalization or deaths in high-risk patients by about 70%** [*emphasis added*]. And when given to an exposed person -- like someone living with an infected person -- monoclonal antibodies reduced their risk of developing an infection with symptoms by 80%."

[526] ***COVID-19 Treatment Guidelines - Anti-SARS-CoV-2 Monoclonal Antibodies***
National Institutes of Health (NIH)
Updated August 4, 2021
https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/

> "Monoclonal antibodies that target the spike protein have been shown to have a **clinical benefit in treating SARS-CoV-2 infection** [*emphasis added*] (as discussed below). Preliminary data suggest that monoclonal antibodies may play a role in preventing SARS-CoV-2 infection in household contacts of infected patients and during skilled nursing and assisted living facility outbreaks."

[527] ***Impact of Bamlanivimab Monoclonal Antibody Treatment on Hospitalization and Mortality Among Nonhospitalized Adults With Severe Acute Respiratory Syndrome Coronavirus 2 Infection***
Open Forum Infectious Diseases
J. Ryan Bariola, Erin K. McCreary, *et al*.
May 17, 2021
https://academic.oup.com/ofid/article/8/7/ofab254/6276906

"**Results**: … After adjustment for propensity to receive treatment, bamlanivimab treatment was associated with a significantly reduced risk-adjusted odds of hospitalization or mortality within 28 days (odds ratio [OR], 0.40; 95% confidence interval [95% CI], 0.24–0.69; P < .001). Bamlanivimab treatment was also associated with a significantly lower risk adjusted odds of hospitalization or emergency department visit without hospitalization (OR, 0.54; 95% CI, 0.35–0.82; P = .004). The results were most strongly associated with patients age 65 years and older.

Conclusions: Bamlanivimab monoclonal antibody monotherapy was associated with reduced hospitalizations and mortality within 28 days among outpatients with mild to moderate COVID-19.

Use of bamlanivimab monotherapy for outpatients with mild to moderate COVID-19 infection was associated with reductions in hospitalizations and mortality within 28 days. Benefit was strongest in those age 65 years or older."

[528] ***Cross-neutralization of SARS-CoV-2 by a human monoclonal SARS-CoV antibody***
Nature magazine
Dora Pinto, Young-Jun Park, *et al*.
May 18, 2020
https://www.nature.com/articles/s41586-020-2349-y

"**Abstract**: … The SARS-CoV-2 spike (S) glycoprotein promotes entry into host cells and is the main target of neutralizing antibodies. Here we describe **several monoclonal antibodies that target the S glycoprotein of SARS-CoV-2**, which we identified from memory B cells of an individual who was infected with severe acute respiratory syndrome coronavirus (SARS-CoV) in 2003. One antibody (named S309) potently neutralizes SARS-CoV-2 and SARS-CoV pseudoviruses as well as authentic SARS-CoV-2, by engaging the receptor-binding domain of the S glycoprotein. Using cryo-electron microscopy and binding assays, we show that S309 recognizes an epitope containing a glycan that is conserved within the Sarbecovirus subgenus, without competing with receptor attachment. Antibody cocktails that include S309 in combination with other antibodies that we identified further enhanced SARS-CoV-2 neutralization, and may limit the emergence of neutralization-escape mutants. **These results pave the way for using S309 and antibody cocktails containing S309 for prophylaxis in individuals at a high risk of exposure** or as a post-exposure therapy to limit or treat severe disease [*emphasis added*]."

[529] ***Effective treatment of severe COVID-19 patients with tocilizumab***
Proceedings of the National Academy of Sciences (PNAS)
Xiaoling Xu, Mingfeng Han, *et al*.
April 29, 2020
https://www.pnas.org/content/117/20/10970

"**Significance**: In patients with coronavirus disease 2019, a large number of T lymphocytes and mononuclear macrophages are activated, producing cytokines such as interleukin-6 (IL-6), which bind to the IL-6 receptor on the target cells, causing the cytokine storm and severe inflammatory responses in lungs and other tissues and organs. Tocilizumab, as a recombinant humanized anti-human IL-6 receptor monoclonal antibody, can bind to the IL-6 receptor with high affinity, thus preventing IL-6 itself from binding to its receptor, rendering it incapable of immune damage to target cells, and alleviating the inflammatory responses."

Other Prophylactics and Treatments

Note: The citations below are presented in reverse, chronological order.

[530] **ADDED since 10/14/2021**
Effect of early treatment with fluvoxamine on risk of emergency care and hospitalisation among patients with COVID-19: the TOGETHER randomised, platform clinical trial
The Lancet Global Health
Gilmar Reis, Eduardo Augosto dos Santos Moreira-Silva, *et al*.
October 27, 2021
https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00448-4/fulltext

"**Findings**: … 741 patients were allocated to fluvoxamine and 756 to placebo…

Interpretation: Treatment with fluvoxamine (100 mg twice daily for 10 days) among high-risk outpatients with early diagnosed COVID-19 reduced the need for hospitalisation defined as retention in a COVID-19 emergency setting or transfer to a tertiary hospital…

Discussion: This is, to the best of our knowledge, the first large, randomised controlled trial to test the efficacy of fluvoxamine for acute treatment of COVID-19. We found a clinically important absolute risk reduction of 5.0%, and 32% RR [*relative risk*] reduction, on the primary outcome of hospitalisation defined as either retention in a COVID-19 emergency setting or transfer to tertiary hospital due to COVID-19, consequent on the administration of fluvoxamine for 10 days."

[531] **ADDED since 10/14/2021**
Potential Clinical Benefits of Quercetin in the Early Stage of COVID-19: Results of a Second, Pilot, Randomized, Controlled and Open-Label Clinical Trial
International Journal of General Medicine
Francesco Di Pierro, Somia Iqtadar, *et al*.
June 24, 2021
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8238537/

"**Background**: … Based on the potential antiviral role of quercetin, and on its described anti-blood clotting, anti-inflammatory and antioxidant properties, we hypothesize that subjects with mild COVID-19 treated with Quercetin Phytosome® (QP), a novel bioavailable form of quercetin, may have a shorter time to virus clearance, a milder symptomatology, and higher probabilities of a benign earlier resolution of the disease…

Discussion: … Quercetin is a natural substance that has multiple pharmacological properties, such as anti-inflammatory action, and is worldwide used as a dietary supplement. There is

some recent evidence of the anti-coronavirus activities of this compound, including against SARS-CoV-2 main proteases and S-protein. Its assumed ability to inhibit coronavirus and its well-described anti-inflammatory role make quercetin a possible new candidate for outpatients' treatment of COVID-19. We have therefore tested as adjuvant supplementation an orally bioavailable form of quercetin in a pilot, randomized, controlled and open-label clinical study in which we have enrolled 42 ambulatory COVID-19 patients. Our results demonstrated the beneficial role played by QP [*Quercetin Phytosome*] after only 1 week of add-on therapy. In particular, the use of QP at the dose of 1500 mg/day for 1 week followed using 1000 mg/day for another week (corresponding to 600 and 400 mg of quercetin per day, respectively), was demonstrated to significantly: 1) **increase the clearance of the virus**, 2) **reduce the symptoms occurrence**, 3) improve disease biomarkers [*emphasis added*]."

[532] **ADDED since 10/14/2021**

Possible Therapeutic Effects of Adjuvant Quercetin Supplementation Against Early-Stage COVID-19 Infection: A Prospective, Randomized, Controlled, and Open-Label Study

International Journal of General Medicine
Francesco Di Pierro, Giurseppe Derosa, *et al*.
June 24, 2021
https://pubmed.ncbi.nlm.nih.gov/34135619/

"**Background**: Quercetin, a well-known naturally occurring polyphenol, has recently been shown by molecular docking, in vitro and in vivo studies to be a possible anti-COVID-19 candidate. Quercetin has strong antioxidant, anti-inflammatory, immunomodulatory, and antiviral properties, and it is characterized by a very high safety profile…

Methods: In the present prospective, randomized, controlled, and open-label study, a daily dose of 1000 mg of QP was investigated for 30 days in 152 COVID-19 outpatients to disclose its adjuvant effect in treating the early symptoms and in preventing the severe outcomes of the disease.

Results: The results revealed **a reduction in frequency and length of hospitalization**, in need of non-invasive oxygen therapy, in progression to intensive care units and in **number of deaths** [*emphasis added*]. The results also confirmed the very high safety profile of quercetin and suggested possible anti-fatigue and pro-appetite properties."

[533] **ADDED since 10/14/2021**

Cannabidiol Inhibits SARS-CoV-2 Replication and Promotes the Host Innate Immune Response

University of Chicago
Long Chi Nguyen, Dongbo Yang, *et al*.
March 10, 2021
https://www.biorxiv.org/content/10.1101/2021.03.10.432967v1.full

"**Abstract**: The rapid spread of COVID-19 underscores the need for new treatments. Here we report that cannabidiol (CBD), a compound produced by the cannabis plant, inhibits SARS-CoV-2 infection. **CBD and its metabolite**, 7-OH-CBD, but not congeneric cannabinoids, **potently block SARS-CoV-2 replication in lung epithelial cells**. CBD acts after cellular infection, inhibiting viral gene expression and reversing many effects of SARS-CoV-2 on host gene transcription [*emphasis added*]. CBD induces interferon expression and up-regulates its antiviral signaling pathway. A cohort of human patients previously taking CBD had significantly

lower SARS-CoV-2 infection incidence of up to an order of magnitude relative to matched pairs or the general population. This study highlights CBD, and its active metabolite, 7-OH-CBD, as potential preventative agents and therapeutic treatments for SARS-CoV-2 at early stages of infection."

[534] ***Differential Effects of Antiseptic Mouth Rinses on SARS-CoV-2 Infectivity In Vitro Pathogens***
Chuan Xu, Annie Wang, *et al*.
March 1, 2021
https://www.mdpi.com/2076-0817/10/3/272

"**Abstract**: … [W]e determined the effect of commercially available mouth rinses and antiseptic povidone-iodine on the infectivity of replication-competent SARS-CoV-2 viruses and of pseudotyped SARS-CoV-2 viruses. We first determined the effect of mouth rinses on cell viability to ensure that antiviral activity was not a consequence of mouth rinse-induced cytotoxicity. Colgate Peroxyl (hydrogen peroxide) exhibited the most cytotoxicity, followed by povidone-iodine, chlorhexidine gluconate (CHG), and Listerine (essential oils and alcohol)… Mouth rinses inactivated the virus without prolonged incubation. The new infectivity assay, with limited impacts of mouth rinse-associated cytotoxicity, showed the differential effects of mouth rinses on SARS-CoV-2 infection. Our results indicate that mouth rinses can significantly reduce virus infectivity, suggesting a potential benefit for reducing SARS-CoV-2 spread."

[535] ***Heparin Inhibits Cellular Invasion by SARS-CoV-2: Structural Dependence of the Interaction of the Spike S1 Receptor-Binding Domain with Heparin***
Thrombosis and Haemostasis
Courtney J. Mycroft-West, Dunhao Su, *et al*.
December 23, 2020
https://www.thieme-connect.de/products/ejournals/html/10.1055/s-0040-1721319

"**Abstract**: … Exogenous heparin prevents infection by a range of viruses, including S-associated coronavirus isolate HSR1. Here, we show that heparin inhibits severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) invasion of Vero cells by up to 80% at doses achievable through prophylaxis and, particularly relevant, within the range deliverable by nebulisation. Surface plasmon resonance and circular dichroism spectroscopy demonstrate that heparin and enoxaparin, a low-molecular-weight heparin which is a clinical anticoagulant, bind and induce a conformational change in the spike (S1) protein receptor-binding domain (S1 RBD) of SARS-CoV-2… The results suggest a route for the rapid development of a first-line therapeutic by repurposing heparin and its derivatives as antiviral agents against SARS-CoV-2 and other members of the Coronaviridae."

[536] ***N-Acetylcysteine to Combat COVID-19: An Evidence Review***
Therapeutics and Clinical Risk Management
Zhongcheng Shi and Carlos A Puyo
November 2, 2020
https://www.dovepress.com/n-acetylcysteine-to-combat-covid-19-an-evidence-review-peer-reviewed-fulltext-article-TCRM

"**Abstract**: … N-acetylcysteine (NAC) has been used in clinical practice to treat critically ill septic patients, and more recently for COVID-19 patients. NAC has antioxidant, anti-inflammatory and immune-modulating characteristics that may prove beneficial in the treatment and prevention of SARS-Cov-2. This review offers a thorough analysis of NAC and discusses its potential use for treatment of COVID-19."

[537] ***In Vitro Antiviral Activity of Doxycycline against SARS-CoV-2***
Molecules
Mathieu Gendrot, Julien Andreani, *et al*.
October 31, 2020
https://www.mdpi.com/1420-3049/25/21/5064/htm

"**Abstract**: … Doxycycline, which is a second-generation tetracycline with broad-spectrum antimicrobial, antimalarial and anti-inflammatory activities, showed in vitro activity on Vero E6 cells infected with a clinically isolated SARS-CoV-2 strain (IHUMI-3) with median effective concentration (EC50) of 4.5 ± 2.9 µM, compatible with oral uptake and intravenous administrations. Doxycycline interacted both on SARS-CoV-2 entry and in replication after virus entry. Besides its in vitro antiviral activity against SARS-CoV-2, doxycycline has anti-inflammatory effects by decreasing the expression of various pro-inflammatory cytokines and could prevent co-infections and superinfections due to broad-spectrum antimicrobial activity. Therefore, doxycycline could be a potential partner of COVID-19 therapies."

[538] ***Lysine Therapy for SARS-CoV-2***
Bio-Virus Research
Christopher Kagan, Alexander Chaihorsky, Rony Tal, and Bo Karlicki
September 2020
https://www.researchgate.net/publication/344210822_Lysine_Therapy_for_SARS-CoV-2

"[O]ur group, Bio-Virus Research, has been working on both universal vaccines and universal therapeutic approaches for decades. In this letter we report our current results using L- lysine therapeutically against SARS-CoV-2…

Approximately 80% of acute stage Covid-19 sufferers given lysine displayed a **minimum 70% reduction in symptoms in the first 48 hours** (not including long term symptomatic subjects) [*emphasis added*]. Excluding long term subjects, treatment times vary from 2 days to 3.5 weeks, with many variables at play. Patients who started lysine in the hospital were discharged an average of 3 days after starting treatment…

One of the most important observations in relation to lysine was the incredibly short time to eliminate/reduce fever presumably due to extinguishing the associated cytokine storm. Cytokine storm appears to be extinguished in hours, based on the 5 inpatients who appeared to be in severe crisis when lysine was administered who showed very rapid reduction in symptoms and stabilization… These clinical results suggest that lysine appears highly suppressive of viral replication, and if these results are confirmed by further studies, lysine should significantly flatten the curve, reduce mortality and hospital bed utilization while we await a curative vaccine or vaccines, ideally one with universal application across the entire Coronavirus group."

[539] ***Mitigation of the replication of SARS-CoV-2 by nitric oxide in vitro***
Redox Biology
Dario Akaberi, Janina Krambrich, *et al*.
September 21, 2020
https://www.sciencedirect.com/science/article/pii/S2213231720309393

> "**Conclusions**: In this study, we demonstrated that NO can inhibit the replication of SARS-CoV-2 in Vero E6 and we identified the SARS-CoV-2 main protease as a target for NO. There is a great need for effective antivirals against SARS-CoV-2 to be used in the on-going COVID-19 pandemic. Based on this study and previous studies on SARS-CoV in vitro, and in a small clinical trial, we conclude that NO may be applied for clinical use in the treatment of COVID-19 and other human coronavirus infections."

[540] ***Anakinra for severe forms of COVID-19: a cohort study***
The Lancet
Thomas Huet, Helene Beaussier, *et al*.
May 29, 2020
https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30164-8/fulltext

> "**Background**: … It has been postulated that anakinra, a recombinant IL-1 receptor antagonist, might help to neutralise the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-related hyperinflammatory state, which is considered to be one cause of acute respiratory distress among patients with COVID-19. We aimed to assess the off-label use of anakinra in patients who were admitted to hospital for severe forms of COVID-19 with symptoms indicative of worsening respiratory function…
>
> **Interpretation**: Anakinra reduced both need for invasive mechanical ventilation in the ICU and mortality among patients with severe forms of COVID-19, without serious side-effects. Confirmation of efficacy will require controlled trials."

[541] ***Triple combination of interferon beta-1b, lopinavir–ritonavir, and ribavirin in the treatment of patients admitted to hospital with COVID-19: an open-label, randomised, phase 2 trial***
The Lancet
Ivan Fan-Ngai Hung, Kwok-Cheung Lung, *et al*.
May 8, 2020
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31042-4/fulltext

> "**Added value of this study**: … Treatment with the triple combination effectively suppressed viral load in all clinical specimens, including the nasopharyngeal swab, throat saliva, posterior oropharyngeal saliva, and stool in most patients 8 days from treatment commencement, which was significantly shorter than the time taken in the control group, treated with lopinavir–ritonavir alone. The triple combination also alleviated symptoms completely within 4 days—a significantly shorter time than the control. The triple combination also suppressed IL-6 levels. The clinical and virological efficacy resulted in shorter hospital stays and facilitated infection control. This treatment regimen was also shown to be safe."

[542] ***Transplantation of ACE2- Mesenchymal Stem Cells Improves the Outcome of Patients with COVID-19 Pneumonia***
Aging and Disease
Zikuan Leng, Rongjia Zhu, *et al*.
April 2020
http://www.aginganddisease.org/EN/10.14336/AD.2020.0228

> "**Abstract**: A coronavirus (HCoV-19) has caused the novel coronavirus disease (COVID-19) outbreak in Wuhan, China. Preventing and reversing the cytokine storm may be the key to save the patients with severe COVID-19 pneumonia. Mesenchymal stem cells (MSCs) have been shown to possess a comprehensive powerful immunomodulatory function. This study aims to investigate whether MSC transplantation improves the outcome… [T]he intravenous transplantation of MSCs was safe and effective for treatment in patients with COVID-19 pneumonia, especially for the patients in critically severe condition."

[543] **Letter: *A retrospective cohort study of methylprednisolone therapy in severe patients with COVID-19 pneumonia***
Signal Transduction and Targeted Therapy (Nature)
Yin Wang, Weiwei Jiang, *et al*.
April 28, 2020
https://www.nature.com/articles/s41392-020-0158-2

> "Aggravation of symptoms always occurs during 5–7 days after onset in patients with COVID-19 pneumonia and severe cases develop rapidly to acute respiratory failure. Therefore, it is important to strengthen the treatment to suppress the pro-inflammatory response and control the cytokine storm at this stage. Methylprednisolone are the classical immunosuppressive drugs, which are important to stop or delay the progress of the pneumonia, and have been proved to be effective for the treatment of acute respiratory distress syndrome (ARDS) [*acute respiratory distress syndrome*]…
>
> In conclusion, early, low-dose and short-term application of methylprednisolone was associated with better clinical outcomes in severe patients with COVID-19 pneumonia, and should be considered before the occurrence of ARDS."

[544] ***SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor***
Cell
Markus Hoffmann, Hanna Kleine-Weber, *et al*.
March 5, 2020
https://www.cell.com/cell/fulltext/S0092-8674(20)30229-4

"**Summary**: … Cell entry of coronaviruses depends on binding of the viral spike (S) proteins to cellular receptors and on S protein priming by host cell proteases. Unravelling which cellular factors are used by SARS-CoV-2 for entry might provide insights into viral transmission and reveal therapeutic targets. Here, we demonstrate that SARS-CoV-2 uses the SARS-CoV receptor ACE2 for entry and the serine protease TMPRSS2 for S protein priming. A TMPRSS2 inhibitor approved for clinical use blocked entry and might constitute a treatment option. Finally, we show that the sera from convalescent SARS patients cross-neutralized SARS-2-S-driven entry. Our results reveal important commonalities between SARS-CoV-2 and SARS-CoV infection and identify a potential target for antiviral intervention."

Treatment Protocols for COVID-19

[545] ***Treatment Protocols***
C19Protocols
August 22, 2021
https://c19protocols.com/

[546] ***Prevention and Treatment Protocols for COVID-19***
Front Line COVID-19 Critical Care (FLCCC) Alliance
https://covid19criticalcare.com/covid-19-protocols/

[547] ***The Zelenko Protocol***
https://faculty.utrgv.edu/eleftherios.gkioulekas/zelenko/index.html

[548] ***The Fleming Method***
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_cfd91d7e664b4e479b56652cbf246145.pdf

[549] ***MATH+ protocol for the treatment of SARS-CoV-2 infection: the scientific rationale***
Expert Review of Anti-infective Therapy
Paul E. Marik, Pierre Kory, Joseph Varon, Jose Iglesias, and G. Umberto Meduri
August 18, 2020
https://www.tandfonline.com/doi/full/10.1080/14787210.2020.1808462

"**Conclusions**: COVID-19 disease progresses through a number of phases, each with a unique treatment approach. There is no 'silver bullet' to cure COVID-19. The pulmonary phase of COVID-19 is a treatable disease; it is inappropriate to limit therapy to 'supportive care' alone. The MATH + protocol consists of multiple drugs that have synergistic and overlapping biological effects that are safe, cheap, and readily available and are likely to significantly reduce the morbidly and mortality of this disease. It is likely that the MATH + protocol will be refined and evolve over time as new therapeutic agents are demonstrated to improve the outcome of this devastating disease."

Note: The citations below are presented in reverse, chronological order.

[550] **ADDED since 10/14/2021**
Physicians Declaration II
International Alliance of Physicians and Medical Scientists (Global Covid Summit)
October 29, 2021
https://doctorsandscientistsdeclaration.org/

For excerpts, see [368].

[551] **Video (6m): *Doctor Cites Early Treatment as Reason for Success with 6,000 Covid Patients***
Global Covid Summit
Interview with Dr. Brian Tyson of Dr. George Fareed Family Medicine
September 24, 2021
https://globalcovidsummit.org/news/doctor-cites-early-treatment-success-with-6000-covid-patients

"**Interviewer**: Dr. Tyson … you have treated how many people for COVID?

Tyson: Over 6,000… and face-to-face, not over telemedicine…

Tyson: … With early treatment between Day 1 and 7, I have not lost a single patient. Over 7 days, I've lost four.

Tyson: This is not a one-drug issue. There's no silver bullet. There is a multitude of drugs that we use, including steroids, aspirin, you name it; antivirals, antibiotics, anti-inflammatories that is in our arsenal. We put together an early-treatment protocol with Dr. Peter McCullough that was published, and it gives you a stepwise approach on how to treat these patients early. And if you follow that protocol, you're going to have a high success rate."

[552] ***Early multidrug treatment of SARS-CoV-2 infection (COVID-19) and reduced mortality among nursing home (or outpatient/ambulatory) residents***
Medical Hypotheses
Paul E. Alexander, Robin Armstrong, *et al*.
June 5, 2021
https://www.sciencedirect.com/science/article/abs/pii/S0306987721001419

"**Abstract**: … [W]e conclude that early empiric treatment for the elderly with COVID-19 in the nursing home setting (or similar congregated settings with elderly residents/patients e.g. LTF or ALF) has a reasonable probability of success and acceptable safety. This group remains our highest at-risk group and warrants acute treatment focus prior to symptoms worsening. Given the rapidity and severity of SARS-CoV-2 outbreaks in nursing homes, in-center treatment of acute COVID-19 patients is a reasonable strategy to reduce the risks of hospitalization and death. If elderly high-risk patients in such congregated nursing home type settings are allowed to worsen with no early treatment, they may be too sick and fragile to benefit from in-hospital therapeutics and are at risk for pulmonary failure, life-ending micro-thrombi of the lungs, kidneys etc…

We therefore hypothesize that early outpatient ambulatory treatment, once initiated as soon as symptoms begin in high-risk positive persons, would significantly reduce hospitalizations and prevent deaths. Specifically, the provision of early multi-drug sequenced therapy with repurposed drugs will reduce hospitalization and death in elderly patients being cared for in long-term-care facilities."

[553] ***COVID-19: Restoring Public Trust During A Global Health Crisis: An Evidence-Based Position Paper to Ensure Ethical Conduct***
GreenMedInfo
Henry L. Ealy, Michael E. McEvoy, John Nowicki, Monica Sava, and Neil M. Ruggles
March 23, 2021
https://cdn.greenmedinfo.com/sites/default/files/cdn/Position_Paper_v24_FINAL.pdf

"During our investigation into the variety of topics this manuscript covers, a theme began to stand out as a consistent concern. Safe and effective treatments for COVID-19 are inexplicably being withheld.

As you read this position paper, you will encounter many similar examples of what appears to be willful misconduct on the part of government agencies supplying inaccurate information to elected officials and the public at large.

While incessant arguments persist regarding the accuracy of polymerase chain reaction (PCR) testing, asymptomatic transmission, dubious projection models, and alleged violations of federal law, the issue that is still inexplicably unresolved is the withholding of safe and effective treatments from millions of people most in need…

We ask, "Is it ethical to withhold evidence-based treatments, proven to be safe and effective, from people in need?" Historically, this question has been answered with a resounding "no." Yet this is where we find ourselves again: once again, more embroiled in an age-old struggle to an ethical question we have already repeatedly answered correctly. **A common ground we must all be able to reach is that it is unethical to withhold evidence-based treatments proven to be safe and effective from people in need**.

The Intention of Our Positon Paper

The intention of our position paper is to honor our departed and everyone who has sacrificed so much so that we all might live free. In our opinion, discriminate censorship of genuine attempts to help this crisis is a major problem, as has been the repeated suppression of effective treatments for COVID-19…

Detailed empirical evidence matters. This position paper is our effort to provide that detailed empirical evidence for your consideration. Difficult conversations remain, and difficult conversations require the most accurate information available."

[554] ***FMTVDM Quantitative Nuclear Imaging finds Three Treatments for SARS-CoV-2***
Biomedical Journal of Scientific & Technical Research
Richard M. Fleming and Matthew R. Fleming
February 8, 2021
https://biomedres.us/fulltexts/BJSTR.MS.ID.005443.php

"**Introduction**: This investigation studied 10 different treatments and 52 treatment combinations to determine if there is an effective treatment regimen for SARS-CoV-2…

Methods: 1800 people testing positive for SARS-CoV-2 from 23 sites in 7 countries were studied including outpatient and inpatient care and treatment…

Results: Of the 1800 patients seeking medical care, 847 received no outpatient treatment with 59.5 % recovering and 40.5 % requiring hospitalization. Of the 953 treated with an aminoquinoline in the outpatient setting, 16.6 % required further treatment and hospitalization… During Phase II of the study patients receiving combination treatments consisting of one of three regimens focusing on treating the immune ITR to SARS-CoV-2 responded 99.83 % of the time. These three ITR regimens consisted of

1. Tocilizumab & Interferon a-2b

2. Primaquine, Clindamycin, Tocilizumab & Interferon a-2b, and

3. Methylprednisolone.

Conclusion: The answer to the question is, Yes. The treatment of SARS-CoV-2, like HIV, requires a multi-drug treatment regimen focusing on the immune ITR to SARSCoV- 2…

These three regimens were effective 99.83 % of the time and shortened hospital stays from 40 ± 3 days to 1-2 weeks [*emphasis added*]."

[555] ***A Guide to Home-Based Treatment: Step-by-Step Doctors' Plan That Could Save Your Life***
Association of American Physicians and Surgeons
Edited by Jane Orient, Peter A. McCullough, Elizabeth Lee Vliet, and Jeremy Snavely
Updated February 1, 2021
https://faculty.utrgv.edu/eleftherios.gkioulekas/zelenko/aaps-Guide-to-Home-Based-Covid-Treatment.pdf

"**Introduction**: We provide a step-by-step guide to medically sound early treatments that have a reasonable probability of success in this emergency pandemic There are oral medications that are approved for other conditions, but not yet proven to be efficacious specifically for COVID-19 by the U.S. Food and Drug Administration. In the global pandemic emergency, large scale randomized clinical trials have not been feasible in the face of such critical illness…

There are four major pillars to infectious disease pandemic response:

1) Contagion control (stop the spread of the virus)

2) Early ambulatory, home-based treatment

3) Late-stage treatment in hospital

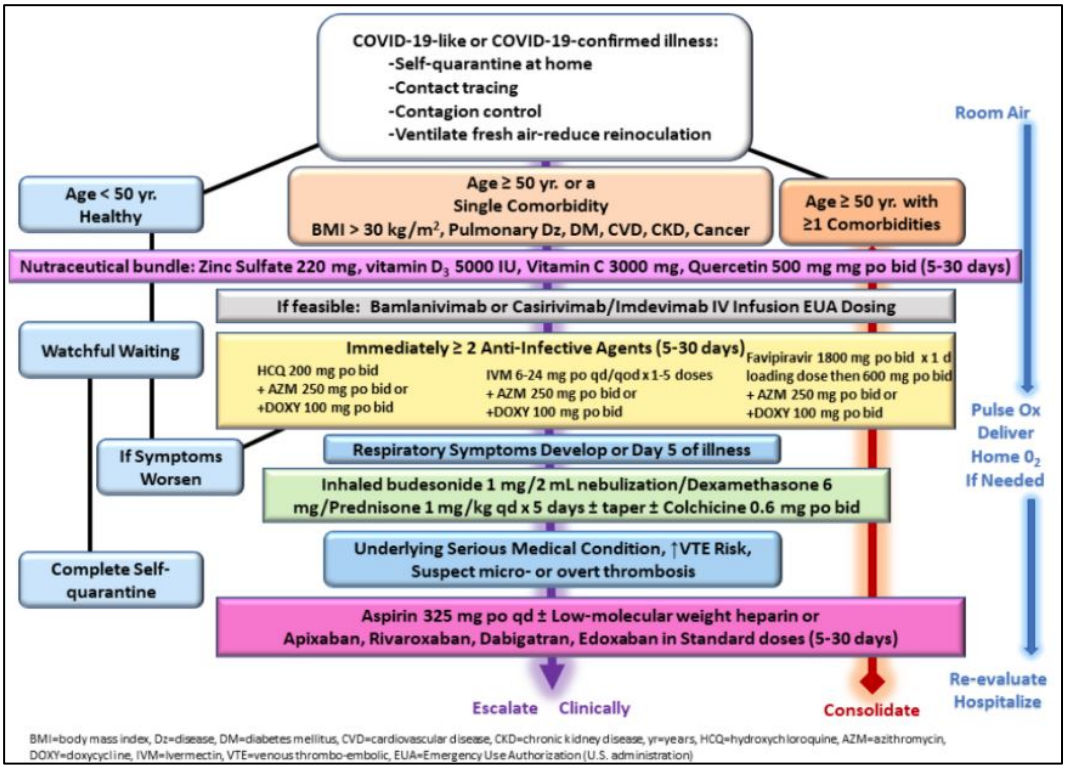
4) Vaccination

This guide will focus on the pillar of early, ambulatory, home-based medical treatment overseen by your physician, using a combination of available medicines, already FDA-approved for other medical conditions, and widely used in clinical medicine every day."

[556] ***Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19)***
Reviews in Cardiovascular Medicine
Peter A. McCullough, Paul E. Alexander, *et al*.
December 30, 2020
Note: A collaborative effort by 61 medical professionals and scientists, this article identifies existing treatment protocols for COVID-19, relevant studies with supporting evidence for the efficacy of protocol components (i.e., pharmaceuticals and supplements), and the therapeutic principles that should guide protocol development.
https://www.researchgate.net/publication/348357893_Multifaceted_highly_targeted_sequential_multidrug_treatment_of_early_ambulatory_high-risk_SARS-CoV-2_infection_COVID-19

"**Abstract and Figures**: … In countries where therapeutic nihilism is prevalent, patients endure escalating symptoms and without early treatment can succumb to delayed in-hospital care and death. Prompt early initiation of sequenced multidrug therapy (SMDT) is a widely and currently available solution to stem the tide of hospitalizations and death. A multipronged therapeutic approach includes 1) adjuvant nutraceuticals, 2) combination intracellular anti-infective therapy, 3) inhaled/oral corticosteroids, 4) antiplatelet agents/anticoagulants, 5) supportive care including supplemental oxygen, monitoring, and telemedicine… **An urgent immediate pivot from single drug to SMDT regimens should be employed** as a critical strategy to deal with the large numbers of acute COVID-19 patients [*emphasis added*] with the aim of reducing the intensity and duration of symptoms and avoiding hospitalization and death…

Fig. 3. Sequential multidrug treatment algorithm for ambulatory acute COVID-19 like and confirmed COVID-19 illness in patients in self-quarantine. Yr = year, BMI = body mass index, Dz = disease, DM = diabetes mellitus, CVD = cardiovascular disease, chronic kidney disease, HCQ =hydroxychloroquine, IVM = ivermectin, Mgt = management, Ox = oximetry, reproduced with permission from reference.



Introduction: Additionally, when feasible, prophylaxis could be viewed as an additional pillar since it works to reduce the spread as well as incidence of acute illness…

Our observations suggest a majority of hospitalizations could be avoided with a first treat-at-home strategy with appropriate telemedicine monitoring and access to oxygen and therapeutics…

In the absence of evidence from or a commitment to clinical trials of early therapy, other scientific information on the pathophysiology, treated natural history, and clinical judgement together must guide contemporary ambulatory management of COVID-19 (McCullough et al., 2020b). Observational studies reporting outcomes in patient populations managed consistently with empirically derived early intervention regimens currently provide an acceptable level of evidence for safety and efficacy of these widely available, inexpensive and safe alternatives to the current standard of non-intervention (Khan et al., 2020)…

Summary: … Precious time is squandered with a "wait and see" approach in which there is no anti-viral treatment as the condition worsens, possibly resulting in unnecessary hospitalization, morbidity, and death. Once infected, the only means of preventing a hospitalization in a high-risk patient is to apply treatment before arrival of symptoms that prompt paramedic calls or emergency room visits. Given the current failure of government support for randomized clinical trials evaluating widely available, generic, inexpensive therapeutics, and the lack of instructive outpatient treatment guidelines (U.S., Canada, U.K., Western EU, Australia, some South American Countries), clinicians must act according to clinical judgement and in shared decision making with fully informed patients. Early SMDT developed empirically based upon pathophysiology and evidence from randomized data and the treated natural history of COVID-19 has demonstrated safety and efficacy. In newly diagnosed, high-risk, symptomatic patients with COVID-19, SMDT has a reasonable chance of therapeutic gain with an acceptable benefit-to-risk profile."

[557] ***Clinical and Scientific Rationale for the "MATH+" Hospital Treatment Protocol for COVID-19***
Journal of Intensive Care Medicine
Pierre Kory, G. Umberto Meduri, Jose Iglesias, Joseph Varon, and Paul E. Marik
December 15, 2020
https://journals.sagepub.com/doi/10.1177/0885066620973585

"**Abstract**: In December 2019, COVID-19, a severe respiratory illness caused by the new coronavirus SARS-CoV-2 (COVID-19) emerged in Wuhan, China. The greatest impact that COVID-19 had was on intensive care units (ICUs), given that approximately 20% of hospitalized cases developed acute respiratory failure (ARF) requiring ICU admission. Based on the assumption that COVID-19 represented a viral pneumonia and no anti-coronaviral therapy existed, nearly all national and international health care societies' recommended "supportive care only" avoiding other therapies outside of randomized controlled trials, with a specific prohibition against the use of corticosteroids in treatment. However, early studies of COVID-19-associated ARF reported inexplicably high mortality rates, with frequent prolonged durations of mechanical ventilation (MV), even from centers expert in such supportive care strategies. These reports led the authors to form a clinical expert panel called the Front-Line COVID-19 Critical Care Alliance (www.flccc.net). The panel collaboratively reviewed the emerging clinical, radiographic, and pathological reports of COVID-19 while initiating multiple discussions among a wide clinical network of front-line clinical ICU experts from initial outbreak areas in China, Italy, and New York. Based on the shared early impressions of "what was working and what wasn't working," the increasing medical journal publications and the rapidly accumulating personal clinical experiences with COVID-19 patients, a treatment protocol was created for the hospitalized patients based on the core therapies of methylprednisolone, ascorbic acid, thiamine, heparin and co-interventions (MATH+). This manuscript reviews the scientific and clinical rationale behind MATH+ based on published in-vitro, pre-clinical, and clinical data in support of each medicine, with a special emphasis of studies supporting their use in the treatment of patients with viral syndromes and COVID-19 specifically. The review concludes with a comparison of published multi-national mortality data with MATH+ center outcomes."

Miscellaneous

Origin of COVID-19

[558] ***COVID-19, SARS and Bats Coronaviruses Genomes Peculiar Homologous RNA Sequences***
International Journal of Research
Jean Claude Perez and Luc Montagnier
July 30, 2020
https://www.granthaalayahpublication.org/journals/index.php/granthaalayah/article/view/IJRG20_B07_3568/691

"**Abstract**: … This article shows how 16 fragments (Env Pol and Integrase genes) from different strains, both diversified and very recent, of the HIV1, HIV2 and SIV retroviruses have high percentage of homology into parts of the genome of COVID_19. Moreover each of these elements is made of 18 or more nucleotides and therefore may have a function. They are called Exogenous Informative Elements (EIE)…

Here are the two main facts which contribute to **our hypothesis of a partially synthetic genome**: … [*emphasis added*]

In the comparative analysis of both SPIKES genes of COVID_19 and Bat RaTG13 we note two abnormal facts:

1) the insertion of 4 contiguous PRRA amino acids in the middle of SPIKE (we show that this site was already an optimal cleavage site BEFORE this insertion).

2) an abnormal distribution of synonymous codons in the second half of SPIKE.

Finally we show the insertion in this 1770 bases SPIKE region of a significant pair of EIEs from Plasmodium Yoelii and of apossible HIV1 EIE with a crucial Spike mutation."

[559] ***The Evidence which Suggests that This Is No Naturally Evolved Virus - A Reconstructed Historical Aetiology of the SARS-CoV-2 Spike***
University of London
Birger Sørensen, Angus Dalgleish, and Andres Susrud
July 1, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_31f83ded084b4b01a97963630dc2ae1d.pdf

"**Abstract**: To discover exactly how to attack SARS-CoV-2 safely and efficiently, our vaccine candidate Biovacc-19 was designed by first carefully analysing the biochemistry of the Spike. We ascertained that it is highly unusual in several respects, unlike any other CoV in its clade. The SARS-CoV-2 general mode of action is as a co-receptor dependent phagocyte. But data shows that simultaneously it is capable of binding to ACE2 receptors in its receptor binding domain. In short, SARS-CoV-2 is possessed of dual action capability. In this paper we argue that **the likelihood of this being the result of natural processes is very small** [*emphasis added*]. The spike has six inserts which are unique fingerprints with five salient features indicative of purposive manipulation. We then add to the bio-chemistry a diachronic dimension by analysing a sequence of four linked published research projects which, we suggest, show by

deduction how, where, when and by whom the SARS-CoV-2 Spike acquired its special characteristics. This reconstructed historical aetiology meets the criteria of means, timing, agent and place to produce sufficient confidence to reverse the burden of proof. Henceforth, those who would maintain that the Covid-19 pandemic arose from zoonotic transfer need to explain precisely why this more parsimonious account is wrong before asserting that their evidence is persuasive, most especially when, as we also show, there are puzzling errors in their use of evidence."

Resources for Personal Use

[560] ***Covid-19 Resources: Medical, Legal, Forms, Jobs & Other Critical Information***
September 15, 2021
https://www.coreysdigs.com/health-science/covid-19-resources-medical-legal-forms-jobs-other-critical-information/

[561] ***Resources***
Doctors for COVID Ethics
https://doctors4covidethics.org/resources-2/

[562] ***Form for Employees Whose Employers Are Requiring Covid-19 Injections***
https://pandemic.solari.com/wp-content/uploads/2021/05/Form_Employees_Whose_Employers_Are_Requiring_Covid-19_Injections.pdf

[563] ***How Americans can resist coronavirus shot mandates – a comprehensive guide***
September 10, 2021
https://www.lifesitenews.com/news/resources-for-americans-pushing-back-against-mandated-coronavirus-vaccines/

Organizations

[564] **America's Frontline Doctors**
https://americasfrontlinedoctors.org/

[565] **Association of American Physicians and Surgeons**
https://aapsonline.org/

[566] **Children's Health Defense**
https://childrenshealthdefense.org/

[567] **Doctors for COVID Ethics**
https://doctors4covidethics.org/

[568] **Front Line COVID-19 Critical Care Alliance**
https://covid19criticalcare.com/

[569] **Great Barrington Declaration**
https://gbdeclaration.org/

[570] **GreenMedInfo**
https://www.greenmedinfo.com/

[571] **Informed Consent Action Network**
https://www.icandecide.org/

[572] **National Health Federation**
https://thenhf.com/

[573] **Stop World Control**
https://www.stopworldcontrol.com/

[574] **Truth for Health Foundation**
https://www.truthforhealth.org/