

To: political leaders and medical regulatory agencies worldwide

## **Do not pause vaccinating**

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Medical agencies throughout the world have repeatedly paused or even halted vaccination programs in response to adverse events out of "an abundance of caution." We are experts in the assessment of risk, the analysis of statistics, and in the value of information and we respectfully disagree. An abundance of caution means minimizing risk and in these cases an abundance of caution dictates that vaccinations should not be stopped while an assessment is made.

We can summarize the situation with the following analogy. If you are running in the woods and you twist your ankle, ordinarily the sensible thing to do is stop running, examine your ankle, try to determine if it is broken and so forth. However, if you are being chased by a bear this is not a good idea.<sup>2</sup> Our current circumstances are akin to being chased by a bear: Covid-19 is a dangerous and deadly disease and will remain so for some time to come. We are in the fortunate position that we can keep running while we examine our ankle and that is exactly what we should do.

In our analysis we will be critical of the decisions of some medical regulatory authorities. As in all things, not all of these authorities are created equal, and we commend the European Medicines Agency (EU) and the Medicines and Healthcare Products Regulatory Agency (UK). Both agencies have recognized the bear chasing us and have offered advice and approval consistent with careful risk assessment. At the same they have engaged in careful acquisition of data about and investigation of adverse events concerning vaccines.

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<sup>1</sup> Departments of Economics, University of North Carolina and the European University Institute respectively. These affiliations are included for identification purposes only and neither organization has reviewed or endorsed the views expressed here. We are grateful to several people, who for the moment shall remain nameless, for their sharp critiques of an earlier version of this document, but they do not endorse the views expressed here - these are ours alone. We also acknowledge that one of us was vaccinated with J&J and the other with AstraZeneca and that neither of us have a conflict of interest beyond a certain amount of gratitude towards the manufacturers and inventors of those vaccines. This document is released under a Creative Commons 4.0 International Attribution License, and we encourage you to copy and share it.

<sup>2</sup> The story of the bear is somewhat fanciful since it is not a good idea to run from a bear, but feel free to substitute whatever mortal danger that you would flee from instead.

Before turning to cases it may be helpful to put the risks and benefits of vaccination in perspective. The chances of dying from either an AstraZeneca or J&J jab is about one in a million. This is an average over many different people, and risks vary according to who you are, never-the-less this is a good overall indication of risk. Is one in a million a large or a small risk? The way to understand small numbers is to compare them to things we are familiar with. By contrast to the risk of vaccination, consider the chances of dying in a single day from all causes. This depends a great deal on age. For 55-64 year olds the risk is about twenty five in one million.<sup>3</sup> In other words the day that you are vaccinated with one of these vaccines your chances of dying increase from twenty five in a million to twenty six in a million and you are twenty five times more likely to die of something else.

Of course nobody would get vaccinated merely in order to increase their risk of dying slightly: the reason is to protect from Covid-19 which is a deadly disease, and while the risk of getting vaccinated is a one (or possibly two) time risk, the risk from Covid-19 is an ongoing risk. By way of background, in 2020 in the USA the chances of dying from Covid-19 were 1,073 in a million,<sup>4</sup> while currently among those who have been fully vaccinated the chances of dying from Covid-19 are reduced to about one in a million.<sup>5</sup> Since many people are now vaccinated and we may hope that the danger of Covid-19 is receding, in our risk assessment we will need to consider what the current risk is and how long that risk is likely to persist.

## Our Assessment of Pauses

We begin our risk assessment in the USA. The CDC reports as follows:<sup>6</sup> *"As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine...[Not mentioned in the press release but widely reported in the media - one of these six has died.]...CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution."* We should add that at the Wednesday meeting the committee opted to continue with the pause, and the committee will only reconvene 10 days later on April 23rd.

The CDC and FDA have not revealed their calculations, and as we are experts in these types of assessments, we have done our own calculations based on the data they have provided. We provide the details of our calculations in the Appendix, but we should indicate that while our computations are firmly rooted in a century of science and agreed to by other experts we have

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<sup>3</sup> <https://www.statista.com/statistics/241572/death-rate-by-age-and-sex-in-the-us/> We averaged men and women as being about equal in numbers.

<sup>4</sup> From <https://ourworldindata.org/coronavirus/country/united-states> the number of deaths was 352,078.

<sup>5</sup> We are unable to locate the original CDC source, but it has been widely reported, see, for example, <https://www.businessinsider.com/infected-after-covid-vaccination-cdc-numbers-breakthrough-infections-2021-4?IR=T> that among 75 million fully vaccinated 74 have died of Covid-19.

<sup>6</sup> <https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html>

consulted with, they are also, as we indicate, common sense. By our calculation, the J&J vaccine could be 1056 times more likely to prevent a death than cause one. Even in a worst case scenario, an unvaccinated adult is on average 66 times more likely to die from Covid-19 than having a severe blood clot following J&J vaccination. In other words, regardless of what the CDC learns in their evaluation the only ethical and moral decision will be to continue to make the vaccine available. A basic rule of decision analysis is that if information acquired will not change the decision it has no value. In plain language: since the result of the evaluation is a foregone conclusion there is no reason for the delay and the delay will only cause unnecessary harm including death. In this case an abundance of caution dictates continued vaccination for as long as the J&J vaccine makes it possible to vaccinate additional individuals.

Denmark makes an interesting counterpoint to the USA because it has a much lower death rate from Covid-19. Circumstances matter in risk assessment and there is less reason to accept the risk of vaccination when the risk from disease is lower. Based on an assessment of the risks Denmark has stopped the use of the AstraZeneca vaccine<sup>7</sup> and despite the lower risk this is probably a mistake. The assessment, however, is remarkably faulty. First, it is based on an estimate of a 1 in 40 thousand risk of blood clotting from an unreleased study. This prevents scrutiny of an estimate that is inconsistent with more reliable estimates, as we explain in the Appendix. Second, in a press conference in which the Danish Health Authority presented their risk assessment they based their decision on the claim that the available 200 thousand doses of AstraZeneca would expect to result in five blood clots but prevent only one person going to intensive care.<sup>8 9</sup> However, this grossly underestimates the benefits of vaccination. With the death rate in Denmark running at two a day, in two weeks one in 200 thousand people who go unvaccinated will die from Covid-19. Moreover, earlier vaccination has many benefits beyond severe disease and death, as we discuss below. Many Danes apparently agree with us as they are asking for the vaccine.

Italy makes a striking contrast with Denmark. In Italy the daily per capita Covid-19 death rate is four times that in the USA while even fewer vaccinations have been administered per capita than in Denmark. That is to say, in Italy the risk of not getting vaccinated is many orders of magnitude larger than that from getting vaccinated. We can say with near certainty that an earlier week-long pause in AstraZeneca vaccinations has resulted in unnecessary deaths. Quite rightly Italy has now decided to proceed with the use of AstraZeneca and with Johnson and Johnson as well..

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<sup>7</sup><https://www.sst.dk/en/English/news/2021/Denmark-continues-its-vaccine-rollout-without-the-COVID-19-vaccine-from-AstraZeneca>

<sup>8</sup> "Vedr. fortsat udrulning af COVID-19 vaccine i Danmark uden Vaxzevria®" (In Danish)  
<https://www.sst.dk/-/media/Udgivelser/2021/Corona/Vaccination/Notater/Notat-vedr-fortsat-udrulning-af-COVID-19-vaccine-i-Danmark-uden-Vaxzevria140421.ashx>

<sup>9</sup> One could argue that a stop of AstraZeneca vaccination in Denmark is actually good for global health, because the vaccines will be more beneficial in locations where Covid-19 is more widespread (Michigan, for example). This is correct. But this reasoning applies equally to all Covid-19 vaccines, and is not a sensible argument for stopping AstraZeneca vaccination in Denmark.

## How Risk Assessment Works

The calculations we have made are simple and there are many nuances. There are several elements of risk analysis we would like to emphasize.

First, there is legitimate uncertainty over adverse consequences of vaccination of which we are not yet aware. For this reason nobody would propose a treatment that was known to kill 10 individuals every time it saved 11 lives. There is a principle of conservatism that indicates that the benefit to risk ratio must exceed a threshold greater than one before proceeding. We do not know what threshold regulatory agencies are using. In engineering it seems that a three to one ratio is often used for safety sake. Be that as it may, we are confident that 66-1 odds is more than good enough.

Second, when an adverse event occurs it should be investigated. There are two reasons for investigation: one is that it enables us better to understand the level of risk. In these cases that is irrelevant because in the worst case the risk of vaccination is not nearly so great as the risk of not being vaccinated. The second reason is that investigation may better identify who is at risk and what measures may be taken to mitigate the risk. Again, while this is useful, it is not a reason to pause while the investigation takes place.

Third, the availability of alternative treatments is crucial. If J&J has some possibility of risk and Pfizer does not \*and\* if Pfizer is widely and readily available it would make perfect sense to pause J&J and use Pfizer vaccines instead.<sup>10</sup> This is the typical case when there is a problem or adverse reaction to a medication in normal times: good alternatives are available so the cost of pausing on the basis of minor risk has little cost associated with it. However: while some medical regulatory agencies are firmly rooted in their normal time experience, these are not normal times. In these pandemic times there are not yet enough vaccine doses to inoculate everyone who would care to be vaccinated. That means that every dose not given, every dose in a warehouse, is a dose denied to someone who would benefit from it and would desperately like to get it. We cannot avoid pointing out as well the unconscionable fact that the USA is sitting on tens of millions of doses of AstraZeneca vaccines which it will not approve and of which only token amounts have been made available to other countries that desperately need them.

This issue of availability is an important one. First, the J&J vaccine has made it easier to reach rural areas that lack ultracold freezers and a single-dose vaccine will be more desirable to some people. Second, it does not appear that the USA overall has yet enough vaccines to go around. We are particularly concerned about Michigan where our calculations show that J&J will save nearly 3000 lives for every blood clot death. In this context it is understandable that the Governor of Michigan requested additional vaccine doses on April 11, 2021.<sup>11</sup> The following day,

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<sup>10</sup> It has recently been reported in the media <https://www.marketwatch.com/story/blood-clots-as-prevalent-with-pfizer-and-moderna-vaccine-as-with-astrazenecas-report-2021-04-15> that an Oxford study shows that Pfizer and Moderna have similar risks to AstraZeneca and Johnson and Johnson.

<sup>11</sup><https://www.bloomberg.com/news/articles/2021-04-11/michigan-governor-whitmer-urges-a-surge-in-covid-vaccine-doses>

on April 12, 2021, the request to speed up vaccine distribution to Michigan was denied by CDC Director, Dr Rochelle Walensky, who argued “[...] we need that vaccine in other places.”<sup>12</sup> CDC had paused J&J vaccination the same day and had more than 10 million J&J vaccine doses in stock.

Fourth, the risk of not being vaccinated is also crucial. To take an obvious example: nobody would give a vaccine that caused a one in a million chance of death if it provided no benefit. For this reason even if the vaccine were to prove to be effective for children under nine it is uncertain if it would be a good idea to vaccinate them. In general it should not be overlooked that risk varies a great deal depending on who you are. For under nine year olds it is essentially non-existent, and we are not urging healthy 25 year olds or pregnant women to rush out and get vaccinated with whatever vaccine they can lay their hands on. If old people are content to stay at home and never see anyone they too might well not rush. For the bulk of people of middle and older age, however, rushing out and getting vaccinated with whatever vaccine you can lay your hands on is not only a good bet, but also a great deal.

## What are the Benefits and Risks?

An important point is that getting vaccinated has many benefits beyond protecting from hospitalization and death. Vaccination is liberating for many because it opens the door to activities that were not possible during the lockdown. It eliminates the need for quarantine periods and recurrent and unpleasant testing. Vaccination also reduces concerns about transmitting the disease to a loved one. Some people, apparently including some of those on medical boards, feel that the benefits of normalcy are outweighed by the risk of blood clots. The issue, however, is who gets to decide. Governments and medical agencies do not generally restrict their citizens from engaging in risky activities such as scuba diving, running a marathon, or skiing, all of which have a risk about ten times higher than that of getting vaccinated.<sup>13</sup> Many people are willing to accept the small risk of vaccination in return for the peace of mind and normalcy it brings and are begging to get vaccinated. Even in Denmark where the risk of Covid-19 is quite low, individuals are asking to have the AstraZeneca vaccine now, rather than wait for a different vaccine at a later date. This willingness clearly shows that they perceive the value from early vaccination to exceed the risk of harm.<sup>14</sup> We think it is wrong to deny the vaccine to those who wish to take it.

For individuals assessing risk, context of other risks is important. As we have indicated, the risks of vaccination with AstraZeneca or Johnson and Johnson is much smaller than other common

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<https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/12/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-27/>

<sup>13</sup> Scuba diving, running a marathon, or ten days of skiing, have a risk of about one in a hundred thousand. This is about the same as the vaccine risk in the faulty Danish analysis: the actual risk of death from the vaccine is about one in a million.

<sup>14</sup> On April 12, 2021, a month after Denmark paused AstraZeneca vaccination, 24% of Danish women and 38% of Danish men said they would take the AstraZeneca vaccine if it was offered to them. <https://borsen.dk/nyheder/politik/undersogelse-bekraefter-danskerne-har-mistet-tilliden-til-astrazenecas-vaccine>

risks that people choose to expose themselves to. It is also the case that Covid-19 poses a much greater danger of blood clots than does any vaccine. The frequency of the severe blood clots (cerebral venous thrombosis) among Covid-19 patients is 39 per million. This is 10 times higher than from vaccination.<sup>15</sup> We should say that we have also seen comparisons with the (very high) risks of blood clots associated with various other activities.<sup>16</sup> However, these we find misleading, because the blood clots that have been associated with vaccinations are far more dangerous than those typically associated with activities such as smoking and taking birth control pills.

## Public Health and Confidence

There are two reasons to get vaccinated. One is to protect yourself. The second is to protect others. Our risk assessment is entirely about protecting yourself. However, just as your right to swing your fist ends where my nose begins, so your right to forego wearing a mask or vaccine ends when you get close enough to me to infect me. As the pandemic recedes individual risks will drop as there are fewer people to spread the disease, yet it may remain desirable that people get vaccinated to protect others: this is what “herd immunity” is all about. While this will become an issue at some point and already there is heated discussion over “vaccine passports” we are far from that point now. At the moment people should get vaccinated to protect themselves: that in doing so they will also protect others is a nice fringe benefit.

Just as there are two reasons to get vaccinated there are two reasons to forgo vaccination. One is foolishness: if people believe that the vaccine is part of a plot by Bill Gates to implant mind controlling chips in their bodies there is little sense - or reason - to urge them to get vaccinated on the grounds that it is thousands of times more likely to be beneficial than harmful. The second is selfishness: much better that everyone else take the risk of getting vaccinated to protect you than undergoing the risk yourself.

In this context we have heard arguments that although pausing or stopping vaccinations will do substantially more harm than good it is never-the-less important to do so to build confidence in the regulatory process. The argument runs that by being ultra cautious regulatory agencies will convince people that all risks have been accounted for and that the vaccines are safe to use. We disagree with this assessment.

For people who are foolish we do not see that pausing vaccinations to build confidence will make much difference. It may be that it will have some impact on selfish people down the road when the only reason to vaccinate is for the public good. However: we have seen no evidence that confidence in vaccines is increased through halting distribution. Although not conclusive there is evidence in the opposite direction, that is, that pauses decrease confidence. In Europe on March 15 France, Germany, Italy, and Spain all paused the use of Astrazeneca vaccine in response to reports of blood clots. Our assessment of this pause is above and indicates that this was a clear mistake. But perhaps it increases confidence in the vaccine to know that the

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<sup>15</sup> <https://www.ox.ac.uk/news/2021-04-15-risk-rare-blood-clotting-higher-covid-19-vaccines>

<sup>16</sup> <https://www.newsweek.com/astrazeneca-blood-clot-risk-compares-pill-smoking-flights-1581940>

regulatory agencies are responding to every risk, no matter how small? In a poll<sup>17</sup> done after the pause we see that confidence in the countries that paused the vaccination cratered, while it dipped only slightly in the UK where there was no pause.<sup>18</sup>

There are several possibilities that must be considered. It might be that when the vaccine is certified again as safe that confidence will rise to an even higher level. We do not know whether that is the case because we do not have post-pause survey data. Another possibility is that confidence dropped because of bad publicity over blood clots and that the regulatory agencies were simply responding to public pressure. There is evidence against this: the pause in the J&J vaccine occurred while a poll was being conducted<sup>19</sup> and comparison of respondents who answered before and after the announcement shows that confidence plummeted after the pause so we can rule out a plunge in confidence as a reason for the pause.

In all these cases the plunge in confidence occurred despite little objective change in the risk assessment. There is common sense behind this: an individual who believed that a decision to continue or halt vaccination was based, as we think it should be, on careful risk assessment would wrongly conclude from a halt in vaccination that the dangers are potentially great and that the risk assessment is a “near thing.”

It is a view sometimes held among some people who consider themselves part of an “elite” that most people cannot assess risks for themselves, and that therefore experts must make decisions on their behalf. We do not agree with this. It is the case, for example, that the chances of dying from Covid-19 in the last year in the US are about 1 in 1000. We suspect that most people have no idea whether that is a big number or a small number. We understand it as experts because we put it in the context of other numbers: for example, if 1 in 1000 flights crashed, then at O’Hare airport alone prior to Covid there would have been about one commercial airplane crash a day. We think put in that context most people can see that 1 in 1000 is a pretty big number: if there were two airplane crashes a day at O’Hare not only would it be unsafe to fly, it would be risky to walk near the airport for danger of falling airplanes.

Some people are richer, some poorer, some better educated and some less well educated, but we think that most people have good common sense. For example, if you don’t understand the numbers, you find someone who can explain it to you. It is a shame that the drug regulatory agencies have not attempted to do so.

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<sup>17</sup><https://yougov.co.uk/topics/international/articles-reports/2021/03/22/europeans-now-see-astrazeneca-vaccine-unsafe-follo>

<sup>18</sup> Similar survey results from the research project, How Democracies Cope with COVID19 (HOPE), do not indicate substantial changes in the willingness to take an approved Covid-19 vaccine from March 2021 to April 2021. <https://t.co/rLDiStlSzC?amp=1>, that is, while confidence in particular vaccines has dropped substantially overall confidence in vaccines seems not to have.

<sup>19</sup>

<https://today.yougov.com/topics/politics/articles-reports/2021/04/15/johnson-johnson-vaccine-confidence>

Although not a scientific study, we found an interesting series of interviews conducted by the Guardian in the US.<sup>20</sup> There are two points that emerge from the article. First, in some places the demand for vaccines is flattening out, and vaccines are going unused. This is a natural consequence of many people having been vaccinated. Second, there are quite a number of people who are neither experts nor skeptics, but genuinely unsure whether it is a good idea to get vaccinated. We believe that if the situation were well explained many of these people would choose to get vaccinated. We do not see how pausing vaccinations communicates the message: "it's much safer to get vaccinated than not to."

A related issue is this. Those who have been vaccinated have typically had to go to some effort to do so: keeping track of ever changing eligibility requirements, locating places that have vaccines, dealing with poorly designed and poorly functioning websites and with various other forms of red tape. People who are poorer and less educated, even if they have the time, are often less able to navigate these sorts of administrative nightmares. Pausing vaccinations with the resulting cancellation of appointments, reduction in the number of places offering vaccines, and generally creating confusion does not seem a good way to reach out to these people.

Finally, regulatory agencies are poorly placed to judge individual risks. We know whether we will violate the rules to get a drink at a speakeasy or whether we are content to stay at home to avoid exposure. Each of us based upon our circumstances, our work, our family, our personal life, and our personality has to judge what is an acceptable risk for us. No agency is positioned to make that determination.

The argument for "confidence building" is based on disrespect for the autonomy of individuals, contradicting an important element of medical ethics. It is also based on a lack of transparency. If a regulatory agency said that they were halting a program not out of an "abundance of caution" but because on careful investigation the benefit to risk ratio might turn out to be as low as 66 to 1 they would be subject to ridicule.

We believe that by taking actions that cannot withstand the scrutiny of careful risk assessment health regulatory agencies damage rather than enhance their reputation. The brief of these agencies is to assess the safety and efficacy of treatment which is the area of their expertise. We do not believe that they should take actions based on political concerns or, indeed, that they have particular expertise in politics.

We emphasize that medical regulatory agencies throughout the world have damaged their credibility by continually reversing their assessment of what is safe and what is not. The most dramatic instance is in Germany where it was initially determined that the AstraZenica vaccine is safe only for those under 55, and later that it is safe only for those over 55. However, this is just the most dramatic of these reversals. In a pandemic and with their credibility in question we do not believe that it is enough for agencies to give vague rationales for their actions such as "an abundance of caution" or "the benefits of the vaccine continue to outweigh the risks." We believe that the actions and recommendations of these agencies should be based on proper risk

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<sup>20</sup> <https://www.theguardian.com/society/2021/apr/19/johnson-johnson-pause-vaccine-hesitancy-us>



assessment and that the calculations and data used in that risk assessment should be communicated to the public. These agencies need to recognize that central to medical ethics is informed consent, and that it should be for individuals not agencies to assess what is an acceptable risk.

You may accept or reject our calculations but we have made them transparent so there can be no question what they are. Medical regulatory agencies need to do the same.

## Appendix: Risk Calculations

An analysis of the individual benefit of vaccination must weigh the risks of vaccination against the risks of not being vaccinated. Here is our calculation for J&J in the USA. In the US, 7.9 million individuals have received the J&J Covid-19 vaccine, and there are eight cases of blood clots with low blood platelets, one case resulting in death.<sup>21</sup> Additional cases may surface and the association with the vaccine might prove to be causal. The risk of death could therefore be higher than 1 in 7.9 million. Currently there are 753 Covid-19 deaths per day in the US<sup>22</sup>, and 67% of the adult population is not yet fully vaccinated, constituting 172.5 million individuals.<sup>23</sup> This corresponds to 4.5 deaths per day per 1 million adults not fully vaccinated, or 134 per month.

The death rate from Covid-19, however, is falling, in large part due to vaccinations: the death rate in the last month has fallen by a factor of nearly two. If we extrapolate, we would calculate that this coming month the death rate will be about 0.75 of the current rate, while if it continues to fall by a factor of two per month, the aggregate deaths will be 1.5 times that of one month, or 201 deaths per million adults. To be conservative we shall assume that the factor is 1.0 rather than 1.5. This is never-the-less 1056 times larger than 1 per 7.9 million. Consider now the extreme supposition that the number of adverse reactions will double to 16 and all will die. Even in this circumstance the vaccine is 66 times more likely to save a life than cause a death. Based on our calculations it is safe to conclude that the J&J vaccine has already prevented hundreds of deaths and can continue to do so.<sup>24</sup> There is little doubt that pausing J&J vaccination had and will result in additional deaths.

Our analysis for the state of Michigan is similar to that of the US. The percentage of fully vaccinated adults is similar but mortality is much higher. Currently there are 60 Covid-19 deaths per day in Michigan among 5.25 million adults that are not fully vaccinated. Over a month this translates to 343 deaths per million, or 2709 times larger than 1 per 7.9 million.

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<sup>21</sup> CDC initially reported six suspected cases and 6.8 million J&J vaccinated individuals. This was updated to 7.9 million J&J vaccinated individuals (vaccine tracker on April 19, 2021), and the New York Times reported the number of suspected cases of blood clotting had risen to 8.  
<https://www.nytimes.com/2021/04/19/us/johnson-vaccine-pause.html>

<sup>22</sup> Among children under 18 the total number of Covid-19 deaths is less than 300, so we can safely ignore them in these calculations.

<sup>23</sup> According to the CDC [https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrendsdeaths](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendsdeaths) on April 19 the seven day moving average of daily death rates in the USA is 753.

<sup>24</sup> There have in fact been 13,650 Covid-19 total deaths per 7.9 million individuals.

Here is our analysis of the Danish data. Their analysis is based on an unpublished study using pooled data from Denmark and Norway in which the chances of death from a rare blood clot after being vaccinated is roughly one in 40 thousand. This estimate is supposedly based on a sample of 150,480 vaccine doses given in Denmark and 132,686 vaccine doses given in Norway,<sup>25</sup> resulting in 7 (2+5) severe adverse events including four deaths. The frequencies are remarkably higher in Norway which had 5 cases of severe blood clotting, or 1 in 26,000.

Data is available from a much larger sample of 34 million AstraZeneca doses in which the EMA found 222 severe adverse events,<sup>26</sup> or a much lower frequency of about 1 in 150,000. Nevertheless, 34 million doses can be partitioned into 261 groups with 130 thousand doses in each. If the true risk of severe adverse events is 1/150,000 (the frequency reported by EMA) then the probability that one of the 261 groups has five or more cases is 7.1%. This is not a particular rare event. In other words even the Norwegian sample is consistent with the observed frequency in the much larger dataset.

On the contrary, if the estimate based on the Danish-Norwegian sample, 1/40,000, was representative, we should expect 850 cases of severe adverse events following 34 million doses. But only 222 cases were recorded, and in the glare of publicity over blood clots it seems improbable that the vast bulk of cases have gone unnoticed. In other words the statistical conclusions of the Danish Health Agency are not credible.

There is also a potential issue with the events in Norway. Three of the five cases were reported the same day, on March 13, 2021. We could not determine the date of their vaccination, or how it relates to AstraZeneca vaccinations given in Norway. Observing three extremely rare cases in a single cluster would be an exceedingly unlikely event. This could indicate that some of the cases in Norway have an unknown common factor. If this is true an investigation would be of tremendous value in determining who is at risk and why. Unfortunately, the Norwegian doctors investigating the cases in Norway seem not to have taken this possibility seriously.<sup>27</sup>

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<sup>25</sup> <https://www.nejm.org/doi/full/10.1056/NEJMoa2104882>

<sup>26</sup> 169 cases of cerebral venous sinus thrombosis (CVST) and 53 cases of splanchnic vein thrombosis (SVT).

<sup>27</sup> <https://sciencenorway.no/covid19/norwegian-experts-say-deadly-blood-clots-were-caused-by-the-astrazeneca-covid-vaccine/1830510>