

To vaccinate or not to vaccinate: COVID-19 and health risks.  
A brief narrative review of the medical literature.

By  
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Many people are concerned about the possible side-effects of receiving vaccines to help prevent COVID-19 disease due to infection by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Some of my friends, extended family, patients, and health professional colleagues have expressed the view that the side-effects of various COVID-19 vaccines may actually be more hazardous and dangerous than the side-effects of being infected with the virus. They have cited concerns over deaths due to severe allergic reactions, deaths due to heart problems, and much else.

Therefore, I conducted the following research using recognized journals that had published in English in 2021. I compared the risks and health consequences in three different scenarios:

- 1) Being infected with the COVID-19 virus
- 2) Receiving certain mRNA SARS-CoV-2 vaccines
- 3) Being vaccinated compared to being neither vaccinated nor infected.

I have not addressed safety issues related to infection nor vaccination during pregnancy.

## 1) How dangerous or deadly is coronavirus disease-2019 (COVID-19)?

**The infection fatality rate.** To understand how dangerous or deadly a virus is, I want to first clarify how one type of research calculates the results. I will do this by the following analogy. Imagine you are trying to estimate the proportion of deaths that occur following, and are caused by, car accidents. So what you are trying to discover could be called the Motor Vehicle Incident Fatality Rate (MV IFR). Although this seems simple at first, there is one big problem: how do you find out how many car accidents have happened? After all, many people will not report a car accident that only causes a bent bumper bar or some scratched paint.

Also, in order for the MV IFR to be fairly understood, the counting must be done over a reasonable length of time. Obviously reporting the MV IFR based on only one day's worth of data is not going to create a real-world accurate estimate of what happens over a month or a year. Finally, so that all the deaths that result from car accidents are included, then it is necessary to know how many of the deaths happened not just at the time of the accident, but even some days after the accident. This is because some car accident victims may be rushed to a hospital after the accident, but then only survive a few more days.

In a similar fashion, to estimate the number of deaths due to individuals being infected by SARS-CoV-2, the calculated result could be called the Covid -19 Infection Fatality Rate

(CV IFR). Although this too seems simple at first, there is one big problem: how can anyone find out how many people have had the virus? After all, not all people who are infected with the virus will get significant symptoms – in fact some will be asymptomatic – and some will not report to a doctor and will ‘escape’ being counted. If the research only counts the number of people who actually develop symptoms then it will not generate a true picture of the CV IFR.

Fortunately, there are ways to create an estimate of the actual number of people infected, and these methods result in producing both a low and a high estimate. This has been reported in 24 different published scientific articles, from a range of countries including those in the Americas, Asia and Europe. One research article examined all of these reports, which were published between February and June 2020, but included data from the beginning of the pandemic.<sup>1</sup> This means that the duration of time during which people were being infected was sufficiently large. The authors estimated that the CV IFR was between 5,300 deaths per million to 6,800 deaths per million people who actually were infected with the virus. Thankfully, at this stage there have not been any large countries where all the citizens have been infected.

**The case fatality rate.** There is a simpler way to investigate the harm due to coronavirus. This involves discovering the proportion of deaths over time due to COVID-19 while ignoring those people who are infected but do not have symptoms or only have minor symptoms. It will therefore be a much higher rate than the CV-IFR. As this simpler rate is based on the number of people who report to a doctor that they have symptoms (and therefore create a file or a case) it is called the case fatality rate (CFR). One review article reported the CFR based on 39 published studies that reported CFRs in 2020.<sup>2</sup> Many countries were included, such as: Canada, China, Italy, Japan, Singapore, South Korea, and the US. They discovered that the overall estimated pooled CFR of COVID-19 was 10.0% from these 39 studies, with a median of 8.7%. The authors then applied various margins for error – such as inadequate numbers of COVID-19 tests being available from time to time – and reported that the overall pooled estimate from all the studies for the general population was 1.0%. That equates to 10,000 deaths per million people who are

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<sup>1</sup> G Meyerowitz-Katz & L Meronec, A systematic review and meta-analysis of published research data on COVID-19 infection fatality rates. *International Journal of Infectious Diseases*, 2020; 101: 138–148. Published online 2020 Sep 29. doi: 10.1016/j.ijid.2020.09.1464.

<sup>2</sup> Y Alimohamadi et al., Case fatality rate of COVID-19: a systematic review and meta-analysis. *J Prev Med Hyg.* 2021 Jun; 62(2): E311–E320. Published online 2021 Jul 30. doi: 10.15167/2421-4248/jpmh2021.62.2.1627. Some researchers refer to a case fatality rate estimate that may well be better referred to as an infection fatality rate, as they attempt to factor in the patients with mild or asymptomatic disease. For example: T Ahammed et al., Estimation of novel coronavirus (COVID-19) reproduction number and case fatality rate: A systematic review and meta-analysis. *Health Sci Rep.* 2021 Jun; 4(2): e274. Published online 2021 May 3. doi: 10.1002/hsr2.274. Their pooled CFR estimate was 1.23, that is 12,300 per million.

infected with the virus **and** who have reported symptoms to a medical authority. Alarming, the estimate for those who had been admitted to hospital or intensive care units (ICUs) was 13% and 37% respectively; these rates are sometimes collectively referred to as in-hospital mortality rates. These figures are extremely concerning, as they are equivalent to 130,000 deaths to 370,000 deaths per million people who have been admitted to hospital or ICU respectively.

To put these figures into context, I have provided a comparison with influenza. A large study examined the outcomes of people with either COVID-19 or influenza for all patients discharged from French hospitals between 1 March and 30 April 2020.<sup>3</sup> The study included 89,530 patients with COVID-19 and 45,819 with influenza. They discovered that the in-hospital mortality rate, generalised for all age groups, for COVID-19 patients was approximately 17% while for patients with influenza it was approximately 6%. The difference became even more stark when only adolescents were considered, as the in-hospital mortality rate for COVID-19 patients was 10 times higher than that of those with influenza. However, there were very few adolescent deaths in both groups and so further research is needed.

**The morbidity rate.** The death rate is sometimes referred to as the mortality rate, whereas the rate of sickness is called the morbidity rate. COVID-19 disease is often characterized as causing respiratory related symptoms such as fever, chills, and shortness of breath. However, the SARS-CoV-2 virus causes pathology in a number of organs, and thus it causes illness – which does not always result in death – in a variety of ways.<sup>4</sup> A very large study was carried out in Israel, and they expressed their findings by comparing the difference in risk between infected and non-infected people by measuring the difference in terms of the risk of adverse health events per 100,000 people.<sup>5</sup> I converted their figures to per million for convenience. This large study examined over 173,100 people who were infected versus those who were not infected but matched for age, sex, place of birth, socioeconomic status and other variables. Infection was most strongly associated with an elevated risk – in terms of events per million people – of:

Myocarditis (inflammation of heart muscle) – increase of 110 events;

Acute kidney injury – increase of 1254 events;

Pulmonary embolism – increase of 617 events;

Intracranial haemorrhage – increase of 76 events;

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<sup>3</sup> L Piroth et al., Comparison of the characteristics, morbidity, and mortality of COVID-19 and seasonal influenza: a nationwide, population-based retrospective cohort study. *Lancet Respir Med.* 2021 Mar; 9(3): 251–259. Published online 2020 Dec 17. doi: 10.1016/S2213-2600(20)30527-0

<sup>4</sup> S Manti, et al., Looking beyond pulmonary disease in COVID-19: A lesson from patients with cystic fibrosis. *Med Hypotheses.* 2021 Feb; 147: 110481. Published online 2021 Jan 4 doi: 10.1016/j.mehy.2020.110481. There is evidence that the ability of the virus to damage the internal lining of blood and lymph vessels – the endothelium – accounts for the multiorgan pathology in COVID-19.

<sup>5</sup> N Barda, et al., Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *New England Journal of Medicine,* 2021 Aug 25: NEJMoa2110475, Published online 2021 Aug 25. doi: 10.1056/NEJMoa2110475

Pericarditis – increase of 109 events;  
Myocardial infarction (death of heart muscle) – increase of 251 events;  
Deep vein thrombosis – increase of 430 events;  
Cardiac arrhythmia – increase of 1661 events.

These diagnostic categories are often serious. A study based in Portugal found that 18% of 339 COVID-19 patients with acute kidney injury died in hospital.<sup>6</sup> Pulmonary embolism occurs when one or more arteries to the lungs are blocked, and typically the blockage is caused by a blood clot. A comparison was made between patients presenting at a university hospital with either COVID-19 and pulmonary embolism, or pulmonary embolism apart from COVID-19. The researchers discovered that those with the virus had a mortality rate of 14% whereas those without the virus had a mortality rate of 3.4%<sup>7</sup> Intracranial haemorrhage (ICH) is bleeding inside the brain, and is just one of several reasons why those infected with the virus can suffer an acute cerebrovascular accident (CVA, also known as a stroke). One study examined 172 patients who had a stroke and were infected with SARS-CoV-2 virus. They found 28 of these 172 had suffered an ICH, and over 58% of these died in hospital.<sup>8</sup>

Apart from the immediate sequelae due to the infection, longer term consequences have been noted. Researchers examined over 1700 COVID-19 patients at approximately 6 months after they had been discharged from hospital. At this time, over 60% of them were experiencing fatigue or muscle weakness, over a quarter were having sleep difficulties, and over 20% of them reported anxiety or depression.<sup>9</sup> Some of these results can be seen in the following graph:

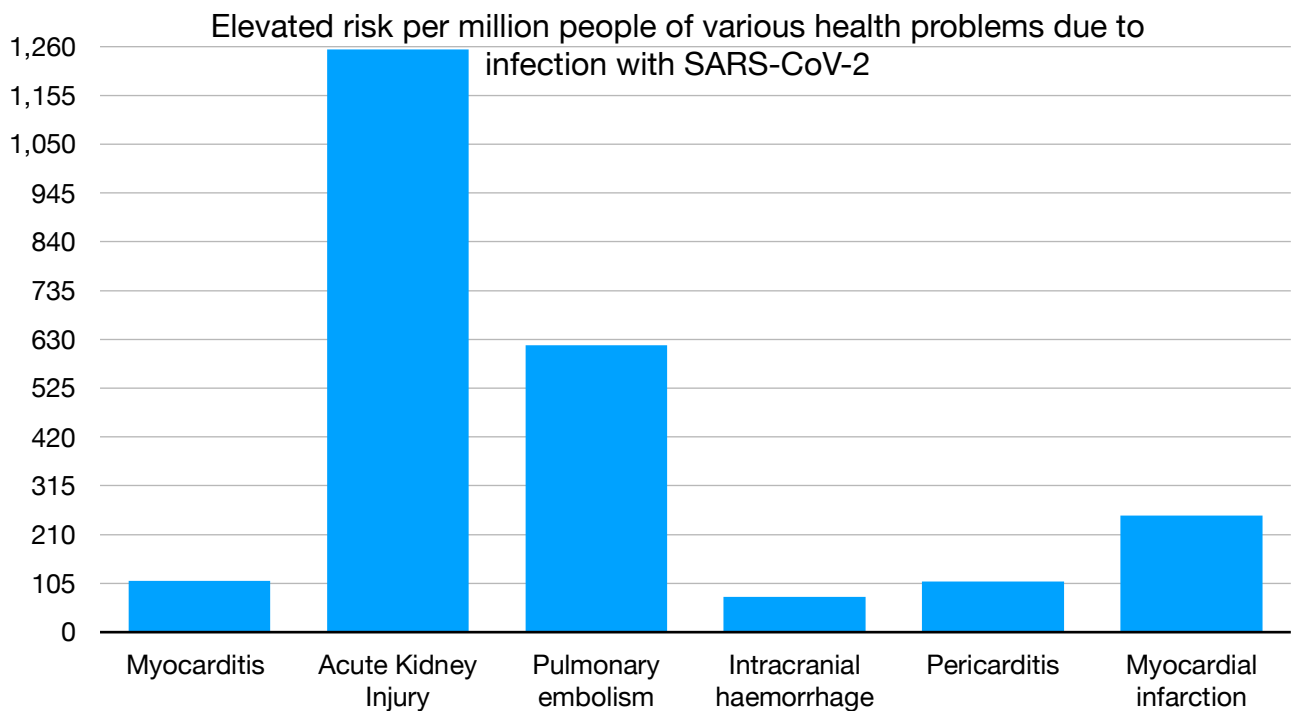
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<sup>6</sup> F Marques, Acute Kidney Disease and Mortality in Acute Kidney Injury Patients with COVID-1. *J Clin Med.* 2021 Oct; 10(19): 4599. Published online 2021 Oct 6. doi: 10.3390/jcm10194599

<sup>7</sup> Marie Hauguel-Moreau, et al., Occurrence of pulmonary embolism related to COVID-19. *J Thromb Thrombolysis.* 2020 Oct 6: 1–7. doi: 10.1007/s11239-020-02292-4 [Epub ahead of print]

<sup>8</sup> JE Sigler et al., Cerebrovascular events and outcomes in hospitalized patients with COVID-19: The SVIN COVID-19 Multinational Registry, *International Journal of Stroke* 2021, Vol. 16(4) 437–447, *Int J Stroke.* 2021 Jun;16(4):437-447. doi: 10.1177/1747493020959216. Epub 2020 Sep 30.

<sup>9</sup> C Huang et al, 6-month consequences of COVID-19 patients discharged from hospital: a cohort study. *Lancet.* 2021 16-22 January; 397(10270): 220–232. Published online 2021 Jan 8. doi: 10.1016/S0140-6736(20)32656-8



## 2) How dangerous or deadly is vaccination against COVID-19?

The next task was to find out how dangerous it is to receive vaccination against COVID-19. To do this, I examined a number of known side effects due to vaccination with mRNA vaccination.

**Anaphylaxis:** One side effect of receiving a vaccine is anaphylaxis, which is a severe allergic reaction. It is important to note that anaphylaxis can happen to anyone, and is currently defined as a serious reaction with rapid onset (minutes to hours) that is potentially life-threatening. It usually readily advances and often involves the skin and oral mucosa (appearing as swelling of the lip or tongue), the gastrointestinal system, or cardiovascular system. It is a serious condition, with yearly fatality rates due to anaphylaxis in the UK being approximately 0.47 cases per million people.<sup>10</sup>

During a period of about 9 days in December 2020, monitoring in the US detected 21 cases of anaphylaxis after more than 1,893,300 first doses of the Pfizer-BioNTech COVID-19 mRNA vaccine had been given.<sup>11</sup> This equates to 11.1 cases per million doses. Of

<sup>10</sup> PJ Turner, et al., Increase in anaphylaxis-related hospitalizations but no increase in fatalities: an analysis of United Kingdom national anaphylaxis data, 1992-2012. *J Allergy Clin Immunol.* 2015 Apr;135(4):956-963.e1. doi: 10.1016/j.jaci.2014.10.021. Epub 2014 Nov 25.

<sup>11</sup> CDC COVID-19 Response Team and Food and Drug Administration, Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine — United States, December 14–23, 2020. *Am J Transplant.* 2021 Mar; 21(3): 1332–1337. Published online 2021 Feb 28.

doi: 10.1111/ajt.16516. See also: M Sokolowska, T Eiwegger et al., EAACI statement on the diagnosis, © Jonathan Clerke, December 2021

those people who developed anaphylaxis, 71% (21) of them developed the anaphylaxis within 15 minutes of vaccination. Of these 21 patients, 17 were treated in an emergency department, but only four were hospitalised. There were no deaths due to anaphylaxis from the vaccination.

**Myocarditis:** Another side effect of receiving a COVID-19 vaccine is inflammation of the heart muscle, which is referred to as myocarditis. The inflammation can cause other tissues to be affected, such as the thin membrane that lines the outside of the heart (called the pericardium). If the heart muscle and the pericardium are inflamed it is called myopericarditis.

One study in the US examined reports of myocarditis – encompassing pericarditis and myopericarditis – that occurred within 7 days of people receiving a second dose of an mRNA vaccine.<sup>12</sup> They found that the rates varied according to age and sex, and ranged from:

40.6 cases of myocarditis per million second doses given to males aged 12–29 years;

2.4 cases of myocarditis per million second doses given to males aged ≥30 years;

4.2 cases of myocarditis per million second doses given to females aged 12–29 years;

1.0 cases of myocarditis per million second doses given to females aged ≥30 years;

When looking at a subgroup of 1,094 patients who had suspected myocarditis, 76% of them developed this only after their second dose of vaccine. By examining those of the 1,094 who were less than 30 years old over a six-week period in 2021, they found that only 323 of the 484 patients actually had myocarditis. The median time span in which they developed symptoms was two days (range zero to forty days). 96% (i.e 304) of the 323 were hospitalised. The most important finding from my point of view was that most individuals only had relatively mild symptoms, and of the 304 that were not only hospitalised but could be traced, 95% of them had been discharged and none of them had died at the time of the review. This is encouraging as myocarditis may cause up to 12% of deaths due to sudden cardiac arrest in young adults.<sup>13</sup>

**Fatalities:** A larger study based in the US examined all patients that were admitted to Accident and Emergency departments (ED) within 10 days of receiving a COVID-19

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management and prevention of severe allergic reactions to COVID-19 vaccines. *Allergy*, 2021 Jan 16 : 10.1111/all.14739. doi: 10.1111/all.14739 [Epub ahead of print]

<sup>12</sup> JW Gargano, et al., Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. *MMWR Morb Mortal Wkly Rep.* 2021 Jul 9; 70(27): 977–982. Published online 2021 Jul 9. doi: 10.15585/mmwr.mm7027e2

<sup>13</sup> Myocarditis Foundation, <https://www.myocarditisfoundation.org/wp-content/uploads/MyocarditisAndSuddenDeath.pdf>. Accessed 20/12/2021

vaccination.<sup>14</sup> This was done during the months of December 2020 to March 2021. During these months, 1,842 patients visited the ED within 10 days of COVID-19 vaccine administration. The average age was 70.3 years. It is important to note that these 1,842 patients may or may not have been admitted due to the vaccination itself. It may have just been coincidence. After making comparisons to an unrelated control group (as discussed in a separate paper) the authors noted several deaths.

Two patients (0.01%) who received the Pfizer BioNTech (BNT-162b2) vaccine died. One of these died from cardiac arrest, and the other from arteriosclerosis which is colloquially called hardening of the arteries. This is compared to four patients (0.02%) in a 'control' group. The low figure of 0.01% equates to 100 deaths per million people vaccinated. In a very parallel manner only two patients (0.01%) who received the Moderna vaccine (mRNA-1273) died. Once more one was from cardiac arrest, but the other died from suicide. This compared to three patients (0.02%) who died in the same 'control' group.

It is unlikely that the fatal arteriosclerosis was related to the vaccine, as arteriosclerosis develops very slowly and is considered to part of the ageing process. Initially the affected arteries become less elastic, followed by the arterial walls developing fatty deposits (plaques).<sup>15</sup> Similarly, it is improbable that the vaccination was an indirect cause of suicide. It was not concluded that any of the four patients who died after being vaccinated definitely did so due to a direct or indirect (in the case of the suicide and arteriosclerosis) effect from the mRNA vaccinations.

### **3) Vaccinated people compared to non-vaccinated people and non-infected people.**

Another way of examining the negative impact of mRNA vaccine is to compare, over time, a large number of people who have been vaccinated against COVID-19 with roughly the same number of people who were unvaccinated. Such a study was done in Israel. For each unwanted health diagnosis, a comparison was made between vaccinated and non-vaccinated individuals matched according to sociodemographic and clinical variables. The sociodemographic variables included age, sex, socioeconomic status, and place of birth. The study had a follow-up period of 21 days after both the first and the second vaccine doses, so a total of 42 days follow up for each vaccinated person. It was a

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<sup>14</sup> T Kewan, et al., Characteristics and outcomes of adverse events after COVID-19 vaccination. *J Am Coll Emerg Physicians Open*. 2021 Oct; 2(5): e12565. Published online 2021 Oct 13. doi: 10.1002/emp2.12565

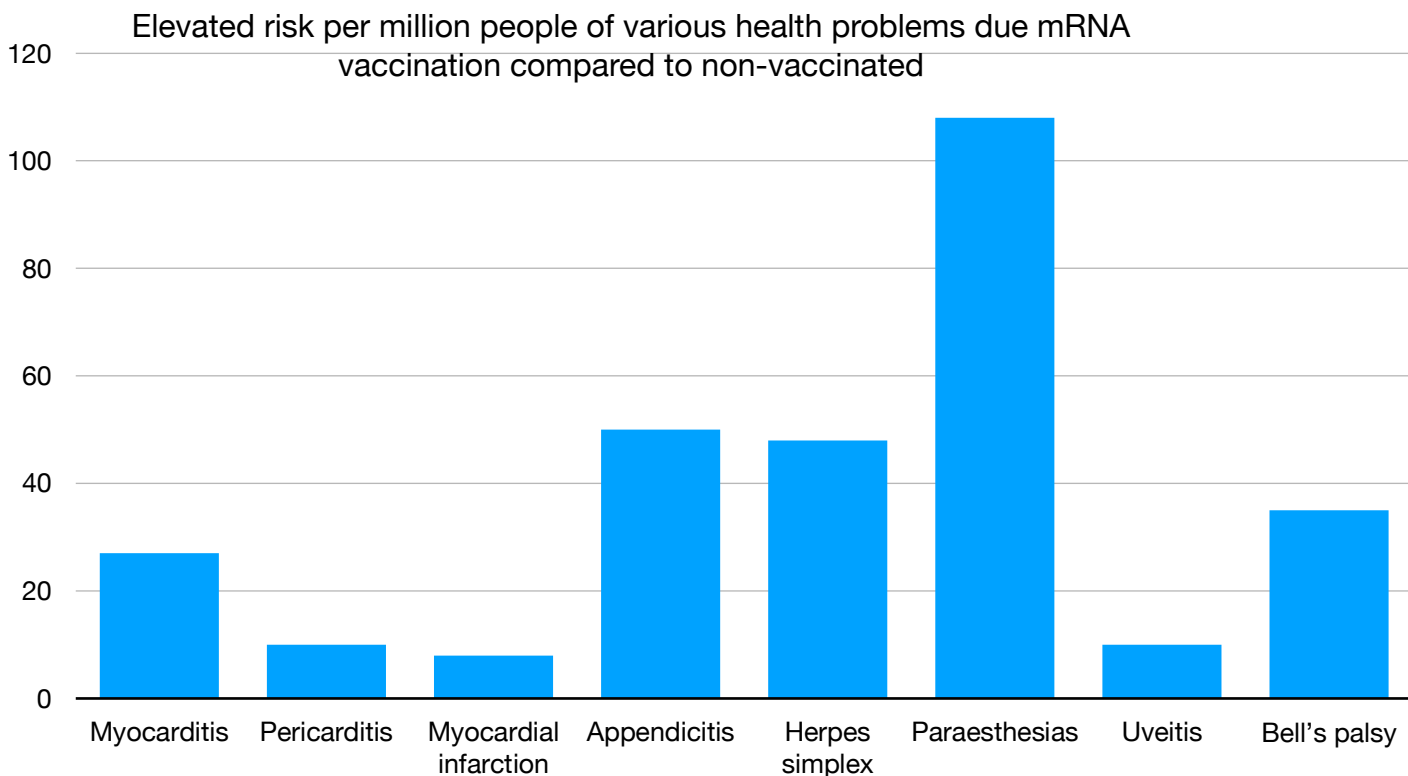
<sup>15</sup> H Ohta et al., Autologous adipose mesenchymal stem cell administration in arteriosclerosis and potential for anti-aging application: a retrospective cohort study. *Stem Cell Res Ther*. 2020; 11: 538. Published online 2020 Dec 11. doi: 10.1186/s13287-020-02067-x

massive study, with vaccinated and non-vaccinated groups each having an average of over 884,800 people. The researchers found that some diagnostic categories were more prevalent among the vaccinated compared to the unvaccinated.<sup>16</sup>

Vaccination was most strongly associated with an elevated risk – in terms of events per million people – of:

- Myocarditis (inflammation of heart muscle) – increase of 27 events;
- Myocardial infarction (death of heart muscle) – increase of 8 events;
- Lymphadenopathy (abnormal lymph nodes) – increase of 784 events;
- Appendicitis – increase of 50 events;
- Herpes simplex infection (a virus) – increase of 48 events
- Herpes zoster infection (a virus) – increase of 158 events;
- Bells’ palsy – increase of 35 events;
- Paraesthesia (pins and needles) – increase of 108 events;
- Pericarditis – increase of 10 events;
- Syncope (fainting) – increase of 62 events;
- Uveitis (inflammation of the eye) – increase risk of 10 events;
- Vertigo (dizziness) – increase risk of 93 events.

Importantly, there were no reports of fatalities in this large study based in Israel. Some of these results can be seen in the following graph:



<sup>16</sup> N Barda, et al., Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. New England Journal of Medicine, 2021 Aug 25 : NEJMoa2110475, Published online 2021 Aug 25. doi: 10.1056/NEJMoa2110475.



On the opposite side of the coin, the researchers also found that vaccination provided significant protection against a number of health problems, including a decreased risk – in terms of events per million people – of:

- Acute kidney injury – decrease of 46 events;
- Anaemia – decrease of 187 events;
- Intracranial haemorrhage – decrease of 29 events
- Pulmonary embolism – decrease of 15 events;
- Lymphopaenia – decrease of 9 events;

Anaemia is a decrease in the number of red blood cells, acute kidney injury and intracranial haemorrhage have been discussed earlier, and lymphopaenia is a decrease in the number of white blood cells called lymphocytes.

To give context to the safety profile of mRNA vaccines, one study compared the adverse events reported from mRNA vaccinations compared to those from influenza vaccinations over a 54-week period.<sup>17</sup> The data was from 18,755 individuals who had received an mRNA vaccine and reported an adverse effect, and from 27,895 who had received an influenza vaccine and also reported health issues. The authors concluded that:

Compared to the influenza vaccine, mRNA COVID-19 vaccines demonstrated a significantly higher risk for a few manageable cardiovascular complications, such as hypertensive crisis ... and supraventricular tachycardia [increased heart rate], but lower risk of neurological complications such as syncope [fainting], neuralgia, loss of consciousness, Guillain-Barre syndrome, gait disturbance, visual impairment, and dyskinesia.... [We did not find] significant safety concerns regarding mRNA vaccination...

## **Conclusion**

Putting it all together, the risk of dying with COVID-19 may be least 5,300 deaths per million people infected. Even more alarming is the fact that there are about 10,000 deaths per million people who are infected with the virus *and* have also developed symptoms (i.e. the infected people were detected by a health authority).

By contrast, it can be seen that the number of deaths related to mRNA vaccination due to a severe allergic response (such as anaphylaxis) or due to myocarditis (inflammation of the heart) appears to be less than one person per million doses of vaccine. One study presented the possibility that deaths due to cardiac arrest following mRNA vaccination may be approximately 50 deaths per million, however due to the small number of deaths

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<sup>17</sup> MS Kim et al., Comparative safety of mRNA COVID-19 vaccines to influenza vaccines: A pharmacovigilance analysis using WHO international database, *M Med Virol*. 2021 Nov 8: 10.1002/jmv.27424. doi: 10.1002/jmv.27424 [Epub ahead of print]

(2) it is possible that there was no causal relationship linking the deaths to the vaccination. Certainly 50 is still much less than the 5,300 CV IFR and the 10,000 CFR mentioned above due to COVID-19.

A similar trend can be seen when comparing the risk of certain adverse health events between the vaccinated and the infected. The risk of having myocarditis related to COVID-19 is about 110 events per million people, whereas the risk of myocarditis related to mRNA vaccination may be between 41 and 1, depending on age and sex.

Unfortunately, not only does the SARS-CoV-2 virus cause death and myocarditis, it also causes a large number of debilitating health events, such as heart arrhythmia, pulmonary embolism, deep-vein thrombosis, myocardial infarction (that is death of heart muscles cells), and pericarditis. Median term post-viral syndromes (also called long COVID-19) have also been discovered.

Finally, there are other unexpected benefits to the mRNA vaccines, such as a decrease in the risk of having various other serious health outcomes, such as anaemia, acute kidney injury, intracranial haemorrhage, and lymphopaenia. The risks associated with mRNA vaccination are favourable compared to those from influenza vaccination.

Given the scale of the current coronavirus pandemic, most people in the world will be exposed to the SARS-CoV-2 virus. This brief narrative review demonstrates that COVID-19 vaccination is the safest way to develop an immune response against the virus.