"A vital contribution to science."

-ALLYSON POLLOCK, professor, Newcastle University

VACCINES

TRUTH, LIES, AND CONTROVERSY



PETER C. GØTZSCHE, DrMedSci PROFESSOR, PHYSICIAN, AND BESTSELLING AUTHOR "Not all vaccines are equal as Peter Gøtzsche details in his powerful, provocative, and informative book. It's straightforward, non-controversial, and piles on facts that help cut through all the misleading information and propaganda out there. Once again proving, just because you question the public health authorities it doesn't make you an anti-vaxxer or anti-drug. It changes you from being a blindly trusting patient to being an informed advocate for your health. Thanks, Peter, for taking a stand for people. You are saving lives and giving us the real story that we are not being told."

-KIM WITCZAK, drug safety and consumer advocate, cofounder of Woodymatters, and consumer representative on the FDA Psychopharmacologic Drugs Advisory Committee

"Peter Gøtzsche is a leader in his field. He has been and continues to be fearless in speaking truth to power. He is always scrupulous in his quest to seek out and analyze the evidence and to dispel confusion when interpreting the science. This book is a vital contribution to science at a time when public trust in vaccines and medicines is falling. It is an example to those academics and scientists who are too nervous or too conflicted to question the role of industry and the many ways in which scientific data are manipulated to sometimes overinflate, sometimes exaggerate, and sometimes manufacture the benefits while concealing the harms and hiding the data."

-ALLYSON POLLOCK, professor, Newcastle University, United Kingdom

"In his traditional style of mixing his reflections with large amounts of factual information, Peter Gøtzsche takes on the challenging topics of vaccines, a battlefield where only the courageous and strong enter willingly. His book is a rare opportunity for the lay reader to read an analysis of vaccine controversies from one of the most respected voices in the field of evidence-based medicine. And Gøtzsche is successful in doing what so many others have failed to do: he acknowledges and explores the complexities, the grey areas, of the topic that so many others have turned into a polarized, black/white, debate. Furthermore, Gøtzsche provides several concrete recommendations and his supporting arguments for them; too often discussions of benefit and harm simply present facts without guidance in how to interpret them. A refreshing take which is sure to improve public confidence in vaccines."

-REBECCA CHANDLER, pharmacovigilance expert, Uppcala Monitoring Centre, Sweden



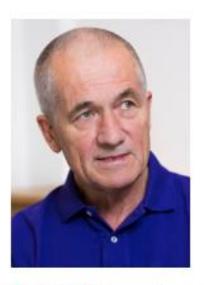


This book will help you navigate the bewildering and often contradictory flood of information about vaccines.

There is substantial misinformation about vaccines on the Internet, particularly from those who reject all vaccines, but also from official sources, which are expected to be neutral and objective. Vaccines: Truth, Lies, and Controversy is based on the best available evidence, and Professor Peter C. Gøtzsche explains when and why we should not have confidence in the science and official recommendations.

Some vaccines are so beneficial and have saved millions of lives—that we should all get them; some are so poor that many healthcare professionals do not use them for themselves or their families; and some are in-between. We must evaluate carefully each vaccine, one by one, assessing the balance between its benefits and harms, just as we do for other drugs, and then form an opinion about whether we think the vaccine is worth getting or recommending to other people.

Vaccines focuses on measles, influenza, COVID-19, and HPV, but discusses also childhood vaccination programs and whether mandatory vaccination can be justified. Raising critical questions to vaccines is essential because there are still many unresolved issues. For example, we know virtually nothing about what happens when we use many vaccines and what the long-term effects are on the immune system. Vaccines demystifies the controversial topic and helps the reader formulate their own opinion.



PETER C. GØTZSCHE is a professor, physician, and a bestselling book author. His scientific works have been cited about 150,000 times. He has published more than seventy-five papers in "the big five" journals (BMJ, Lancet, JAMA, Annals of Internal Medicine, and New England Journal of Medicine). He has also appeared on The Daily Show.



Cover photograph: Getty Images Author photo: Bertel Rüdinger Printed in the United States of America

Vaccines

Vaccines were developed with a stunning speed, never seen before in health-care. It only took one year from the outbreak in Wuhan until the first three vaccines had received approval for emergency use and interim analyses of large trials had been published, in the *Lancet*⁷⁸ and *New England Journal of Medicine*.⁷⁹

This was thanks to our governments that invested a huge amount of money in the research, after which big drug companies commercialized the vaccines and did the randomized trials.

The University of Oxford-AstraZeneca vaccine uses a replication-deficient chimpanzee adenoviral vector containing the spike protein of the coronavirus. ⁸⁰ The BioNTech-Pfizer and the NIH-Moderna vaccines are messenger RNA vaccines that instruct cells to manufacture a protein that looks like the spike protein of the coronavirus. About storage, the published Pfizer trial report only says that "very cold temperatures are required." According to an FDA briefing document, "very cold" means between -60°C and -80°C, ⁸² which is indeed very, very cold. The two other vaccines can be stored in a refrigerator.

Only one of 50 severe cases of COVID-19 occurred in the vaccine groups, and two COVID-19 deaths occurred in the control groups. The data in the individual trials were 0 vs. 10 (one death), 83 1 vs. 9, 84 and 0 vs. 30 (one death). 85

There were 5 vs. 10 deaths not related to COVID-19 in the trials (cardiovascular causes 6, unknown 2, and road traffic accident, trauma, homicide, suicide, fungal pneumonia, intraabdominal perforation, and leukemia 1 each).

These results are highly encouraging. We do not know yet if the vaccines reduce mortality, but it is very likely, and we will hopefully soon get the answer now that many millions of people get vaccinated.

As death is the most important and also the only unbiased outcome, it is surprising that the primary outcome for the vaccine trials was confirmed COVID-19 infection, which in most cases is a banal infection like the common cold.

All three trial reports are confusing to read, and essential data on harms are missing. I needed to do cumbersome detective work that included reading supplements, protocols, and FDA reports. This should not have been necessary.

None of the trial reports defined what they meant by a serious adverse event. According to the FDA, it means that the outcome is death;

life-threatening; hospitalization (initial or prolonged); disability or permanent damage; congenital anomaly/birth defect; intervention to prevent permanent impairment or damage (devices); or jeopardy of the patient and medical or surgical intervention to prevent one of the other outcomes, e.g., allergic bronchospasm.

None of the efficacy trials was adequately blinded, as the staff administering the vaccine knew its identity. This fragile arrangement means that some of the patients or investigators might have been aware if vaccine or control had been given.

The Oxford-AstraZeneca vaccine

The published report describes four trials. 86 Only two contributed to the efficacy analyses. In one, 3,744 participants received the vaccine and 3,804 a meningococcal vaccine; in the other, these numbers were 2,063 vs. 2,025, but the second dose was not the meningococcal vaccine, but a saline placebo.

All four trials contributed data to the safety analyses. In one of the additional trials, 534 vs. 533 participants received the vaccine or a meningococcal vaccine; in the other, 1,008 vs. 1,005 received the vaccine or a saline placebo. Only the safety trial with a saline placebo was double blind.

The participants were asked to contact the study site if they experienced symptoms associated with COVID-19 and received regular reminders to do so. If they had any one of the following—fever of at least 37.8°C, cough, shortness of breath, and loss of smell or taste—a swab was taken for a PCR test (polymerase chain reaction test, also called a nucleic acid amplification test, NAAT).

Vaccine efficacy was 70% (30 of 5,807 vs. 101 of 5,829 were infected and had symptoms). In participants who received two full vaccine doses, vaccine efficacy was 62%, whereas it was 90% in those who received a low dose plus a full dose (p = 0.01 for the difference). This could be a chance finding.

There are no data on numbers of patients with severe adverse events (those preventing daily activity), only on the numbers of such events, 84 vs. 91 (175 in total, but only 168 patients had events). Thus, the vaccine did not increase severe adverse events, but the trials were not adequate to study vaccine harms, as 86% of the patients in the control groups received another vaccine and not placebo.

Serious adverse events occurred in 79 patients receiving the vaccine and in 89 receiving the meningococcal vaccine or saline. A supplement describes all these events.

Three of the authors were employees of AstraZeneca; one reported personal fees from the company and one nonfinancial support. Three were inventors of patents related to the vaccine; one had received personal fees; and four had other conflicts of interest. Seventy of the 82 authors (85%) had not declared any conflicts of interest.

The BioNTech-Pfizer vaccine

Pfizer did not tell its readers that the blinding of the trial was compromised.⁸⁷ The trial report only mentioned—and only in the abstract—that the study was "observer-blinded." As the control was a saline placebo, one would expect the vials to be identical in appearance. A supplement contained Pfizer's protocol, which explained that "the physical appearance of the investigational vaccine candidates and the placebo may differ."

Another reason why this trial cannot have been effectively blinded is that the vaccine causes substantial harms compared to placebo. This was also obscured in the article. The reporting of adverse events took up 2.5 pages, but they were shown in bar charts and split into subgroups after age, first or second vaccine dose, and type of event, which is immensely irritating and unhelpful. A supplement showed that any adverse event occurred in 26.7% vs. 12.2% of the patients. Thus, the number needed to vaccinate to harm one patient was only 7 (the inverse of the risk difference).

There were other problems. FDA's briefing document showed that 311 vs. 60 patients were excluded from the efficacy analyses because of "other important protocol deviations" $(p = 2 \times 10^{-42})$ for this huge difference, my calculation). There was no explanation why many more patients had been excluded from the vaccine group than from the placebo group.

Vaccine efficacy was 95% (8 of 21,720 vs. 162 of 21,728 patients became infected). This assessment might have been biased. According to FDA criteria, confirmed COVID-19 was defined as a positive PCR test and the presence of at least one of the following symptoms: fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting.

The problem with this is that the vaccine causes some of the same symptoms. Pfizer's trial protocol contains a remarkable statement: "During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with specific systemic events (i.e., fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity. If, in the

investigator's opinion, the symptoms are considered more likely to be vaccine reactogenicity, but a participant is required to demonstrate that they are SARS-CoV-2—negative, a local SARS-CoV-2 test may be performed."89

The investigators were discouraged from finding out if patients with symptoms were infected unless the patient needed a negative test, e.g., to be allowed to go to work. According to the FDA report, suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. only 287 in the placebo group (p = 3 x 10⁻⁶, my calculation), and patients over 55 years of age used antipyretics or pain medications more commonly after the vaccine than after placebo; the difference in usage was 8% after the first dose and 28% after the second. Pfizer's inappropriate instructions to investigators and the greater use of drugs that could mask symptoms of COVID-19 mean that the true effect of the vaccine could be less than what was reported but, judged by the incidence curves of confirmed cases, this was likely a minor problem.

It was more concerning that the protocol stated that "Three blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events."

A secondary outcome was severe COVID-19 defined by the FDA as confirmed infection plus clinical signs at rest with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death. "Clinical signs at rest that are indicative of severe systemic illness" is left entirely to the clinician's discretion. This is subjective, and when the blinding is not impeccable, it can introduce bias, as the clinician could be more inclined to make this decision for patients on placebo.

Pfizer's article was obscure for severe adverse events. A supplement showed that 240 patients (1.1%) had severe adverse events on the vaccine versus 139 (0.6%) on placebo. Pfizer did not provide a p-value, but p = 2 x 10⁻⁷. The number needed to vaccinate to harm one patient severely was therefore 200. As severe harm "prevents daily activity," one in 200 became temporarily incapacitated when they received the vaccine who would have been fine without the vaccine. Pfizer's article was seriously misleading, as it said nothing about this, only that "The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache."

In the FDA report, severe adverse events were detailed in a so-called reactogenicity subset of patients.⁹¹ In patients 18 to 55 years of age, the

differences between vaccine and placebo after the second dose were 3.9% for severe fatigue, 2.5% for severe headache, and 2.1% for severe muscle pain. Even though the median duration of these symptoms was only one day, the FDA report told a totally different story to the journal publication. The number needed to harm was only 26 for severe fatigue.

The difference in solicited systemic adverse events (all severities) within 7 days after the first vaccine dose was 12%, which increased to 36% (70% vs. 34%) after the second dose. Thus, the number needed to harm was only 3 after the second dose.

Serious adverse events were extremely poorly reported. Apart from deaths, the trial report mentioned only those considered related to the vaccine: none in the placebo group and four in the vaccine group, shoulder injury related to vaccine administration, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, and right leg paraesthesia.

The Discussion noted that "The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively)." That was all. No numbers. The FDA report revealed that the numbers were 126 vs. 111 (p = 0.33, my calculation). I could not see anywhere what these 237 serious adverse events were about.

The most important numbers are ALL patients with serious adverse events, not just a tiny fraction of them (2%) that investigators, most of whom were on Pfizer's payroll, opined were related to the drugs. A supplement showed that 18 of the 29 authors of the trial report had received personal fees from Pfizer and 15 held stock in Pfizer. Only 8 authors (28%) had not declared any conflicts of interest. We do not expect authors who are so conflicted to report honestly on the harms they found, which they didn't do, either.

The FDA report acknowledged that more patients "would be needed to confirm efficacy of the vaccine against mortality. However, non-COVID vaccines (e.g., influenza) that are efficacious against disease have also been shown to prevent disease-associated death." This is blatantly false (see Chapter 4). Drug regulators should stick to the facts and refrain from wishful thinking. We have enough of this from the drug companies.

The NIH-Moderna vaccine

This trial was described in the abstract as an "observer-blinded, placebo-controlled trial," which is somewhat contradictory, as we use placebos to blind trials, not only to blind observers.⁹³ However, even though the control was

a saline placebo, the pharmacists and vaccine administrators were aware of treatment assignments.

Vaccine efficacy was 94.1% (11 of 14,134 vs. 185 of 14,073 were infected and had symptoms). However, as 15,210 were randomized to each group, 1,076 vs. 1,147 patients were missing. It was very difficult to find out what had happened, but it seems that the analysis only included patients in "the per-protocol population," with "no major protocol deviations" (noted in a figure legend only), who were seronegative at baseline, who developed illness with onset at least 14 days after the second injection, and who met the regulatory agencies' requirement of a median follow-up duration of at least two months. This is not an appropriate way of reporting a randomized trial, but there were also data for all the patients, 19 vs. 269 cases, which is a vaccine efficacy of 93.4%.

A secondary end point was severe COVID-19 defined by one of the following criteria: respiratory rate at least 30; pulse at least 125; oxygen saturation at most 93% (or a ratio of the partial pressure of oxygen to the fraction of inspired oxygen below 300 mm Hg); respiratory failure; acute respiratory distress syndrome; evidence of shock (systolic blood pressure less than 90 mm Hg, diastolic blood pressure less than 60 mm Hg, or a need for vasopressors); clinically significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death.

The reporting of adverse events was similarly obscure as in the other *New England Journal of Medicine* article, ⁹⁴ and a lot was missing or seriously misleading even though these events were described over two pages.

In the main text, adverse events were downplayed, and the reporting was inappropriate. In several cases, adverse events were only reported for the vaccine group, and the grades used for severity were not defined in the article, only in a supplement.

Solicited adverse events at the injection site occurred in 84.2% vs. 19.8% after the first dose and in 88.6% vs. 18.8% after the second dose (number needed to harm only 1.4). The most common harm was pain (88.2% vs. 17.0%). The harms lasted 3 days, on average.

Solicited systemic adverse events occurred in 54.9% vs. 42.2% after the first dose and in 79.4% vs. 36.5% after the second dose. Not only the difference in occurrence (42.9%), but also the severity increased after the second dose, with an increase in grade 3 events from 2.9% to 15.8% in the vaccine group.

There were no data on placebo in the article, but the supplement revealed how bad this really was. The most common harms after the second dose were fever (15.5% vs. 0.3%), headache (58.6% vs. 23.4%), fatigue (65.3% vs. 23.4%), myalgia (58.0% vs. 12.4%), arthralgia (42.8% vs. 10.8%), nausea or vomiting (19.0% vs. 6.4%), and chills (44.2% vs. 5.6%). The systemic harms lasted 3 days, on average.

The grading was explained on page 157 in the supplement: Grade 3 was pretty much the same as a severe adverse event, defined on page 160 as preventing daily activity and requiring intensive therapeutic intervention. Grade 4 was similar to serious adverse events, as it required emergency room visits or hospitalization. These are the data for grades 3 and 4 after the second dose:

| | Vaccine N = 14,677 | Placebo N = 14,566 |
|---------|-----------------------|-----------------------|
| Grade 3 | 2,325 (15.8%) | 282 (1.9%) |
| Grade 4 | 14 (0.1%) | 3 (0.1%) |

There could be a printing error in Moderna's table because the percentages for both grade 4 numbers are 0.1. If not, the numbers mean that for every 1,337 patients who are vaccinated, one would need to go to hospital because of a serious systemic harm.

The numbers for grade 3 mean that for every 7 patients vaccinated, one is severely harmed and unable to perform daily activities. The published article did not report on all severe adverse events but only mentioned the unsolicited ones, which were only 234 vs. 202 (1.5% vs. 1.3%), and those unsolicited ones considered treatment-related, only 71 vs. 28 patients (0.5% vs. 0.2%). Using these highly misleading data, numbers needed to harm are 478 and 353, respectively, which are over 50 times higher than the true number of 7 from the supplement. It will escape most readers that the authors only reported on unsolicited harms in the article, as there are 332 words between "unsolicited" and "71." The published article has no information on ALL severe adverse events. This is so misleading that I consider it scientific misconduct, particularly considering that most people only read the abstract, which was even worse: "Moderate, transient reactogenicity after vaccination occurred more frequently" in the vaccine group.

The numbers for serious adverse events were 207 vs. 211. Hypersensitivity reactions were reported in 1.5% vs. 1.1% of the patients; the number needed to harm was 250.

Of the 37 authors on the trial report, 13 (35%) had nothing to declare. Six were employees and held stock in Moderna, 4 were employees of Moderna, 1 had a patent for a COVID-19 vaccine, 4 had grants or fees from other companies, and 9 had grants from the NIH or similar institutions. The paper was tightly controlled by Moderna, which had used three medical writers to, as it was called, assist in drafting the manuscript for submission and for editorial support. These euphemisms can be shortened to: Moderna did it.

Other issues about vaccines

Currently, about 50 vaccines are under clinical evaluation. Results from trials conducted by Pfizer, Moderna, and the Gamaleya National Research Centre (which developed the Russian Sputnik V vaccine) were first "published" in press releases, with claims of over 90% vaccine efficacy.

Science by press release was scorned by the editor of the *Lancet* ("Publishing interim results through a press release is neither good scientific practice nor does it help to build public trust in vaccines") and the editor of *BMJ* ("Science by press release is just one of many flaws in the way new treatments are evaluated"), who pointed to previous flascos involving remdesivir and Tamiflu.⁹⁷ It also leaves stock markets vulnerable to manipulation.

The Gamaleya National Center of Epidemiology and Microbiology in Moscow says about itself that it is the world's leading research institution. Self-praise is not convincing, and the lengthy press release from November 11 about preliminary results obtained with the Sputnik V vaccine is totally devoid of meaningful facts: "Vaccine efficacy amounted to 92% (calculation based on the 20 confirmed COVID-19 cases split between vaccinated individuals and those who received the placebo)." It is impossible to get 92% efficacy if the numbers randomized to vaccine and placebo are about equal: 1 vs. 19 gives 95% and 2 vs. 18 gives 90%. Furthermore, 20 cases are far too little to say much about the efficacy of the vaccine. If we assume the correct numbers are 18 out of 20, the 95% confidence interval for this proportion is 68% to 99%.

Drug firms and authorities have misinformed the public about what the purpose of the vaccine trials is. Moderna called hospital admissions a "key secondary endpoint" in statements to the media, and the NIH stated in a press release that Moderna's trial "seeks to answer if the vaccine can prevent death caused by covid-19." But Moderna's chief medical officer has admitted that the company's trial lacks adequate statistical power to assess these outcomes. None of the vaccine trials have been designed to study them, or to determine if the vaccines can reduce transmission of the virus. ¹⁰⁰

The UK rushed ahead of everyone else and approved the BioNTech-Pfizer vaccine nine days before the FDA did. This caused the Trump administration to call the FDA commissioner to the White House to explain why the United States wasn't the greatest this time.¹⁰¹

Noncoronavirus vaccines are also being investigated. A trial has started in the Netherlands where health personnel are vaccinated against tuberculosis because this vaccine also has positive effects against other infections (see Chapter 1). The polio vaccine is another interesting candidate.¹⁰²

Should You Get Vaccinated?

From a public health perspective, it is highly rational to vaccinate broadly based on the knowledge we currently have about the coronavirus vaccines and the devastating consequences of the pandemic.

It is less clear what the individual should do. We should not repeat the mistakes we made with the influenza vaccines, which have never demonstrated an effect on outcomes that really matter. On the other hand, based on the preliminary evidence, the coronavirus vaccines seem to be a lot better than flu shots.

Currently, we know absolutely nothing about long-term harms, and some people have argued that the approvals happened too quickly. Moreover, governments in several countries have given the vaccine manufacturers legal indemnity protecting the companies against being sued by patients for vaccine harms. Thus, the only ones that have acquired 100% immunity are the drug companies.

On this background, it is less surprising that a survey of several countries from December showed that "if there was a COVID-19 vaccine that was proven to be safe and effective," only about two-thirds of the population would take it.¹⁰⁴ In the United States, three-quarters would take it, in Brazil 85%, but in Russia, only 55%.

We do not know for how long the protection lasts, but it could be short-lived. Serial measurements from 452 infected healthcare workers demonstrated that the antibody levels rose to a peak 24 days after the first positive PCR test; had an estimated half-life of only 85 days; and an estimated median time to loss of a positive antibody result of 166 days. The durability is similar to the seasonal coronaviruses, where reinfection can occur within a year, and is much shorter than for those coronaviruses causing SARS and MERS, where most long-term studies have found antibodies up

to 1–3 years later. Even though the innate and cellular responses contribute importantly to conferring immunity, these results are worrying.

It seems to me that what we are confronting is similar to a bad influenza. Many mutations of the coronavirus have been described, infectivity and case mortality rates are similar to those of influenza, and acquired immunity after infection is likely to be poor. This suggests that coronavirus vaccines may be ineffective in the long run and that vaccinated people may become infected.

Statistics are absolutely essential but cannot tell the full story. It is also important to listen to patients. A research nurse who participated in Pfizer's trial has described her experiences. 106 After the first injection, her arm was sore. After the second, her arm became much more painful than the first time. By the end of the day, she felt light-headed, chilled, nauseated, and had a splitting headache. She went to bed early but woke up around midnight feeling worse—feverish and chilled, nauseated, dizzy, and hardly able to lift her arm from muscle pain at the injection site. She slept badly, and, in the morning, her temperature was 104.9 °F (40.5 °C). She got scared and reported the harms to the research office. Two days later, her symptoms were gone except for a sore, swollen bump at the injection site. The worst part was that, despite the extensive information she had received, she did not anticipate a reactogenic response. Her gut reaction was: do I have COVID-19? When she texted a few friends about her experience, their response was the same: "Wait, does this mean you have COVID-19? Are you contagious?"

* * *

The American Academy of Family Physicians provides information on the messenger RNA vaccines on its website. It is undated, but a reference shows it was written on December 17 or later.¹⁰⁷

They write: "An mRNA vaccine . . . can cause mild symptoms in some people (e.g., fatigue, achiness, fever). Based on data from the clinical trials, the most common reactions to the vaccine are pain at the injection site, fatigue, headache, and muscle aches."

This information is seriously misleading, and the dishonesty continues: "By getting vaccinated, you are reducing your risk of disease, hospitalization, severe complications, and even death. Getting vaccinated and reducing the risk of disease also helps prevent the health care system from being further overwhelmed."

Then comes even more wishful thinking and a contradiction: "We do know that seasonal coronaviruses (a source for the common cold) do not induce a robust immune response, which leads to limited immunity to these viruses. It is likely that a vaccine will have a stronger and more lasting immune response, but data are limited and the research is ongoing . . . It is known that natural immunity to the virus wanes over time, so currently, under the EUA [Emergency Use Authorization], individuals who have previously been infected are eligible for receiving the vaccine."

How can the Academy find it likely that the vaccine will have a stronger and more lasting immune response than natural infection with coronaviruses? For vaccines in general, it is the other way around. Natural infection usually provides much better immunity than vaccines.¹⁰⁸

Our experience with the influenza vaccines (see Chapter 4) suggests that the Academy will not be alone in spreading totally dishonest information to Americans about the benefits and harms of the coronavirus vaccines. This is very sad, as it reduces people's confidence in the advice they receive and therefore increases resistance toward all vaccines.

* * *

The pandemic panic caused the Danish National Board of Health to violate its own guidelines. They plan to vaccinate children against COVID-19 even though the introduction of a vaccination in the childhood vaccination program requires that the disease being vaccinated against must have a certain severity and occurrence and therefore be important to prevent. The severity criterion is the reason why we do not vaccinate children against influenza and chicken pox. COVID-19 is not a serious disease for children, and none of the first 975 Danes who died from COVID-19 were under 30 years of age.

Other criteria that also disqualify the coronavirus vaccines are: "The vaccine must have been tested on larger groups of children to ensure that the vaccine's effect and side effects are known among children" and there must be "sufficient evidence that the benefits of vaccinating against a disease clearly outweigh the risk of harms."

We know that vaccinations with nonlive agents increase the risk of other infections and total mortality (see Chapter 1). There is a risk that by vaccinating children against COVID-19, we will send them on a path where they will have to be vaccinated frequently if the new vaccines do not provide

long-term immunity—while they would not have had the same need after natural infection.

For children in low-income countries, UNICEF should prioritize using vaccines with proven benefit to children. Despite the beneficial nonspecific effects of the BCG vaccine against tuberculosis and the measles vaccine, around 30% of the poorest children do not get the BCG vaccine on time or the measles vaccine at all. Both vaccines are associated with almost a halving of the mortality rate among those vaccinated.¹¹⁰

* * *

The huge effects touted in press releases, 95% vaccine efficacy, are much smaller in absolute numbers, only 0.84% efficacy.¹¹¹ Thus, by getting vaccinated, a person will lower the risk of getting infected in the next two months by a small amount, and we do not know what happens in the ensuing months, only that revaccinations might be needed.

A common argument is that we should vaccinate children to protect the elderly. I find this unethical, particularly because the vaccines cause severe harms and have unknown harms yet to be elucidated.

No one has the right to ask another person about vaccination status. If a doctor is asked by a colleague if she is vaccinated, she can say that she has not had the time yet, or something similar. She should avoid replying, as it is a private matter. We do not want a situation like in former East Germany, where neighbors spied on you and reported to Stasi (the Ministry for State Security, also called the secret police) if they thought you did not comply with what the regime wanted.

* * *

Whether you should get vaccinated or not depends on age, other risk factors, and particularly where you live, as the death risk varies more than 3,000 times between countries.

If you live in Taiwan, I cannot see any good reason for getting vaccinated. But let us assume you live in Denmark and are between 50 and 59 years old. In 2020, 36 people in this age group died from COVID-19,¹¹² which is 1.1% of all deaths.¹¹³ Thus, your risk of dying of COVID-19 is only about 1% of your total risk of dying.

Most of the other causes of death are beyond our control, but some are not. If you smoke, for example, it is more important to stop smoking than to get vaccinated. For all age groups, the table looks like this:

| Age group | Deaths | Corona Deaths | Risk |
|-----------|--------|------------------|------|
| 0-39 | 983 | 3 | 0.3% |
| 40-49 | 1,046 | 1 | 0.1% |
| 50-59 | 3,270 | 36 | 1.1% |
| 60-69 | 7,295 | 115 | 1.6% |
| 70-79 | 14,271 | 347 | 2.4% |
| 80+ | 28,367 | 796 | 2.7% |
| Total | 55,232 | 1,298 | 2.3% |

A recent paper using data from 45 countries found that, from age 30, there is a log-linear increase in COVID-19 mortality by age.¹¹⁴ This is scary news for old people, but it is misleading, as it does not take into account that competing death risks increase with age.

By far most people who die from COVID-19 have serious comorbidity. If you don't have that, your relative risk of dying from COVID-19 will be much lower than shown in the table. If you mix little with crowds, your risk will also be much lower. You might also consider that even after a year with COVID-19, the Danish death toll (all ages) is still at the same level as our annual deaths from influenza and that the median age at death is over 80 (in the United States, it is around 80).¹¹⁵ Thus, if you don't get flu shots, then why should you get a coronavirus vaccine?

People in leading positions in Denmark, e.g., the director of the drug agency, have come forward on TV and declared that they will get vaccinated. Celebrity announcements have a huge influence on people. I therefore provide a little balance by declaring that I shall not get a coronavirus vaccine, at least not now. My age is at the upper end of the table, but I am in good shape, with no risk factors. Some people will call me irresponsible, but derogatory adjectives help no one, and my decision is based on the facts.

Pandemrix, an influenza vaccine, caused narcolepsy (see Chapter 4). Even though the risk is presumably very small, I would never forgive myself if I became seriously and irreversibly harmed by a coronavirus vaccine. The situation is totally different for the measles vaccine, which we know much

more about and which I believe we should all take in solidarity with other people in order to obtain herd immunity.

In the corona vaccine trials, 7 vs. 1 patients developed Bell's palsy, which is a one-sided facial paralysis with a good prognosis. This does not worry me, and it could easily be a chance finding. Unfortunately, vaccine deniers are spreading a lot of worries about people who have died after a coronavirus vaccine, which is only expected given the average age people have. As just noted, my expectation is that the vaccines will lower mortality dramatically. But I shall wait and see what happens when millions of people have been vaccinated before I possibly change my mind.

Greed, Corruption, and Unethical and Unlawful Interventions

It is during humanitarian crises that we can see clearly if we have good leaders and if people's moral compasses are intact.

Early on, commercial vendors took advantage of the crisis. Supplies could take months to deliver, market manipulation was widespread, and stocks were often sold to the highest bidder. Prices of gowns doubled, prices of respirators more than tripled, and prices of face masks increased sixfold. The panic caused the public to purchase so many face masks that it caused a shortage at hospitals.

There was also corruption. Little is known about the interests of the doctors and scientists on whose advice our governments rely to manage the pandemic. Corporate interests are always granted access to government decision makers, whereas the public is kept in the dark. When the *BMJ* sought further information, the information was denied, or requests were unanswered.

BMJ's executive editor wrote a scathing editorial in November explaining how COVID-19 has unleashed state corruption on a grand scale where science is being suppressed by politicians for political and financial gain, and also where industry, scientists, and health experts have contributed to the opportunistic embezzlement.¹¹⁸

The membership, research, and deliberations of the UK Scientific Advisory Group for Emergencies (SAGE) were initially secret until a press leak forced transparency. The leak revealed inappropriate involvement of government advisers in SAGE, while exposing underrepresentation from public health, clinical care, women, and ethnic minorities who have been hit the most by the pandemic.