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Serious harms of the COVID-19 vaccines: a systematic review

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38 **Abstract**

39

40 *Introduction:* Serious harms of the COVID-19 vaccines have been underreported in
41 published trial reports.

42 *Methods:* Systematic review of papers with data on serious adverse events (SAEs)
43 associated with a COVID-19 vaccine.

44 *Results:* We included 18 systematic reviews, 14 randomised trials, and 34 other
45 studies with a control group. Most studies were of poor quality. The most reliable
46 one was a systematic review of regulatory data on the two pivotal randomised trials
47 of the mRNA vaccines. It found significantly more SAEs of special interest with the
48 vaccines than with placebo, and the excess risk was considerably larger than the
49 benefit, measured as the risk of hospitalisation. The adenovirus vector vaccines
50 increased the risk of venous thrombosis and thrombocytopenia, and the mRNA-
51 based vaccines increased the risk of myocarditis, with a mortality of about 1-2 per
52 200 cases. We also found evidence of serious neurological harms, including Bell's
53 palsy, Guillain-Barré syndrome, myasthenic disorder and stroke, which are likely due
54 to an autoimmune reaction, as has been suggested also for the HPV vaccines. Severe
55 harms, i.e. those that prevent daily activities, were hugely underreported in the
56 randomised trials. These harms were very common in studies of booster doses after
57 a full vaccination and in a study of vaccination of previously infected people.

58 *Discussion:* Serious and severe harms of the COVID-19 vaccines have been ignored or
59 downplayed, and sometimes been deliberately excluded by the study sponsors in
60 high impact medical journals. This area needs further study. Authorities have
61 recommended virtually everyone get vaccinated and receive booster doses. They fail
62 to consider that the balance between benefits and harms becomes negative in low-
63 risk groups such as children and people who have already acquired natural
64 immunity.

65

66

67 **Keywords:** COVID-19 vaccines, serious adverse events, harms

68 **1. Introduction**

69

70 Vaccines to prevent SARS-CoV-2 infection were considered to be the most promising
71 approach for curbing the COVID-19 pandemic. The major drug regulators such as the
72 US Food and Drug Administration (FDA) and the European Medicines Agency (EMA),
73 authorised the first COVID-19 vaccines under emergency or conditional use in
74 December 2020 through accelerated pathways,^{1,2} which involved a lower burden of
75 proof for efficacy and safety than traditional approval pathways.³ The impression
76 was that the vaccines were highly effective at preventing infection and severe
77 disease, as only one severe case of COVID-19 occurred in the vaccine groups
78 compared with 49 in the control groups in the three pivotal trials from Pfizer,
79 Moderna and AstraZeneca.⁴⁻⁶ Governments commenced population-wide
80 vaccination campaigns immediately, prior to any of the conventional phases of
81 clinical trials had been completed or any medium or long-term harms could be
82 elucidated.

83 Serious concerns have been raised about the reliability of the clinical trial data,
84 partly because the pharmaceutical industry has a history of falsifying data and
85 deliberately hiding harms.⁷ We have documented that incapacitating harms have
86 been deliberately left out of the published trial reports of the COVID-19 vaccines.^{8,9}
87 However, data from other types of research, mainly pharmacovigilance studies, have
88 associated thrombosis, myocarditis and the Guillain-Barré syndrome with COVID-19
89 vaccination.¹⁰

90 Neither the vaccine manufacturers, nor the drug regulators have allowed
91 independent researchers access to the raw trial data of the COVID-19 vaccines.¹¹
92 Transparency advocates sued the FDA for access and a court ordered the agency to
93 release regulatory documents, but not the raw data.¹²

94 We performed a systematic review of the published studies on all types of
95 COVID-19 vaccines to analyse the risk of serious harms.

96

97 **2. Methods**

98

99 We carried out a systematic review of systematic reviews and observational studies
100 that included data on serious adverse events (SAEs) associated with a COVID-19
101 vaccine. According to the European Medicines Agency, an SAE is an adverse event
102 that results in death, is life-threatening, requires hospitalisation or prolongation of
103 existing hospitalisation, results in persistent or significant disability or incapacity, or
104 is a birth defect.

105 In clinical trials, drug harms are often divided into mild, moderate, and severe
106 where severe means preventing usual activity.

107 We noted in our protocol that we might limit the inclusion of reviews and studies
108 according to methodological rigour or number of patients, if the workload became
109 excessive. This was the case, and we therefore excluded studies that addressed
110 special groups of people, e.g. patients with inflammatory bowel disease and
111 pregnant women; studies based on questionnaires; studies that did not have a
112 comparator group; and randomised trials and comparative cohort studies that had
113 less than 1000 participants. We also needed to abandon our aim of reviewing
114 adverse events lasting at least one year, as the studies did not provide such data.

115

116 2.1 *Search strategy and selection of studies*

117

118 We searched PubMed on 4 April 2022 with this strategy: (COVID-19 OR SARS-CoV-2)
119 AND (vaccin*) AND (safety OR adverse event* OR harm*).

120 One researcher (MD) screened the search results by title and abstract and
121 excluded articles that clearly did not fulfil our inclusion criteria. Any records where
122 there was doubt were examined by both researchers. Next, we examined the full
123 reports for possible inclusion independently, resolving disagreements by discussion.

124

125 2.2 *Data management and data extraction*

126

127 We used Zotero to manage the search results and MS Excel and Word to handle the
128 extracted data. One researcher extracted data, and doubts were resolved by
129 discussion.

130 We described the risks for adverse events and focused on bias and confounders
131 in the studies. As we expected huge heterogeneity in the way the studies were
132 carried out and reported, we aimed primarily at producing a narrative review, which
133 could be useful for decision making and for planning research.

134

135 **3 Results**

136

137 Our search yielded 4,637 records. We initially excluded 4,074 obviously irrelevant
138 records. After browsing or reading the remaining records, we excluded another 479
139 records: 242 cohort studies without an adequate control group, 36 comparative
140 studies with less than 1000 participants, five reports with data included in other
141 papers, a study of a typhoid vaccine, a small study with a meningococcal vaccine in
142 the control group, 126 reports of single cases, 61 reports of multiple cases, five
143 reports with no cases, and two studies based on questionnaires.

144 We also excluded 26 of the 42 systematic reviews we found: 13 (including one
145 about “safety and efficacy” of the vaccines that included over 100,000 patients from
146 randomised trials)¹³ did not look for serious adverse events or reported that there
147 were none; three were in pregnancy; one from Wuhan in China did not report SAEs
148 by treatment group;¹⁴ two were about inflammatory bowel disease; one about eye
149 diseases; two were not about COVID-19 vaccines; one was a protocol; one was an
150 autopsy study that established a causal relationship in 15 of 38 deaths;¹⁵ and one
151 from Hong Kong was unreliable, as it combined data from trials with those from
152 observational studies and concluded that the 95% confidence intervals did not
153 indicate a relationship between the vaccines and SAEs, which was incorrect as
154 several confidence intervals excluded the possibility of no relationship.¹⁶

155 We included 17 systematic reviews,¹⁷⁻³³ 14 randomised trials,³⁴⁻⁴⁷ and 31 other
156 studies with a control group.⁴⁸⁻⁷⁸ Four of these were not identified in our search. A
157 systematic review¹⁷ and two registry studies^{53,78} were published after the cut off for
158 our search, and a comparative study was provided by a colleague.⁶⁶

159

160 3.1 *Serious adverse events in general*

161

162 The most methodologically rigorous, reliable, and relevant research paper we
163 retrieved was a systematic review conducted by researchers from USA, Spain, and
164 Australia of regulatory data on the two pivotal randomised trials of the mRNA
165 vaccines, one from Pfizer and one from Moderna.¹⁷

166 The review analysed SAEs in general and SAEs of special interest (AESI) according
167 to the Brighton Collaboration criteria adopted by the WHO.

168 The trials were expected to follow participants for two years. However, within
169 weeks of the FDA emergency use authorisation, the sponsors began to unblind the
170 participants and offered the vaccine also to those in the placebo group.¹⁷ Therefore,
171 the review authors used the interim datasets that were the basis for the emergency
172 authorisation, covering about 4 months after the trials commenced.

173 The authors included journal publications and SAEs results tables from the
174 websites of the FDA and Health Canada. Based on blinded tables, two clinicians
175 judged independently whether an SAE was also an AESI. To account for multiple SAEs
176 occurring in the same patient, a standard adjustment was used to widen the
177 confidence intervals.

178 For SAEs, the risk difference was 13.2 per 10,000 vaccinated people (95%
179 confidence interval -3.2 to 29.6) and the risk ratio was 1.16 (0.97 to 1.39).

180 For SAEs of special interest, the risk difference and the risk ratio were
181 significantly increased, 12.5 (2.1 to 22.9) and 1.43 (1.07 to 1.92), respectively. The
182 largest excess risk occurred amongst the Brighton category of coagulation disorders
183 (36 vs 23 patients). Only 6 vs 6 patients developed myocarditis/pericarditis.

184 Even though the researchers blinded their classifications, critics have claimed
185 that they should have excluded some events and excluded others. Out of curiosity,
186 the researchers redid their analyses based on this, which only rendered the results
187 slightly worse for the vaccines (Peter Doshi, personal communication).

188 The SAEs in the Moderna trial were underreported. For reasons not documented
189 in the trial protocol, Moderna included efficacy outcomes in its SAEs tabulations,
190 while Pfizer excluded them.

191 Pfizer's vaccine increased SAEs significantly, risk difference 18.0 per 10,000 (1.2
192 to 34.9) and risk ratio 1.36 (1.02 to 1.83). In contrast, FDA concluded that SAEs were
193 "balanced between treatment groups." This discrepancy may in part be explained by
194 the fact that FDA analysed participants experiencing one or more SAEs because they
195 had access to individual participant data, whereas the researchers did not, and
196 therefore analysed total SAEs. Hence, FDA's analysis did not reflect the observed
197 excess of multiple SAEs in the vaccine group. More importantly, FDA used a different
198 analysis population with different follow-up windows, which resulted in 126 vs 111
199 participants with SAEs whereas the researchers found 127 vs 93, also using FDA data.

200 In a follow-up of Pfizer's trial, 24 of the 32 authors were from Pfizer.³⁴ Even
201 though the additional data contributed to the full approval of the vaccine in the
202 United States, there were no numerical data on SAEs in the trial report in *New*
203 *England Journal of Medicine*, which just noted that no new SAEs "were considered
204 by the investigators to be related to BNT162b2" and that "No new safety signals
205 relative to the previous report were observed during the longer follow-up period."
206 This was highly misleading. The journal article specified that safety would be
207 evaluated through 6 months after the second dose, but what was published in a
208 supplement on a website was in violation of Pfizer's own protocol and the study

209 report. The supplement only showed data reported up to one month after the
210 second vaccine dose. Thus, Pfizer had omitted five months of safety data.
211 Deliberately hiding harms data could be considered fraud.

212 In a trial of Janssen's vaccine, 19 of the 20 authors were from Janssen.³⁵ SAEs
213 occurred in 223 of 21,898 vs 265 of 21,890 patients, and 19 vs 2 patients had SAEs
214 considered by the investigator to be related to vaccination. The authors noted the
215 following imbalances in adverse events occurring within 28 days after vaccination:
216 tinnitus (15 vs 4), urticaria (13 vs 6), convulsion (9 vs 4), pulmonary embolism (10 vs
217 5), and deep vein thrombosis (11 vs 3). We calculated that the vaccine reduced total
218 mortality, 28 vs 55 deaths, risk ratio 0.51 (0.32 to 0.80), and COVID-19 related
219 mortality, 5 vs 22 deaths, risk ratio 0.23 (0.09 to 0.60). The authors found the same
220 but used person-years as denominators, which is a potentially flawed approach.

221 In a trial of AstraZeneca's vaccine, 101 of 21,587 vs 53 of 10,792 patients had an
222 SAE within 28 days after a vaccine dose.³⁶ However, the paper specified that SAEs
223 would be recorded from "the time of signed informed consent through day 730." As
224 it is implausible that no one of 32,379 patients would be admitted to hospital for two
225 years, many SAEs must be missing, not only from the trial report but also in its
226 supplementary data. There were 7 vs 7 deaths, but yet again, not within two years
227 but only within 28 days after each vaccination, which could also be considered fraud.
228 Yet again, in *New England Journal of Medicine*.

229 A trial in India of ZyCoV-D, a DNA-based vaccine, was also highly problematic. It
230 randomised 27,703 patients, either aged 12-17 years or 60 years and older.³⁷ A
231 supplement reported one SAE in the vaccine group and none in the placebo group
232 among the elderly and one vs two in "comorbid subjects." The main text was totally
233 different, with no division as per randomised group. It described 15 SAEs, but seven
234 of these were merely being COVID-19 positive, which is not an SAE and furthermore
235 belongs to the reporting of the benefits, not the harms. There was one death in each
236 group. This totally confusing paper was published in *The Lancet*.

237 In a UK trial of a recombinant nanoparticle vaccine (NVX-CoV2373), published in
238 *New England Journal of Medicine*, there were 41 patients with SAEs of 7,569 in the
239 vaccine group and 41 of 7,570 in the placebo group.³⁸ But in another table, the
240 numbers were 44 vs 44 SAEs.

241 In a US-Mexican trial, also of the NVX-CoV2373 vaccine, a supplement showed
242 that 228 of 19,729 patients had an SAE in the vaccine group and 128 of 9,853 in the
243 placebo group.³⁹ Treatment-emergent systemic adverse events grade 4 within 7 days
244 (which are life-threatening) were more common in the vaccine group, 17 vs 5 after
245 first dose and 21 vs 5 after second dose. There was no mention of grade 4 events in
246 the main text. The trial was published in *New England Journal of Medicine*.

247 An Indonesian trial of inactivated SARS-CoV-2 whole virion vaccine from Sinovac
248 randomised 1620 people:⁴⁰ "there were nine serious adverse events (SAEs) that
249 occurred in all subjects with a classification not related to vaccine products (five
250 SAEs)." This unintelligible text was published in *Vaccine*.

251 A Taiwanese trial of a recombinant protein subunit vaccine (MVC-COV1901)
252 provided no data in the article, which only stated that "No serious adverse events
253 were considered related to the study intervention."⁴¹ However, in a supplement, 18
254 of 3295 patients had an SAE on the vaccine and 1 of 549 on placebo. Unsolicited
255 adverse events grade 3 or above occurred in 93 vs 11 patients. Grade 3 was not

256 defined, but it is commonly defined as being serious and interfering with a person's
257 ability to do basic things like eat or get dressed. The trial was published in *Lancet*
258 *Respiratory Medicine*.

259 In an Indian trial of the AstraZeneca vaccine, 12 of 900 patients had an SAE on
260 the vaccine and 2 of 300 on placebo.⁴²

261 Systematic reviews of mainly published trials were of poor quality and found
262 other results. One from India included both randomised and nonrandomised studies
263 and did not find an increase in SAEs: 0.7% in the groups treated with the
264 AstraZeneca vaccine and 0.8% in the control groups.¹⁸ The authors stated that their
265 search strategy, "(COVID-19 Vaccine)" retrieved 196 records, but when we repeated
266 it for the same time period, we retrieved 3,371 records. Some of the data were also
267 erroneous. In a table, the authors stated that there were only 4 SAEs in Pfizer's
268 pivotal trial,⁵ but there were 126 vs 111, which they in the text described as 126 vs
269 11.

270 A Chinese review did not find an increase in the risk of SAEs, risk ratio 0.94 (0.71
271 to 1.25), and the vector based vaccines decreased the risk, risk ratio 0.79 (0.63 to
272 0.99).¹⁹

273 Another Chinese review only presented data in a supplement, divided by organ
274 class, with no statistical estimates.²⁰

275 A review from Indonesia presented no summary data on SAEs.²¹

276 A review from Canada, of 25 randomised trials and 105,527 patients, only
277 mentioned three anaphylactic shocks on the vaccine and one on placebo.²²

278 A US register study of nursing home residents reported lower 7-day mortality
279 after first vaccination than among unvaccinated people, risk ratio 0.34 (0.22 to 0.54)
280 but no difference in hospitalisations, risk ratio 0.95 (0.72 to 1.24).⁴⁸ These results are
281 not reliable, as the researchers adjusted for 11 confounders (see Discussion).

282

283 3.2 Thromboses

284

285 Most systematic reviews were of poor quality. The Canadian review of randomised
286 trials mentioned just above described 37 blood clots in the Results section on the
287 AstraZeneca vaccine, but they did not come from the trials but from 17 million
288 vaccinated people, which is 0.2 cases per 100,000.²²

289 A systematic review of non-randomised studies from South Korea identified 664
290 patients who developed vaccine-associated thrombosis with thrombocytopenia after
291 an adenovirus vector vaccine.²³ The mean age was 46 years, 70% were females, 91%
292 had antibodies against platelet factor 4, and 32% died. The pooled incidence of
293 venous thrombosis after AstraZeneca's vaccine was 28 (12-52) per 100,000 doses, or
294 130 higher than in the Canadian study. The pooled incidence rate of cerebral venous
295 thrombosis after the AstraZeneca vaccine was much higher than the background
296 rate, 23 vs 0.9 per 100,000 person-years.

297 A systematic review from USA, mainly of case reports, identified 144 patients
298 with thromboembolic events after the AstraZeneca vaccine.²⁴ The mean age was
299 21 to 68 years, 65% were females, and 75% had thrombocytopenia. Mean time
300 for onset of symptoms was 8 days; 50% died. The denominators vary, which makes it
301 difficult to interpret the review.

302 A systematic review from Pakistan of case reports identified 80 patients with
303 cerebral venous sinus thrombosis after vaccination.²⁵ In 83% of cases, the patients
304 had received an adenovirus vector vaccine. The mean age was 43 years, 74% were
305 females, and 56% had antibodies against platelet factor 4. Mean time for onset of
306 symptoms was 11 days; 39% died.

307 Another systematic review from Pakistan of case reports included 65 patients
308 with thrombosis with thrombocytopenia after vaccination.²⁶ In 92% of cases, the
309 patients had received an adenovirus vector vaccine. The mean age was 54 years,
310 79% were females, and 82% had antibodies against platelet factor 4. Some numbers
311 were wrong, e.g. 36 of 51 females survived and 15 died but the percentages were
312 80% and 62.5% respectively. Mean time for onset of symptoms was 9 days; 37%
313 died.

314 A systematic review from Qatar included mainly case reports but also five
315 observational studies and one “multinational study.”²⁷ The authors in- and excluded
316 studies along the way. We were unable to extract any meaningful data from this
317 9,641-word long article.

318 In a self-controlled case series study of hospital admissions and deaths based on
319 UK register data, the risk of thrombocytopenia was increased after the AstraZeneca
320 vaccine, incidence rate ratio 1.33 (1.19 to 1.47) and after a SARS-CoV-2 infection,
321 5.27 (4.34 to 6.40).⁴⁹ The risk was also increased for venous thromboembolism, 1.10
322 (1.02 to 1.18) and 13.86 (12.76 to 15.05), respectively, and for cerebral venous sinus
323 thrombosis, 4.01 (2.08 to 7.71) and 13.43 (1.99 to 90.59), respectively, where the
324 risk was also increased for Pfizer’s vaccine, 3.58 (1.39 to 9.27).

325 The risk of arterial thromboembolism was increased for Pfizer’s vaccine and after
326 an infection, 1.06 (1.01 to 1.10) and 2.02 (1.82 to 2.24), respectively. The risk was
327 also increased for ischaemic stroke, 1.12 (1.04 to 1.20) and 2.00 (1.70 to 2.35) after
328 an infection, respectively, and for other rare arterial thrombotic events after the
329 AstraZeneca vaccine, 1.21 (1.02 to 1.43). Censoring the data to the time before
330 concerns about thrombosis were raised made no difference, and the incidence of
331 coeliac disease, which was a negative control outcome, did not change.

332 A study from Scotland using a national cohort also found an increased risk of
333 thrombocytopenia after the AstraZeneca vaccine, adjusted rate ratio 5.77 (2.41 to
334 13.83), which was confirmed in a self-controlled case series analysis, risk ratio 1.98
335 (1.29 to 3.02).⁵⁰

336 Indian researchers used the Vigibase for disproportionality analyses but their
337 methods were doubtful and they did not explain what the COVID vaccines were
338 compared with.⁵¹ They noted that, “based on IC₀₂₅ values, acute myocardial
339 infarction, cardiac arrest, and circulatory collapse were associated with the vaccine
340 used in the age group > 75 years.”

341 A UK study used registry data from 8 December 2020 to 18 March 2021, in which
342 period 21 of 46 million had their first vaccination.⁵² The researchers adjusted their
343 estimates for a total of 30 confounders, and they used lower limb fracture as a
344 control condition unlikely to be affected by vaccination. However, there were
345 significantly fewer fractures after vaccination. In the Discussion, the authors mention
346 six limitations but do not discuss fractures and avoid mentioning that their data on
347 fractures mean that their data, which were published in *PLoS Medicine*, are
348 unreliable.

349 Indeed, they were. For example, the authors reported a hugely protective effect
350 of the AstraZeneca vaccine against venous thrombosis in the elderly (at least 70
351 years of age), hazard ratio 0.58 (0.53 to 0.63), whereas other research shows that
352 this vaccine causes thrombosis. Data on all-cause mortality were also implausible,
353 e.g. a hazard ratio of 0.19 (0.19 to 0.20) after the Pfizer vaccine. It is hard to imagine
354 that a COVID-vaccine could reduce total mortality by 80% in elderly people, as they
355 die from so much else.

356 In a European-US register study, the researchers estimated incidence rate ratios
357 in adults after propensity scores matching and calibration using 92 negative control
358 outcomes.⁵³ The statistical methods were highly complex and involved nine
359 confounders. Compared with Pfizer's vaccine, the AstraZeneca vaccine increased the
360 risk of thrombocytopenia, rate ratio 1.33 (1.18 to 1.50), risk difference 8.21 (3.59 to
361 12.82) per 100,000 recipients. The paper is difficult to interpret because there is an
362 enormous amount of data on various types of thromboses; the data from country to
363 country are not consistent; there were systematic errors, especially in the US Open
364 Claims database; and immunisation practices were different. There was no increase
365 in myocardial infarction.

366 A registry study of Danish frontline workers included data from 27 Dec 2020 to
367 13 April 2021.⁵⁴ Even though people were their own controls, the outcomes were
368 adjusted for 10 confounders. The AstraZeneca vaccine increased the risk of deep
369 vein thrombosis, risk difference 8.4 (0.2 to 16.5) per 100,000 vaccinations. The Pfizer
370 vaccine but not the AstraZeneca vaccine reduced the mortality risk, risk difference -
371 4.2 (-8.2 to -0.1) and -1.6 (-7.2 to 4.0), respectively. These results are the direct
372 opposite to those from the randomised trials, where the AstraZeneca vaccine
373 lowered mortality, risk ratio 0.37 (0.19 to 0.70), which the Pfizer vaccine didn't, risk
374 ratio 1.03 (0.63 to 1.71).⁷⁹ This suggests that when analyses are adjusted for many
375 confounders, this may ruin the advantage of using people as their own controls.

376 Italian researchers used the EudraVigilance European database to compare the
377 vaccines from AstraZeneca, Janssen and Pfizer for cardiovascular, neurological, and
378 pulmonary events.⁵⁵ Their paper is uninterpretable. They mistakenly talk about
379 severe adverse events, abbreviated as SAEs, when the events are serious, which is
380 worse than just being severe; the issue with confounders didn't even appear in their
381 10,856 word article; the age was unknown in over half of the people vaccinated; and
382 they presented large hazard ratios with no confidence intervals.

383 In a similar study by partly the same authors, the risk ratios for cerebral vein
384 thrombosis, splanchnic vein thrombosis, thrombocytopenia, and other bleeding
385 events in people at least 65 years of age were 2-7 times higher for the AstraZeneca
386 vaccine than for the Pfizer vaccine, with narrow confidence intervals.⁵⁶ The data
387 used were those added to data bank until 16 April 2021, before concern was raised
388 about the AstraZeneca vaccine causing blood clots.

389 The authors noted that while EMA reported only one SAE per million vaccine
390 doses related to blood clots and thrombocytopenia, they found 151 and 36,
391 respectively, for the two vaccines, with 13 and 4 deaths possibly related to this. They
392 also reported that SAEs in the categories "nervous system disorders",
393 "gastrointestinal disorders" and "musculoskeletal and connective tissue disorders"
394 occurred 9 times more often with the AstraZeneca vaccine than with the Pfizer

395 vaccine but listed no confidence intervals. Yet again, they called serious events
396 severe events.

397 In a French registry study of people at least 75 years old where the patients were
398 their own controls, the researchers wrote that in the first two weeks after each dose
399 of Pfizer's vaccine, "no significant increased risk was found for any outcome."⁵⁷ They
400 actually found a *decreased* risk after the first dose for ischaemic stroke, relative
401 incidence 0.90 (0.84 to 0.98) and for pulmonary embolism, 0.85 (0.75 to 0.96).

402 A registry study with US and Indian authors was seriously misleading.⁵⁸ The title
403 was declarative: "Cerebral venous sinus thrombosis is not significantly linked to
404 COVID-19 vaccines or non-COVID vaccines in a large multi-state health system," but
405 the study was vastly underpowered and unable to detect anything. There were only
406 3 cases after Pfizer's vaccine and none after Moderna's vaccine. The abstract was
407 also totally misleading. There were no numerical data, only a mention of "not
408 significantly associated."

409 Italian researchers used data on cerebral vein thrombosis reported to the
410 EudraVigilance database during the first six months of 2021.⁵⁹ The reporting rate per
411 million people who received their first dose of vaccine was 21.6 (20.2 to 23.1) for
412 AstraZeneca, 11.5 (9.6 to 13.7) for Janssen, 5.6 (4.7 to 6.6) for Moderna and 1.9 (1.7
413 to 2.1) for Pfizer. Cerebral vein thrombosis occurred alongside thrombocytopenia
414 with all four vaccines, and the observed to expected ratio was significantly increased
415 for all four vaccines, also using the highest estimated background incidence. Two
416 limitations of the study are that the use of the vaccines in various age groups was
417 not the same throughout Europe and that half of the observation period was after
418 EMA had raised concern about possible blood clots caused by the adenovirus vector
419 vaccines.⁸⁰

420 A study from India reported on 89 patients with acute coronary syndrome, 37 of
421 whom had a prior vaccination history.⁶⁰ It is not possible to conclude anything about
422 possible vaccine harms based on this paper.

423

424 3.3 *Myocarditis and pericarditis*

425

426 A systematic review from India included 2184 patients with myocarditis.²⁸ The mean
427 age was 26 years, 73% were males, and 99% had received an mRNA-based vaccine.
428 Mean time for onset of symptoms was 4 days. The paper is difficult to comprehend,
429 e.g. 1339 patients had definite, probable or possible myocarditis but there were 845
430 more patients with myocarditis, and the percentage of patients admitted to the
431 intensive care unit is derived from a denominator of only 1169. Six patients died
432 among 1317 for which data were available. This is one per 200, which the authors
433 call "only."

434 A systematic review from Singapore included published articles based on five
435 vaccine safety surveillance databases and 52 case reports totalling 200 cases of
436 possible COVID-19 vaccine-related myocarditis.²⁹ The authors tried to cover too
437 much ground in one article, which makes it difficult to read, and what they found
438 was not new and has been better described by other authors.

439 A systematic review with European authors included 129 cases,³⁰ but cannot be
440 used for a risk assessment.

441 A systematic review of myocarditis after an mRNA vaccine included data from 69
442 patients based on case reports and case series.³¹ The mean age was 21 years, 93%
443 were males, and 89% developed symptoms after the second dose. Patients were
444 admitted to hospital a median of three days post-vaccination.

445 A systematic review from China of children and adolescents included both
446 randomised trials, observational studies, and case reports.³² The authors
447 “summarized the basic information of 27 cases from included studies,” which did not
448 allow a risk assessment.

449 In a self-controlled case series study of hospital admissions and deaths based on
450 UK registry data, the AstraZeneca vaccine and the mRNA vaccines increased the risk
451 of myocarditis, with incidence rate ratios between 1.33 and 1.72, which were lower
452 than the risk after a SARS-CoV-2 infection, 11.14.⁶¹

453 The authors confirmed their results in a similar study, which found decreased
454 risks of cardiac arrhythmia, apart from an increase after the second dose of
455 Moderna’s vaccine, incidence rate ratio 1.93 (1.25 to 2.96 at 1-7 days).⁶² There was
456 no increased risk of encephalitis, meningitis and myelitis after the vaccines from
457 AstraZeneca and Pfizer, 1.07 (0.87 to 1.31) and 1.14 (0.86 to 1.51), respectively,
458 whereas infection increased the risk, 2.07 (1.78 to 4.11).

459 A French disproportionality study of myocarditis and pericarditis after an mRNA
460 vaccine reported to VigiBase, the WHO’s pharmacovigilance database, included data
461 till 30 June 2021.⁶³ Compared with older patients, myocarditis was much more
462 commonly reported in young people; the reporting odds ratio (ROR) was 22.3 (19.2
463 to 25.9) for adolescents and 6.6 (5.9 to 7.5) for 18–29 years old. Myocarditis was also
464 much more common in males, ROR 9.4 (8.3 to 10.6). Median time to onset was 3
465 days for myocarditis and 8 days for pericarditis; 21% of the cases were life-
466 threatening, and 1% died. The estimated rate of myocarditis was 3.6 (3.3 to 3.9) per
467 100,000 fully vaccinated persons in the United States, and 7.8 (6.9 to 8.9) in young
468 adults.

469 A US study using the Vaccine Adverse Event Reporting System (VAERS) found that
470 patients with myocarditis after an mRNA vaccine reported between December 2020
471 and August 2021 had a median age of 21 years and that 82% were males.⁶⁴ The
472 incidence in young males was over 10 times higher than in middle-aged males, and
473 82% of cases occurred after the second vaccination. The reporting rates in young
474 adults were 30 times higher than the expected background rate. Glucocorticoids
475 were used in 12% of the patients, but the most common treatment was nonsteroidal
476 anti-inflammatory drugs, used in 87% of the patients. This is surprising because
477 these drugs, despite their name, have no anti-inflammatory properties⁸¹⁻⁸³ and
478 increase the risk of heart attacks and death.⁷

479 Another US VAERS study, with US and Chinese authors, came to different results
480 even though it used the same observation period.⁶⁵ The adverse event rate in
481 adolescents was three times higher than in the former study, which cannot be
482 explained by inclusion also of pericarditis and by having no 7-day limit for reporting.
483 Most cases occur within the first couple of days and myocarditis is diagnosed about
484 10 times as often as pericarditis.⁶⁵ The risk was greater for Pfizer’s vaccine, ROR 5.4
485 (4.1 to 7.0) than for Moderna’s, ROR 2.9 (2.2 to 3.8), but, as the authors noted, only
486 Pfizer’s vaccine was approved for use in minors where the risk is greatest, and the
487 risks were similar in other age groups.

488 The authors wrote that Janssen’s vaccine “was not associated with signals of
489 myocarditis/pericarditis.” This statement is extremely misleading. First, even though
490 few people received this vaccine, the estimate was very close to being statistically
491 significant, ROR 1.39 (0.99 to 1.97), which is surely a signal. Second, Janssen’s
492 vaccine was only approved for adults. Third, the authors wrote that the incidence
493 rate was higher after the mRNA vaccines than after viral vector vaccines, but they
494 reported that these rates were 5.98 (5.73 to 6.25) vs 5.64 (4.46 to 7.04) per million,
495 which are similar rates, and the confidence interval for Janssen’s vaccine includes
496 the whole confidence interval for the mRNA vaccines. We looked up if the authors
497 had a conflict of interest related to Janssen, but they declared they had none.

498

499 3.4 *Inflammatory neuropathies*

500

501 In the randomised trials, there were seven cases of Bell’s palsy among people
502 receiving an mRNA vaccine versus one among placebo recipients ($P = 0.07$), and the
503 incidence rate was 3.5-7 times higher than the background rate.⁶⁹

504 This signal was also found in a self-controlled case series study of hospital
505 admissions based on UK register data.⁶⁶ There was an increased risk of Bell’s palsy,
506 incidence rate ratio 1.29 (1.08 to 1.56), Guillain-Barré syndrome, 2.90 (2.15 to 3.92),
507 and myasthenic disorder 1.57 (1.07 to 2.30) with the AstraZeneca vaccine. Pfizer’s
508 vaccine increased the risk of haemorrhagic stroke, 1.38 (1.12 to 1.71). The risk of
509 neurological outcomes was also increased after infection with SARS-CoV-2. There
510 were 4 excess cases of Guillain-Barré syndrome per million people receiving the
511 AstraZeneca vaccine and 15 excess cases after an infection.

512 No such signals were found in a study using data from primary care records in the
513 UK and Spain, not even in a series of self-controlled cases of Bell’s palsy.⁶⁷ The risks
514 for Bell’s palsy, Guillain-Barré syndrome, and encephalomyelitis were lower than
515 expected background rates or about the same for the vector based and mRNA
516 vaccines.

517 A case-control study from Israel with 37 cases of facial nerve palsy did not find an
518 association to Pfizer’s vaccine, odds ratio 0.84 (0.37 to 1.90).⁶⁸

519 An Israeli register study of Pfizer’s vaccine compared the rates of Bell’s palsy with
520 background rates.⁶⁹ The standardised incidence ratio after the first dose was 1.36
521 (1.14 to 1.61). This is a weak signal in a study with a historical control. Expected
522 cases cannot be determined with sufficient precision and they vary over time. The
523 signal was even weaker after the second dose, 1.16 (0.99 to 1.36). In elderly females
524 where the strongest association was observed in this study, the excess risk of Bell’s
525 palsy was estimated to be 5 cases per 100,000 vaccinees.

526 Another Israeli register study matched vaccinated with unvaccinated people for
527 seven factors and adjusted for socioeconomic status for which matching was poor.⁷⁰
528 Pfizer’s vaccine did not increase the occurrence of Bell’s palsy, risk ratio 0.96 (0.54 to
529 1.70) or Guillain-Barré syndrome (1 vs 0 cases), whereas there were more cases of
530 numbness or tingling, risk ratio 1.22 (1.08 to 1.37).

531 Using Vigibase for disproportionality analyses, Swiss researchers found *lower*
532 risks for COVID-19 vaccines than for other viral vaccines for neuralgic amyotrophy,
533 ROR 0.23 (0.17 to 0.30) vs 0.12 (0.09 to 0.16), and for Guillain-Barré syndrome, ROR

534 0.15 (0.13 to 0.16) vs 0.06 (0.05 to 0.06).⁷¹ In contrast, Bell's palsy was more
535 frequently reported with COVID-19 vaccines, ROR 1.12 (1.07 to 1.17).

536 Indian researchers also used Vigibase for disproportionality analyses, but their
537 methods and conclusions were doubtful.⁷² They referred to IC₀₂₅ values without
538 explaining what it meant and did not state what the COVID vaccines were compared
539 with. They listed 52 neurological diagnoses, which they "considered to be associated
540 with the administration of the vaccine."

541 A systematic review from Kuwait and Egypt was also problematic, e.g. there was
542 no reproducible search strategy,³³ which is essential for systematic reviews. The
543 authors reported on 32 cases of CNS demyelination following various COVID-19
544 vaccines.

545 A study based on 555 reports in VAERS of hearing loss did not find an increase in
546 risk, compared to the background rate.⁷³

547

548 3.5 *Serious adverse events in people with previous infection*

549

550 In an Israeli study, Pfizer's vaccine was given to 78 people with a previous COVID-19
551 infection and to 177 matched controls.⁷⁴ Some numbers and percentages are
552 erroneous. Emergency department visit or hospitalisation was required for 5 (6%) vs
553 1 patients (0.6%). Even though the authors showed in a table that this difference was
554 statistically significant ($P = 0.01$), they concluded that the vaccine was safe in people
555 with previous infection. This is not correct. Hospitalisation is a serious harm, and
556 harms occurred ten times as often if the patients had been infected earlier,
557 suggesting that those with acquired immunity are at higher risk of experiencing SAEs
558 post vaccination.

559

560 3.6 *Serious adverse events after a booster dose*

561

562 In a US study, 305 people previously vaccinated with two doses of 100 µg of Pfizer's
563 vaccine received a third, booster dose and were compared with the second dose of
564 the vaccine in 584 historical controls and with a 50 µg booster in separate studies.⁷⁵

565 The 100 µg booster caused more local and systemic adverse reactions than the
566 second 100 µg vaccine dose and the 50 µg booster. A supplement showed that there
567 was a large difference for moderate or severe solicited systemic adverse reactions;
568 59% experienced this on the 100 µg booster vs 39% on the 50 µg booster ($P =$
569 $0.000,05$, our calculation). There was no such difference between the 100 µg booster
570 and the 100 µg second dose, 59% vs 54% ($P = 0.12$).

571 There were two serious adverse events (not six, as the authors claim, as the
572 other four were asymptomatic infections with positive tests) but no information
573 about which groups they came from.

574 In another US study, the patients used v-safe, a voluntary, smartphone-based
575 safety surveillance system developed by the Centers for Disease Control and
576 Prevention to provide information on adverse reactions after vaccination.⁷⁶ The
577 occurrence of adverse reactions was very similar for dose three and dose two (99.7%
578 of the doses were mRNA vaccines). There were many severe adverse events: 28%
579 were unable to perform normal daily activities after the booster; 11% were unable
580 to work or attend school; 0.2% had an emergency visit; and 0.1% were hospitalised.

581 In a US study of Pfizer's vaccine, organised by Pfizer, patients were randomised
582 to receive a third dose or placebo.⁴³ The study was published in *New England Journal*
583 *of Medicine*, and 24 of the 32 authors were from Pfizer or hired by Pfizer. After a
584 third dose, 16 of 5,055 patients had an SAE on the vaccine and 24 of 5,020 on
585 placebo.

586 In contrast, in a self-controlled case series study of hospital admissions based on
587 UK registry data, the risk of myocarditis was increased after a booster dose of
588 Pfizer's vaccine, incidence rate ratio 1.72 (1.33 to 2.22).⁶¹

589 A UK study of 2,878 people was uninterpretable, as they were randomised to 12
590 different groups including a meningococcal vaccine and as there were only 24
591 SAEs.⁴⁴

592

593 3.7 *Serious adverse events in children*

594

595 We found three randomised trials with data on SAEs in children. In all cases, the data
596 were hidden in supplements to the article. In two trials of mRNA vaccines, 6 of 2486
597 vs 2 of 1240 children 12-17 years of age and 4 of 1131 vs 1 of 1129 children 12-15
598 years of age had SAEs, respectively.^{45,46} In a trial of a Chinese attenuated virus, the
599 term SAEs was not used but the numbers for grade 3 reactions were 1 of 251 vs 0 of
600 84 in children 6-12 years of age.⁴⁷ The pooled risk ratio for these three trials was 1.90
601 (0.57 to 6.29, $P = 0.29$, $I^2 = 0$).

602

603 3.8 *Other issues*

604

605 Appendicitis has been suggested as a possible adverse because of a numerical
606 increase in a vaccine trial.^{53f} A US study reviewed cases of appendicitis reported to
607 VigiBase and found 358 cases compared to 329 expected cases.⁷⁷ We explored this
608 and found a Danish registry study that reported an adjusted risk ratio of 0.93 (0.79 to
609 1.11) after the first dose and 0.99 (0.84 to 1.18) after the second dose of the
610 suspected agent, an mRNA vaccine.⁷⁸

611

612 4 Discussion

613

614 Our systematic review demonstrates the difficulty of determining vaccine related
615 SAEs in published trial data. Theoretically, systematic reviews of randomised trials
616 should be the most reliable source of evidence, but serious harms are vastly
617 underreported, if reported at all, in published drug trials.⁷

618 The underreporting seems to be particularly pronounced in vaccine trials.^{8,9,84} For
619 the COVID-19 vaccines, there is the additional problem that, within weeks of the
620 vaccines receiving an emergency use authorisation, when far too little time had
621 elapsed to identify late occurring or diagnosed harms, the unblinding of trials
622 commenced and placebo recipients were offered the vaccine.⁸⁵

623 The safety of vaccines is important because they are preventive, but editors of
624 our most prestigious journals chose to relegate the data on serious harms to
625 supplements, which few readers will access, particularly if they read the paper
626 version.

627 Severe harms – which are defined as those preventing usual activity – have also
628 been vastly underreported in the published trial reports. Pfizer’s pivotal trial report,
629 published in *New England Journal of Medicine*, was highly misleading.⁵ It mentioned
630 only serious adverse events considered related to the vaccine: four in the vaccine
631 group and none in the placebo group, but, according to FDA, there were 126 vs 111
632 SAEs.¹⁷ Pfizer’s article was also obscure for severe adverse events. A supplement
633 showed that 240 patients (1.1%) had severe events on the vaccine versus 139 (0.6%)
634 on placebo. Pfizer did not provide a P-value, but $P = 2 \times 10^{-7}$. The number needed to
635 vaccinate to harm one patient severely was only 200, which Pfizer’s article said
636 nothing about, only that “The safety profile of BNT162b2 was characterized by short-
637 term, mild-to-moderate pain at the injection site, fatigue, and headache.”

638 In AstraZeneca’s trials, 86% of the controls did not receive placebo but another
639 vaccine,⁴ which means that the harms of its COVID-19 vaccine cannot be estimated,
640 as all vaccines cause harms. The pivotal trial report noted that serious adverse
641 events were less common after the COVID-19 vaccine than after the control vaccine,
642 79 vs 89 patients.⁴ The rate of severe adverse events was 1% but the first 14
643 employees at the department of clinical microbiology at Rigshospitalet in
644 Copenhagen where the spouse to one of us works became so ill after the
645 AstraZeneca vaccine that all of them required a sick leave. The discrepancy between
646 100% in practice and 1% in the report in *The Lancet* is so huge that we suspect
647 AstraZeneca committed fraud in its vaccine trials. The harms were so pronounced
648 and common that Denmark stopped using the AstraZeneca vaccine.

649 The mRNA vaccines can also cause severe harms. As noted above, many people
650 were unable to perform normal daily activities after a booster with an mRNA
651 vaccine.⁷⁶

652 By far the most reliable study we identified was the systematic review that used
653 regulatory data from the two pivotal randomised trials of the mRNA vaccines and
654 restricted the observation period to reduce the contamination caused by offering
655 the vaccine to patients in the placebo group.¹⁷ The researchers put their findings into
656 perspective by comparing them with hospitalisations. The excess risk of SAEs of
657 special interest was considerably larger than the reduced risk of hospitalisation, 10.1
658 vs 2.3 per 10,000 vaccinated people for Pfizer’s vaccine, and 15.1 vs 6.4 for
659 Moderna’s vaccine. Even after the researchers adjusted for multiple events in the
660 same patient in a sensitivity analysis, the risk was larger.

661 Serious adverse events are not directly comparable to hospitalisations. They are
662 rarely lethal whereas a reduction in hospitalisations would be expected to reduce
663 mortality. On the other hand, the lower the risk of dying, the more important the
664 serious harms are of the vaccine. These findings are therefore important for
665 considerations about whether vaccination should be recommended for young
666 people.

667 Another low-risk group involves people who have already been infected with
668 SARS-COV-2 and recovered, and therefore have acquired natural immunity. The
669 issue of whether to vaccinate such people is highly pertinent since most of the
670 vaccine related harms have been attributed to over-activation of the immune
671 system.⁷⁴ In the only study we found of this, severe harms, defined as emergency
672 department visit or hospitalisation, occurred ten times more often if the patients
673 had been infected earlier.⁷⁴ Even though it was an observational study, this finding

674 raises serious concerns about the ubiquitous recommendations to also vaccinate
675 people who have had a COVID-19 infection.

676 The vast majority of our populations, those who have been vaccinated, constitute
677 another low-risk group. In the autumn of 2021, booster doses were being
678 recommended,^{86,87} and in many cases mandated, worldwide. However, while it was
679 generally accepted that the vaccines were still protective against COVID-19
680 hospitalisations, it was evident that protection against infection waned quickly.⁸⁸

681 The data underpinning the authorisation of booster doses were based on inferior
682 observational and immune-bridging studies, and there was great uncertainty and
683 confusion. In December 2021, EMA recommended boosters as frequently as every
684 three months,⁸⁹ but in an extraordinary backflip only one month later warned that
685 repeated boosters might weaken people's immune responses.⁹⁰ This has been
686 shown to be the case for influenza vaccines. Canadian researchers, who replicated
687 their findings in three different studies, found that people who received a seasonal
688 influenza vaccine had an increased risk of getting infected with another strain the
689 following year.⁹¹

690 For observational studies, the main problem is confounding. In a little known but
691 ingenious study, a statistician used raw data from two randomised multicentre trials
692 as the basis for observational studies that could have been carried out.⁹² He showed
693 that the more variables that are included in a logistic regression, the further we are
694 likely to get from the truth. He also found that comparisons may sometimes be *more*
695 biased when the groups appear to be comparable than when they do not; that
696 adjustment methods rarely adjust adequately for differences in case mix; and that all
697 adjustment methods can on occasion increase systematic bias. He warned that no
698 empirical studies have ever shown that adjustment, on average, reduces bias.⁹²

699 Another main problem is underreporting, particularly when doctors have been
700 reassured by authoritative messages that the vaccines are safe. In addition, there is a
701 fear among doctors that they can be threatened with disciplinary action if they do
702 anything that could undermine the government's COVID-19 vaccine rollout. We have
703 had contact with a junior doctor working in the emergency department of a major
704 hospital who began noticing patients being rushed in with what he suspected to be
705 serious COVID-19 vaccine injuries. His colleagues dismissed the symptoms as
706 unrelated to the vaccine, but he felt his patients' observations were valid. He
707 decided to write up a report and submit it to the drug regulator but was discouraged
708 by his head of the department as there was no protocol in place for reporting
709 vaccine injuries. Moreover, as many doctors are stressed and overworked and do
710 not have time to fill out the paper work, very little gets reported.

711 Underreporting is prevalent when the event is common in the general
712 population, e.g. thrombosis in the elderly. Overreporting can also occur, e.g. because
713 of increased attention related to a particular harm. In mid-March 2020, EMA warned
714 about blood clots possibly being caused by the AstraZeneca vaccine,⁸⁰ but the
715 warning was downplayed so much that it was unlikely to inflate reports about
716 vaccine injuries. EMA not only stated that "the vaccine is not associated with an
717 increase in the overall risk of blood clots" but even that there had been *fewer*
718 thromboembolic events than expected, both in studies before licensing and in
719 reports after rollout of vaccination campaigns. However, EMA also noted that there

720 had been 12 cases of cerebral venous sinus thrombosis and that only 1.4 cases was
721 expected.

722 It is pretty unreliable to estimate expected rates. A register study found that the
723 incidence of deep vein thrombosis in women aged 35-54 years was five times higher
724 in USA than in Spain.⁹³ The researchers also observed large variations between
725 electronic health records and claims data sources when using the same analysis and
726 outcome definitions. Other studies have reported a 10-fold difference in rates of
727 transverse myelitis; a 38 times higher rate of Bell's palsy in USA than in Italy; and a
728 12-fold to a 190-fold difference in rates of narcolepsy between USA and Europe.⁹³

729 Many of the studies we reviewed were of very poor quality and published in
730 journals that failed to identify fundamental errors. In 2021, for example, *Vaccines*
731 (distinct from the respected journal *Vaccine*) published an article claiming that
732 COVID-19 vaccines kill about as many as they save, but the authors made the basic
733 error of assuming that all reported deaths following vaccination in
734 pharmacovigilance data are caused by the vaccine.⁹⁴ Tensions after its publication
735 led to the resignation of six editors and the article was retracted a week later.⁹⁵

736 Another example, from the same journal, was an abstract from an article we
737 excluded, which noted that "about 50.88%" reported side effects.⁹⁶ It was not
738 "about," but precisely 50.88%, and one should not give two decimals. We calculated
739 that the confidence interval is 47% to 55%. Furthermore, the harms were divided
740 into mild, moderate, and severe, where mild meant lasting less than 24 hours,
741 moderate from 24 to 72 hours, and severe more than a week. There was no category
742 for harms lasting more than 3 and less than 8 days, and duration it not a sign of
743 severity. A mild harm can last for weeks, and a life-threatening harm can disappear
744 in a few minutes, e.g. an anaphylactic shock.

745 A systematic review used the Jadad 5-point scale for scoring the "quality" of the
746 randomised trials.²² The authors claimed to have adhered to the PRISMA guidelines,
747 but these say that "scales that numerically summarise multiple components into a
748 single number are misleading and unhelpful."⁹⁷ The Jadad scale has not been
749 recommended for the last 25 years. This review was also published in *Vaccines*.

750 Despite their shortcomings, we can draw some firm conclusions based on the
751 studies we reviewed.

752 The adenovirus vector vaccines increase the risk of venous thrombosis and
753 thrombocytopenia whereas we did not find reliable data in our search to suggest
754 that COVID-19 vaccines increase the risk of arterial thrombosis. However, this area
755 develops quickly. Our search on 4 April 2022 identified 4637 records but this number
756 had increased by 2816 already on 2 December. A colleague notified us of a recent
757 Israeli register study that raises concerns.⁹⁸ It found an increase of over 25% in
758 people aged 16-39 years in both cardiac arrest and acute coronary syndrome that
759 was closely related to vaccination rates whereas there was no relation to COVID-19
760 infection rates. A so-called Reuters Fact Check concluded that their study was
761 misleading because it did not prove that this increase was caused by the vaccines.⁹⁹
762 However, these researchers stated clearly in their paper that they had not
763 established a causal relationship.

764 Infections and vaccines, e.g. against smallpox,¹⁰⁰ can cause myocarditis, which is
765 also the case for mRNA-based COVID-19 vaccines, particularly in young males. The
766 mortality is about 1-2 per 200 cases.^{28,63}

767 Based on biological plausibility and temporal association, inflammatory
768 neuropathies like neuralgic amyotrophy, Bell's palsy, and the Guillain-Barré
769 syndrome, have been linked to other vaccines, most often to the influenza vaccine.⁷¹
770 The mounting cases of the Guillain-Barré syndrome in 1976 were closely related to
771 the use of a swine influenza vaccine.¹⁰¹ However, serious neuropathies can be very
772 difficult to detect. For example, it took a long time before it was accepted that the
773 influenza vaccine Pandemrix causes narcolepsy.^{102,103}

774 When our research group analysed the clinical study reports of the HPV vaccines
775 submitted to EMA for marketing authorisation, we showed a statistically significant
776 increase in serious neurological adverse events.¹⁰⁴ EMA denied this but based its
777 conclusion on the data provided to the agency by the manufacturers. They did not
778 check if this reporting was accurate despite knowing that one of the companies had
779 previously been deceptive with its HPV vaccine harms data.^{9,105}

780 We found evidence of serious neurological harms, and a survey of 508 US
781 patients suffering from persistent neurological symptoms after a COVID-19 vaccine
782 showed a wide array of symptoms of which painful neuropathy/paraesthesias were
783 the worst.¹⁰⁶ Prior to the vaccination, 94% of the patients had never reacted to a
784 vaccine. Since the symptoms are so varied, doctors tend to dismiss them and
785 conclude that the patients suffer from a psychiatric problem. However, this is
786 unlikely. Researchers from the US National Institutes of Health studied 23 self-
787 referred patients who reported new neuropathic symptoms beginning within three
788 weeks after SARS-CoV-2 vaccination (for 9 patients, after the second dose).¹⁰⁷ All
789 patients had sensory symptoms comprising severe face or limb paraesthesias, and 12
790 had objective evidence of small-fiber peripheral neuropathy. Autonomic testing in 12
791 identified 7 with reduced distal sweat production and 6 with postural orthostatic
792 tachycardia syndrome.

793 Some patients have experienced similar symptoms after an HPV vaccine, which
794 suggests autoimmunity directed against the autonomic nervous system. In a Danish
795 study, antibodies directed against the adrenergic β -2 receptor were found in 75% of
796 108 patients with symptoms and in only 17% of 98 age- and sex-matched vaccinated
797 controls ($P < 0.001$).¹⁰⁸ Antibodies against the muscarinic M-2 receptors were found
798 in 82% vs 16% ($P < 0.001$) and against either β -2 or M-2 receptors in 92% vs 19% ($P <$
799 0.001). Similar symptoms and neuroendocrine antibodies have been reported in
800 patients suffering from long-term complications after SARS-CoV-2 infection.¹⁰⁸⁻¹¹⁰

801 SARS-CoV-2 infection can cause transverse myelitis, with acute onset of paralysis,
802 sensory level, and sphincter deficits due to spinal cord lesions demonstrated by
803 imaging.¹¹¹ The occurrence of 2 reported cases among 5,807 participants within two
804 weeks after vaccination in the pivotal AstraZeneca trial,^{4,111} is an extremely high
805 incidence considering a worldwide incidence of 0.5 cases per million after
806 infection.¹¹¹

807 SAEs have been systematically eliminated from the pivotal trials.⁸ In the Pfizer
808 and AstraZeneca vaccine trials, participants were given digital apps to record adverse
809 events remotely, but the apps only allowed the participants to record what the
810 company deemed as "expected" events. If they developed thrombosis, myocarditis,
811 Guillain-Barré Syndrome, transverse myelitis, or other serious neurological events,
812 there was no option for them to record it on the app.

813 Brianne Dressen, a participant in an AstraZeneca trial, became disabled after her
814 first injection.⁸ She is still disabled today, but there is no mention of this in the trial
815 report in *New England Journal of Medicine*.³⁶ As Dressen was concerned about the
816 lack of reporting of her serious adverse event (and others) in the trial's publication,
817 she wrote to Dr Eric Rubin, editor in chief of the journal, and asked for the
818 inaccuracies to be corrected and demanded complete reporting of the results. Rubin
819 refused to correct the inaccurate data in his journal. The full email exchange has
820 been made public.⁸

821 When Pfizer had recruited 12-15 year olds for its mRNA vaccine trial, the
822 published data in *New England Journal of Medicine* stated that there were "no
823 serious vaccine-related adverse events."⁴⁶ One of the participants, however, was 13
824 year old Maddie De Garay who suffered a serious adverse reaction following her first
825 injection, which left her in a wheelchair and fed by a nasogastric tube.⁸ She was
826 referred to hospital for a full assessment and a doctor diagnosed her with a
827 "functional disorder." This doctor decided she had a pre-disposition to hysteria, and
828 she was referred to a mental health facility. Professor and psychiatrist David Healy
829 subsequently conducted a thorough review of her medical records, including an
830 interview with her family, and found no such history of pre-existing conditions or
831 mental illness.

832 Even if data are honestly reported, it is extremely difficult to find rare events in
833 randomised trials. One would need a trial with 30,000 people in the vaccine arm to
834 have a 95% chance of detecting a serious harm if it occurs in 1 of 10,000 cases,¹¹²
835 and one case is not enough to establish a cause-effect relationship.

836 A rare condition is multisystem inflammatory syndrome in children. A survey of
837 21 people aged 12–20 years found a reporting rate of one case per million after
838 vaccination whereas the incidence among unvaccinated people in this age group
839 who have had a SARS-CoV-2 infection is about 200 cases per million.¹¹³

840 An important issue, which has received virtually no attention, is that vaccines
841 have non-specific effects, which are very different for live attenuated vaccines and
842 for non-live vaccines. Peter Aaby and co-workers have shown in several studies, that
843 live attenuated vaccines, e.g. against measles, polio and tuberculosis, decrease
844 mortality from other infections than the targeted one, whereas non-live vaccines
845 increase mortality.^{84,114}

846 Aaby's team has also analysed the randomised trials of the COVID-19 vaccines.
847 They found that the adenovirus vector vaccines reduced total mortality, risk ratio
848 0.37 (0.19 to 0.70), in contrast to the mRNA vaccines, risk ratio 1.03 (0.63 to 1.71).⁷⁹
849 The difference between the two estimates was statistically significant ($P = 0.03$). It is
850 a missed opportunity that nowhere in the world was the vaccine roll-out done as
851 part of a randomised trial that could tell us if some vaccines lower mortality more
852 than others. But now that boosters are being recommended, such trials should be
853 performed. There is also a need for additional placebo-controlled trials, e.g. in
854 people who have already been infected.

855 Another missed opportunity is that the drug regulators and other authorities
856 have been very slow in following up signals of serious harms. In July 2021, based on
857 medical claims data in older Americans, FDA reported detecting four potential
858 adverse events of interest: pulmonary embolism, myocardial infarction, immune
859 thrombocytopenia, and disseminated intravascular coagulation after Pfizer's

860 vaccine.¹⁷ FDA stated it would further investigate the findings, but the agency did
861 not disclose its data, did not warn the doctors or the public, and 1½ years later, had
862 still not updated its findings.¹¹⁵

863 The US Centers for Disease Control and Prevention were also slow. A study using
864 VAERS and EudraVigilance comparing the disproportionality of adverse event reports
865 for the influenza vaccine and the mRNA COVID-19 vaccines reported excess risks for
866 four Brighton serious adverse events of special interest: cardiovascular events,
867 coagulation events, haemorrhages, gastrointestinal events, and thromboses.^{115,116}
868 CDC published a protocol in early 2021 for disproportionality analyses in the VAERS
869 database,¹⁷ but they have not reported the results.

870 Given all the difficulties, obstacles with getting access to regulatory data,
871 obfuscations, and documented underreporting, we find it likely that there are other
872 serious harms than those uncovered so far.

873 This area needs further study. Authorities have recommended virtually everyone
874 get vaccinated and receive booster doses, and fail to consider that the balance
875 between benefits and harms becomes negative in low-risk groups such as children
876 and people who have already acquired natural immunity.

877

878 **Author contributions**

879

880 Both authors had full access to all of the data and take responsibility for the integrity
881 of the data and the accuracy of the data analysis.

882 Study concept and design: Gøtzsche.

883 Protocol: both authors.

884 Acquisition of data: both authors.

885 Analysis and interpretation: both authors.

886 Statistical analysis: Gøtzsche.

887 Drafting of the manuscript: Gøtzsche.

888 Critical revision of the manuscript for important intellectual content: both
889 authors.

890

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892

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895

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897

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899

900 **Ethical review statement**

901

902 Not relevant.

903

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