

# Covid-19 vaccine boosters for young adults: A risk-benefit assessment and five ethical arguments against mandates at universities

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## Abstract

Students at North American universities risk disenrollment due to third dose Covid-19 vaccine mandates. We present a risk-benefit assessment of boosters in this age group and provide five ethical arguments against mandates. We estimate that 22,000 - 30,000 previously uninfected adults aged 18-29 must be boosted with an mRNA vaccine to prevent one Covid-19 hospitalisation. Using CDC and sponsor-reported adverse event data, we find that booster mandates may cause a net expected harm: per Covid-19 hospitalisation prevented in previously uninfected young adults, we anticipate 18 to 98 serious adverse events, including 1.7 to 3.0 booster-associated myocarditis cases in males, and 1,373 to 3,234 cases of grade  $\geq 3$  reactogenicity which interferes with daily activities. Given the high prevalence of post-infection immunity, this risk-benefit profile is even less favourable. University booster mandates are unethical because: 1) no formal risk-benefit assessment exists for this age group; 2) vaccine mandates may result in a net expected harm to young people; 3) mandates are not proportionate: expected harms are not outweighed by public health benefits given the modest and transient effectiveness of vaccines against transmission; 4) US mandates violate the reciprocity principle because rare serious vaccine-related harms will not be reliably compensated due to gaps in current vaccine injury schemes; and 5) mandates create wider social harms. We consider counter-arguments such as a desire for socialisation and safety and show that such arguments lack scientific and/or ethical support. Finally, we discuss the relevance of our analysis for current 2-dose Covid-19 vaccine mandates in North America.

## 45 **1. Introduction**

46 Covid-19 vaccine booster mandates have been controversial, especially in younger age groups.  
47 Two main factors are driving scientific controversy: a lack of evidence that booster doses  
48 provide meaningful reduction in hospitalisation risk among young people and mounting  
49 evidence that (widespread) prior infection confers significant protection against hospitalisation  
50 due to (re-)infection. Further, mandates have deleterious societal consequences and are eroding  
51 trust in scientific and government institutions.<sup>1</sup> In North America, as of May 2022 at least 1,000  
52 colleges and university campuses required Covid-19 vaccination, and over 300 required  
53 boosters.<sup>2</sup> More than fifty petitions have been written opposing these vaccine mandates<sup>3</sup>,  
54 raising specific legal and ethical complaints.<sup>4</sup> In many cases, young people, parents, and faculty  
55 have been ignored by administrators and mandate proponents.

56  
57 Policymakers, public health scholars and bioethicists have argued both for and against Covid-  
58 19 vaccine mandates. The strongest argument made by mandate proponents is based on the  
59 harm principle: insofar as vaccines prevent transmission and thereby reduce harm to others,  
60 restrictions on individual freedom are viewed as more ethically justifiable.<sup>5</sup> Of course, a  
61 reduction in risk to others (especially if this is a small or temporary effect) might not alone be  
62 sufficient to justify a booster mandate in young people. Savulescu<sup>6</sup> and colleagues<sup>7</sup> have argued  
63 that, to be ethical, mandates require four conditions: that the disease be a grave public health  
64 threat; that there is a safe and effective vaccine; that mandatory vaccination has a superior  
65 cost/benefit profile in comparison to other alternatives; and that the level of coercion is  
66 proportionate.

67  
68 Proportionality is a key principle in public health ethics.<sup>1</sup> To be proportionate, a policy must  
69 be expected to produce public health benefits that outweigh relevant harms, including harms

70 related to coercion, undue pressure, and other forms of liberty restriction. Williams<sup>8</sup> has argued  
71 that Covid-19 vaccine mandates may be justified for older but not younger people, among  
72 whom such policies are not proportionate given a lack of clarity that benefits outweighs harms.  
73 Such ethical assessments should rely on empirical data: thorough risk-benefit assessment  
74 requires quantification (where possible) of relevant risks and benefits *for the group affected by*  
75 *the policy*. With respect to poor outcomes due to Covid-19, the most consistent predictors are  
76 age<sup>9</sup> and comorbidities.<sup>10</sup> Similarly, age and sex are prominent risk factors for vaccine-  
77 associated reactogenicity<sup>11</sup> and serious adverse events such as myocarditis, which is more  
78 common in males.<sup>12</sup> Vaccine requirements must therefore be predicated on an age- and sex-  
79 stratified risk-benefit analysis and consider the protective effects of prior infection.

80

81 In this paper, we provide (to our knowledge) the first risk-benefit assessment of SARS-CoV-2  
82 boosters for young previously *uninfected* adults under 40 years old. Our estimate suggests an  
83 expected net *harm* from boosters in this young adult age group, whereby the negative outcomes  
84 of all severe adverse events and hospitalizations may on average outweigh the expected  
85 benefits in terms of Covid-19 hospitalizations averted. We also examine the specific harms to  
86 males from myo/pericarditis. Our analysis is conservative given the fact that we did not account  
87 for the protective effects of prior infection, which is estimated to be substantive.<sup>13</sup> We then  
88 outline a five-part ethical argument against booster mandates for young people informed by  
89 our empirical assessment. First, we argue that there has been a lack of transparent risk-benefit  
90 assessment; second, that vaccine mandates may result in a net expected harm to individual  
91 young adults; third, that vaccine mandates are not proportionate; fourth, that US mandates  
92 violate the reciprocity principle because of current gaps in vaccine injury compensation  
93 schemes; fifth, that mandates are even less proportionate than the foregoing analyses suggest  
94 because current high levels of coercion or pressure create wider societal harms. We consider

95 possible counterarguments including potential rationales for mandates based on a desire for  
96 social cohesion or safety and summarise why such arguments cannot justify current Covid-19  
97 vaccine mandates. We suggest that general mandates for young people ignore key data, entail  
98 wider social harms and/or abuses of power, and are arguably undermining rather than  
99 contributing to social trust and solidarity.

100

## 101 **2. Background**

102 To provide background for our risk-benefit assessment and ethical arguments, we outline recent  
103 controversies among experts regarding vaccine boosters and summarise current data on Covid-  
104 19 vaccines, specifically: vaccine effectiveness against transmission, effectiveness in those  
105 with prior infection, and the age-stratified risk of severe COVID-19.

106

### 107 **2.1. Controversy Among Experts**

108 The rapidly shifting policy response to the pandemic has exacerbated a crisis in the  
109 *trustworthiness* of scientific institutions, health agencies and regulatory bodies. Transparency  
110 in policy making has been threatened in part by political expediency, sometimes even to the  
111 point of government agencies over-ruling appointed scientific expert groups without clear  
112 explanation of the reasons for such reversals. For example, in July 2021, the CDC released a  
113 joint statement with the FDA<sup>14</sup> reassuring the public that boosters were not necessary. Just two  
114 months later, in September 2021, a US FDA advisory committee overwhelmingly voted 16-2  
115 against boosting healthy young adults.<sup>15</sup> Yet, this recommendation was overruled by the White  
116 House and CDC leading to the resignation of two high-level FDA vaccine experts. These  
117 experts wrote in *The Lancet* about the “...need to identify specific circumstances in which the  
118 direct and indirect benefits of doing so are, on balance, clearly beneficial.”<sup>16</sup> To date, no such  
119 favourable risk-benefit assessment has been made public.<sup>17</sup>

120 Because the mRNA vaccine 3<sup>rd</sup> dose booster trials were too small to measure important clinical  
121 endpoints, additional doses have been granted Emergency Use Authorisation (EUA) based on  
122 observational data suggesting benefits in older populations.<sup>18</sup> Prior to the emergence of the  
123 Omicron variant, the US CDC estimated<sup>18</sup> that administering a booster dose to 9,000 (Pfizer)  
124 or 12,000 (Moderna) 18–29-year-olds would prevent one Covid-19 hospitalisation over six  
125 months. As of August 2022, this estimate has not been updated to reflect increasing natural  
126 immunity or waning vaccine effectiveness. Data on vaccine effectiveness specific to young  
127 adults is scarce, but reports from the UK<sup>19</sup> and Israel<sup>20</sup> failed to identify additional protective  
128 effects of boosters against severe disease for people younger than 40. In a recent CDC  
129 publication, which stratified for ages 18-49, a booster dose increased effectiveness against  
130 emergency department encounters and hospitalizations among immunocompetent adults  
131 during the Omicron wave, but the analysis did not adjust for comorbidities and excluded those  
132 with a history of prior infection “to reduce the influence of protection from previous  
133 infection.”<sup>21</sup>

134

135 Risk-benefit calculations for the primary series among younger children and adolescents are  
136 similarly scant. A cohort study conducted in Hong Kong estimated the number needed to harm  
137 (NNH) from myo/pericarditis for dose two of BNT162b2 was 2563 among adolescent males<sup>22</sup>  
138 yet the CDC never published a U.S.-specific NNH, nor recommended shifting to a one-dose  
139 policy for adolescents as did the UK, Norway, Taiwan and Hong Kong.<sup>22</sup> The most recent  
140 Covid-19 number needed to vaccinate (NNV) calculation conducted by the CDC in June 2022  
141 estimated that 1660 to 3320 children ages 6 months to 4 years would need to be vaccinated to  
142 prevent one hospitalisation; no NNH was offered for comparison.<sup>23</sup> Moreover, the CDC’s  
143 outdated risk-benefit analysis for adolescents and young adults does not distinguish important  
144 subgroups such as or those who have recovered from previous infection or healthy young

145 people (as opposed to those with comorbidities or immunocompromised status). Finally, many  
146 countries have not required or mandated booster doses for young healthy adults at  
147 universities<sup>24</sup>, suggesting that, at a minimum, there is a diversity of expert views on whether  
148 the expected benefits of such policies outweigh their potential harms.

149

## 150 **2.2. Current Data Regarding Covid-19 vaccines**

151 A thorough *ethical* evaluation of risks and benefits requires relevant *empirical* data, especially  
152 where risks and benefits can be quantified to a reasonable degree of certainty. Relevant data  
153 include not only those regarding average individual vaccine safety and effectiveness but also  
154 age-stratification of these data as well as the protective effect of prior infection and the  
155 effectiveness of vaccines against transmission.

156

157 Proponents of mandates have argued that current vaccines “prevent transmission,” which  
158 would support a standard ethical reason in favour of mandates: the protection of others. Yet it  
159 is increasingly clear that current vaccines provide, at most, partial and transient protection  
160 against infection, which decreases precipitously after a few months<sup>25,26</sup>, with secondary  
161 transmission largely unaffected (in other words: an infected vaccinated person poses similar  
162 risks to others as an infected unvaccinated person).<sup>27,28</sup> The CDC states: “anyone with Omicron  
163 infection, regardless of vaccination status or whether or not they have symptoms, can spread  
164 the virus to others.”<sup>29</sup> It is therefore inaccurate to infer a sustained or long-term reduction in  
165 transmission from a short-term reduction in infection.<sup>30</sup>

166

167 A second limitation is ignoring the protective effects of prior infection. In February 2022, the  
168 CDC estimated that 67% of adults 18-49 had infection-induced SARS-CoV-2 antibodies, up  
169 from 30% in September 2021.<sup>13</sup> By now (August 2022), the majority of young adults, both

170 vaccinated and unvaccinated, have most likely already been infected with Covid-19. Evidence  
171 increasingly shows that prior SARS-CoV-2 infection provides at least similar clinical  
172 protection to current vaccines<sup>31-33</sup>, something that is not acknowledged in current university  
173 policies. It is not clear whether vaccination of previously infected individuals provides any  
174 meaningful benefits with respect to severe disease, especially for healthy young people.<sup>34</sup>

175

176 Mass vaccination had been proposed as a way to “end the pandemic.”<sup>35</sup> However, elimination  
177 or eradication of the virus is not a tenable goal with vaccines that provide only temporary and  
178 incomplete reduction in infection risk, and the presence of multiple animal reservoirs. Because  
179 of this, nearly all human beings will eventually be infected with SARS-CoV-2, as with other  
180 endemic coronaviruses (and every pandemic influenza virus on record), many times in their  
181 lifetime.<sup>36</sup> Denmark has, for example, acknowledged vaccinating children was not effective at  
182 curbing spread of the virus and is thus no longer recommending vaccination against Covid-19  
183 for most children.<sup>37,38</sup>

184

185 A final point relates to the burden of Covid-19 in young adults under 40. Using pre-vaccine era  
186 mortality data from 190 countries, an adjusted infection fatality ratio (IFR) for 18 to 29 year-  
187 olds ranges from 100 per million (18 year-olds) to 500 per million (29 year-olds) with  
188 significant variation by country within each age stratum.<sup>39</sup> During the Omicron surge, and  
189 stratified by vaccination status, the CDC’s maximum reported crude mortality incidence rate  
190 (IR) for 18-29 year-olds was 1 per million among the vaccinated and 5 per million among the  
191 unvaccinated.<sup>40</sup> Taking population immunity into account with variant severity and projected  
192 coincident surges of influenza, SARS-CoV-2, and respiratory syncytial virus in the winter of  
193 2022-2023, the UK’s Joint Committee on Vaccination and Immunisation (JCVI) currently  
194 recommends for its fall booster campaign that the following groups at high risk for severe

195 outcomes be *offered* a booster: residents and staff in care homes for older adults; frontline  
196 healthcare and social care workers; adults over 50 years; people aged 5 to 49 years in a clinical  
197 risk group or living with someone who has immunosuppression; and persons age 16 to 49 who  
198 are care givers.<sup>41</sup> Both vaccination and prior infection can substantially reduce the likelihood  
199 of mortality<sup>32,33,41</sup> but the protection against hospitalisation afforded by a booster wanes at 15  
200 weeks to an estimated 80% during BA.1 and 56.5% during for BA.2.<sup>42</sup> Using a national  
201 population-wide dataset in Qatar, both previous infection alone and vaccination alone were  
202 found to provide >70% protection against severe, critical or fatal Omicron (BA.1 or BA.2).<sup>43</sup>  
203 Prior infection alone was 91% effective whereas protection from two or three doses of vaccine  
204 alone was 66% and 83%, respectively. Covid-19 does cause acute illness, and may have long-  
205 term effects for some, particularly those who develop critical illness, but vaccination appears  
206 to confer at best modest protection against longer-term sequelae<sup>44</sup> and the existing data are non-  
207 randomized, from variants that predate Omicron and with unclear relevance for current adults  
208 under age 40. The existence of effective treatments for clinical management<sup>45</sup> is also an  
209 argument against vaccine mandates, especially for groups not considered at risk for severe  
210 illness.

211

### 212 **3. Risk-Benefit Assessment**

213 In a recent editorial, vaccine developer and paediatrician Paul Offit<sup>34</sup> argued that “because  
214 boosters are not risk-free, we need to clarify which groups most benefit....It is now incumbent  
215 on the CDC to determine who most benefits from booster dosing and to educate the public  
216 about the limits of mucosal vaccines.”<sup>1</sup> Below, we provide an Omicron-specific risk-benefit  
217 assessment of booster vaccination for young adults ages 18 to 29 years for both Pfizer

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<sup>1</sup> Offit recommended that his own son not receive a booster dose due to concerns that benefits would not outweigh risks [<https://www.theatlantic.com/health/archive/2022/01/should-teens-get-booster-omicron/621222/>].



218 (BNT162b2) and Moderna (mRNA-1273) vaccines. This analysis builds on the first stratified  
219 risk-benefit analysis of vaccination among adolescents 12-17 years of age which considered  
220 age, sex, health status, virulence of the dominant variant, and population prevalence of post-  
221 infection immunity.<sup>46</sup> For the booster among young adults ages 18-29, the calculations leverage  
222 the CDC's pre-Omicron number needed to vaccinate, the estimated reduction in severity of  
223 Omicron vs Delta<sup>47</sup>, and current estimated seroprevalence.<sup>13</sup> While harms from Covid-19  
224 vaccines are rare<sup>48</sup> they should be factored into policy recommendations. This risk-benefit  
225 analysis considers the overall rate of reported SAEs and grade  $\geq 3$  reactogenicity (Figure 1) and  
226 myo/pericarditis among males (Figure 2). Rates and definitions are consolidated in Table 1.

227

228 Serious adverse events are defined by the FDA and the National Institutes of Health<sup>49</sup> as an  
229 adverse event that results in any of the following conditions: death; life-threatening at the time  
230 of the event; inpatient hospitalisation or prolongation of existing hospitalisation; persistent or  
231 significant disability/incapacity; a congenital anomaly/birth defect; or a medically important  
232 event, based on medical judgement. Grade 3 or 4 reactogenicity is defined as local/systemic  
233 events that prevent daily routine activity or require use of a pain reliever (grade 3) or requiring  
234 an emergency room visit or hospitalisation (grade 4).<sup>49,50</sup>

235

236 To estimate the expected harms (SAEs including myocarditis and grade  $\geq 3$  reactogenicity) and  
237 benefits (Covid hospitalizations prevented) specific to boosting 18–29-year-old young adults,  
238 we used data reported by CDC from phase 2/3 clinical trials<sup>18,50-52</sup>, peer-reviewed observational  
239 data from large integrated health systems<sup>53-57</sup>, post-marketing surveillance collected via V-Safe  
240 by the CDC<sup>58</sup>, and an international estimate in a young adult population.<sup>54</sup>

241

242

243 **3.1. Serious adverse event (SAE) rates reported from manufacturer-provided data**

244

245 Of the 12 SAEs reported by Pfizer in the booster trial (n=5055), three were found by blinded  
246 investigators to be attributable to the vaccine, providing a rate of 1 in 1685 (3/5055)<sup>18</sup> as the  
247 lower bound while the upper bound is drawn from the CDC’s Grading of Recommendations,  
248 Assessment, Development, and Evaluation (GRADE) review which reported a rate of 1 in  
249 306.<sup>50</sup> For a campus of 30,000 boosted with the Pfizer product, the expected SAE rate is  
250 therefore 18 (3/5055\*30,000) to 98 (1/306\*30,000). Surprisingly, Moderna found that none of  
251 the 5 SAEs experienced by 4 out of 344 participants<sup>50</sup> in its open-label booster trial  
252 (4/344=1.2%)<sup>2</sup> were attributable to the vaccine, thus our SAE estimates are for Pfizer only.

253

254 **3.2. Reactogenicity rates**

255

256 According to self-report data, side effects from the booster dose prevent up to a third of  
257 recipients from being able to carry out normal daily activities in the days following  
258 vaccination.<sup>55</sup> Sponsor-reported rates for grade  $\geq 3$  reactogenicity are 1 in 22 (14/306)<sup>50</sup> for the  
259 Pfizer booster to 1 in 9 (18/167)<sup>50</sup> for the Moderna booster. For a campus of 30,000 boosted  
260 previously uninfected young adults, the expected number of grade  $\geq 3$  reactogenicity cases is  
261 therefore 1373 (14/306\*30,000) to 3234 (18/167\*30,000), respectively. In those with a prior  
262 SARS-CoV-2 infection, post-vaccination symptoms causing missed work or daily activities are  
263 reported two- to three-fold more often than those without a history of infection<sup>56,57</sup>, a major  
264 concern given that seroprevalence among adults aged 18-49 is now well above the February  
265 2022 estimate of 67%.<sup>13</sup> Conservatively assuming 67% as the proportion with a history of

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<sup>2</sup> [Table 3e footnote h](#): Overall, 4/344 (1.2%) participants experienced 5 SAEs during a median follow-up of 5.7 months after booster dose (administered at least 6 months after a 50 mcg (n=173) or 100 mcg (n=171) 2-dose primary series); the sponsor deemed these unrelated to mRNA-1273. Data on an equivalent primary series comparison group was not available at the time of the GRADE assessment.

266 Covid-19 infection, and a two- to threefold increased likelihood of systemic effects, expected  
267 grade  $\geq 3$  reactogenicity cases would be at least 1839 to 4333 for Pfizer and Moderna boosters,  
268 respectively. Even without taking into account prior infection, the proportion reporting to V-  
269 Safe being “unable to perform daily activities” was between 20-40% depending on booster  
270 product, and higher among those receiving a heterologous booster.<sup>58</sup>

271

### 272 **3.3. Booster vaccine-associated myocarditis rates in university-age males 18-29 years**

273

274 The CDC estimated the rate of post-booster myocarditis during days 0 to 7 following  
275 BNT162b2 vaccine administration in 16–17 year-old males to be 1 in 41,500<sup>51</sup> using passive  
276 surveillance through the Vaccine Adverse Event Reporting System (VAERS), and 1 in 5000<sup>51</sup>  
277 using active surveillance with the Vaccine Safety Datalink (VSD). In 18–29 year-old males,  
278 the post-booster myocarditis rate for both products combined using VAERS was reported to be  
279 1 in 101,000<sup>52</sup> (ages 18–24) to 1 in 208,000<sup>52</sup> (ages 25–29) while the VSD rate was much higher  
280 at 1 in 14,200<sup>52</sup> (mRNA-1273) to 1 in 21,000<sup>52</sup> (BNT162b2). Two other population-based  
281 studies from the US and Israel in 18–24-year-old males found the rate to be 1 in 7000<sup>53</sup> to  
282 9000.<sup>54</sup> In both of these studies, BNT162b2 was the vaccine administered prior to diagnosis.  
283 For our estimates, and assuming a precautionary stance, we have used active surveillance rates  
284 or population-based rates. For 16–17 year old males we use the VSD rate of 1 in 5000<sup>51</sup>; for  
285 18–29 year olds we consider the rate 1 in 7000<sup>53</sup> to be the most reliable because the same  
286 method was used to estimate the dose-two myocarditis rate for adolescents ages 12–17<sup>59</sup>, based  
287 on CDC definitions and databases, and was consistent with international estimates for this age  
288 group.<sup>46</sup> We provide a 16–17 year-old rate given that academic acceleration allows younger  
289 adults to attend college along with the freshman cohort. In our figures, we provide a range of  
290 myopericarditis estimates for consideration.

291 **3.4. Hospitalizations prevented**

292

293 To estimate the benefits of hospitalizations prevented by boosters, we updated the CDC's  
294 estimated number needed to vaccinate (NNV)<sup>18</sup> for a strain such as Omicron which was found  
295 to be approximately 59% less virulent<sup>47</sup> than Delta. Scaling the CDC's NNV estimates of 9,000  
296 for BNT162b2 and 12,000 for mRNA-1273 by this reduced severity, we estimate that 22,000  
297 (9000/0.41) to 30,000 (12,000/0.41) young adults would need to be boosted with BNT162b2  
298 or mRNA-1273, respectively, to prevent one Covid-19 hospitalisation over six months.

299

300 **3.5. Risk-benefit estimates**

301

302 At this scale, and as shown in Figure 1, a hypothetical campus with 30,000 young adults  
303 receiving the BNT162b2 booster could expect *more* SAEs (18 to 98) than Covid-19  
304 hospitalizations averted (1.0-1.4). Our hypothetical campus may also expect 1373 to 3234  
305 young adults (rate of 1 in 9-22<sup>50</sup>) to experience Grade  $\geq 3$  reactogenicity disrupting daily  
306 activities or requiring medical care when vaccinated with BNT162b2 or mRNA-1273,  
307 respectively. Given that prior SARS-CoV-2 infection increases the rate of systemic reactions  
308 by two- to three-fold<sup>56,57</sup>, the number of young adults expected to experience disruptions in  
309 their school and daily activities is likely to exceed 1839 with BNT162b2 and 4333 with mRNA-  
310 1273.

311

312 If the 15,000 males and 15,000 females ages 18-29 years on the hypothetical campus were all  
313 boosted under a universal mandate, we estimate between 1.7 to 3.0 occurrences of myocarditis  
314 (rates of 1 in 7,000<sup>53</sup> to 1 in 5000<sup>51</sup>) among males and 0.7 cases among females.<sup>51</sup> Boosting the

315 entire campus could thus cause approximately 3-4 myo/pericarditis cases, among males  
316 predominantly, per single hospitalisation averted. (Figure 2)

317

318 Most media reports, as well as a recent systematic review<sup>60</sup> and expert opinion from the  
319 American College of Cardiology<sup>61</sup> present vaccination-associated myo/pericarditis as rare,  
320 (typically) “mild” and followed by rapid recovery with anti-inflammatory treatment. The  
321 reviews have not framed vaccine-associated risks versus infection-associated risks using  
322 compatible denominators based on exposure (vaccination) and infection (seroprevalence), thus  
323 the infection-associated risks may have been overstated by at least a factor of four according  
324 to CDC estimates of the burden of Covid-19 illness.<sup>62</sup> However, it has been found to occur in  
325 as many as 1 in 2652 males aged 12–17 years old and 1 in 1862 males aged 18–24 years old  
326 after the second dose<sup>59</sup> (and as high as 1/1300 after the second dose in a Pfizer-Moderna  
327 combination).<sup>63</sup> An Israeli study described 1 in 5 cases among 16–29 year-olds to be of  
328 intermediate severity, meaning these cases had persistent new/worsening abnormalities in left  
329 ventricular (LV) function, or persistent ECG anomalies, or frequent non-sustained ventricular  
330 arrhythmias without syncope.<sup>64</sup> The CDC reported that 1200 of the 1314 verified myocarditis  
331 cases with known hospitalisation status following primary series or booster had been  
332 hospitalized.<sup>65</sup> Among adolescents, 69%<sup>66</sup>-80%<sup>67</sup> of those diagnosed with vaccine associated  
333 myopericarditis had findings consistent with cardiac scarring on MRI testing three to eight  
334 months after the second dose. The potential long-term impact of scar tissue on heart conduction  
335 remains unknown.<sup>66,67</sup> Post-vaccination myocarditis has been found to be equivalent to or  
336 exceed the risk of post-Covid myocarditis in males less than 40 years old despite the lack of  
337 seroprevalence-based estimates of Covid-associated myocarditis.<sup>68</sup> Rare incidences of death in  
338 young males attributed to mRNA vaccine induced myocarditis have also been reported.<sup>69,70</sup>

339

340 **Table 1. Risk-benefit analysis inputs: definitions and rates for serious adverse events (SAEs), reactogenicity, and myo/pericarditis**

341

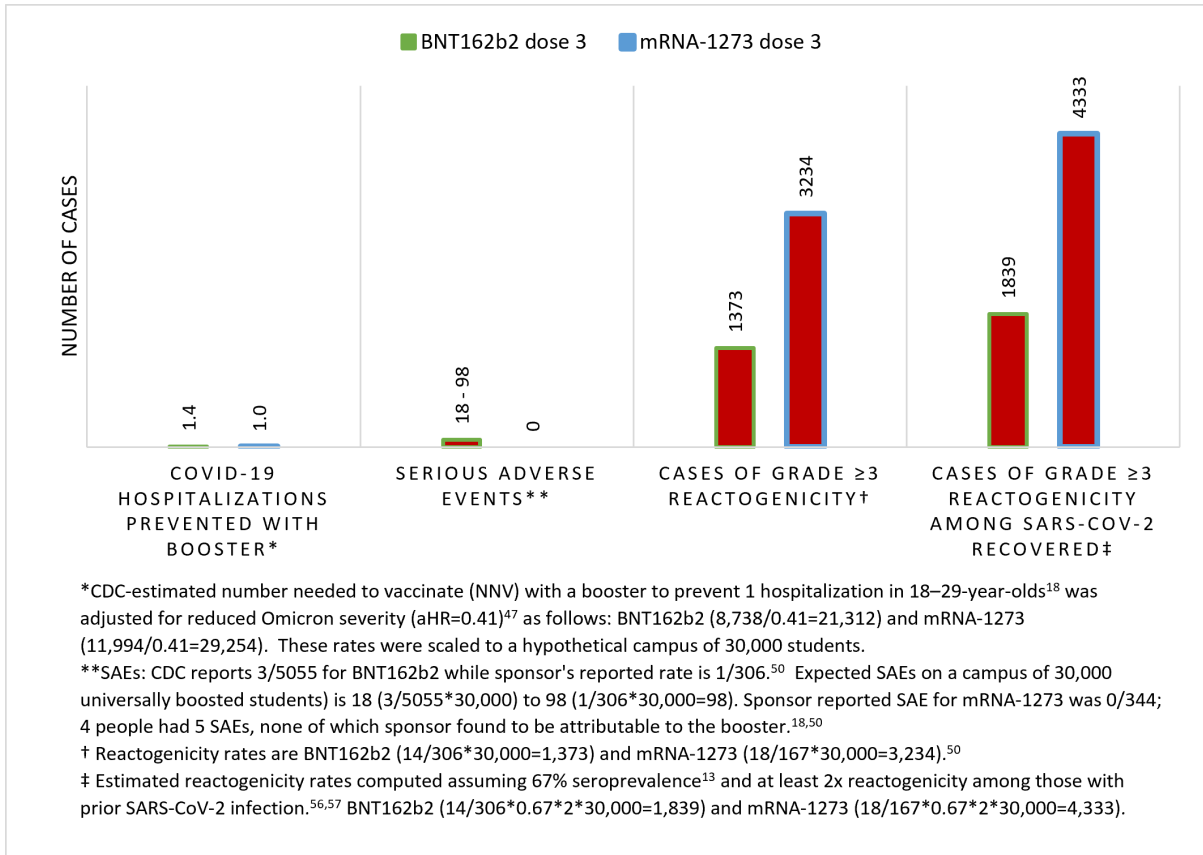
Rate	Definition	Numerator/Denominator		Risk	
Serious Adverse Events (SAEs)	An adverse event that results in any of the following conditions: death; life-threatening at the time of the event; inpatient hospitalisation or prolongation of existing hospitalisation; persistent or significant disability/incapacity; a congenital anomaly/birth defect; or a medically important event, based on medical judgement.	Pfizer: <a href="#">3 / 5055</a> <sup>18</sup> Slide 26		1 in 1685	
		Pfizer: <a href="#">1 / 306</a> <sup>50</sup> Table 4a		1 in 306	
		Moderna: <a href="#">0 / 171</a> <sup>*50</sup> Table 4b			
Reactogenicity	Grade 3 or 4 reactogenicity is defined as local/systemic events that prevent daily routine activity or require use of a pain reliever (grade 3) or requiring an emergency room visit or hospitalisation (grade 4).	Pfizer: <a href="#">14 / 306</a> <sup>50</sup> Table 3f		1 in 22	
		Pfizer: <a href="#">19 / 289</a> <sup>50</sup> Table 4a		1 in 15	
		Moderna: <a href="#">18 / 167</a> <sup>50</sup> Table 3f, 4b		1 in 9	
Myo/pericarditis	<p><a href="#">CDC case definitions</a><sup>17</sup></p> <p><b>Myocarditis</b></p> <p><u>Probable</u></p> <p>1. Presence of ≥1 new or worsening of the following clinical symptoms:*</p> <ul style="list-style-type: none"> <li>-Chest pain/pressure/discomfort</li> <li>-Dyspnea/shortness of breath</li> <li>-Palpitations</li> </ul> <p>2. Abnormal testing</p> <ul style="list-style-type: none"> <li>-Elevated troponin</li> <li>-ECG or EKG findings</li> </ul>	<p><u>Confirmed</u></p> <p>1. Symptoms</p> <ul style="list-style-type: none"> <li>-Chest pain/pressure/discomfort</li> <li>-Dyspnea/shortness of breath</li> <li>-Palpitations</li> </ul> <p>2. Abnormal testing</p> <ul style="list-style-type: none"> <li>-Biopsy</li> </ul>	<p><b>Males Booster</b></p> <p><b>Ages 18-29</b></p> <p><a href="#">147/mill</a><sup>53</sup></p> <p>Sharff et al</p> <p><a href="#">112.5/mill</a><sup>54</sup></p> <p>Friedensohn et al (IDF)</p> <p>Pfizer (VAERS):</p> <p>18-24 <a href="#">9.9/mill</a><sup>52</sup></p> <p>25-29 <a href="#">4.8/mill</a><sup>52</sup></p>	<p><b>Females Booster</b></p> <p><b>Ages 18-29</b></p> <p>n/a</p> <p>n/a</p> <p>Pfizer (VAERS):</p> <p>18-24 <a href="#">0.6/mill</a><sup>52</sup></p> <p>25-29 <a href="#">2.0/mill</a><sup>52</sup></p>	<p>Male: 1 in 6800</p> <p>Male: 1 in 8900</p> <p>Male: 1 in 101k</p> <p>Female: 1 in 1.7 mill</p> <p>Male: 1 in 208k</p>

Rate	Definition		Numerator/Denominator		Risk
	-Decreased function on ECHO or MRI -cMRI findings consistent with myocarditis 3. No other identified cause  <b>Pericarditis</b> Presence of $\geq 2$ new or worsening of the following clinical features: -acute chest pain -pericardial rub on exam -new ST-elevation or PR-depression on EKG -new or worsening pericardial effusion on ECHO or cMRI	-Elevated troponin AND MRI findings consistent with myocarditis 3. No other identified cause	slide 11  Pfizer (VSD): <a href="#">47.6/mill</a> <sup>52</sup> slide 23  Moderna (VSD): <a href="#">70.3/mill</a> <sup>52</sup> slide 23  <b>Ages 16-17</b>  Pfizer (VAERS): <a href="#">24.1/mill</a> <sup>51</sup> slide 10  Pfizer (VSD): <a href="#">200.3/mill</a> <sup>51</sup> slide 25	slide 11  Pfizer (VSD): <a href="#">4.7/mill</a> <sup>52</sup> slide 23  Moderna (VSD): <a href="#">13.9/mill</a> <sup>52</sup> slide 23  <b>Ages 16-17</b>  Pfizer (VAERS): <a href="#">0.0/mill</a> <sup>51</sup> slide 10  Pfizer (VSD): <a href="#">44.0/mill</a> <sup>51</sup> slide 25	Female: 1 in 500k  Male: 1 in 21k Female: 1 in 213k  Male: 1 in 14k Female: 1 in 72k  Male: 1 in 41.5k Female: 0  Male: 1 in 5000 Female: 1 in 23k

342 \*Footnote from GRADE: Overall, 4/344 (1.2%) participants experienced 5 SAEs during a median follow-up of 5.7 months after booster dose (administered at least 6 months  
 343 after a 50 mcg (n=173) or 100 mcg (n=171) 2-dose primary series); the sponsor deemed these unrelated to mRNA-1273. Data on an equivalent primary series comparison  
 344 group was not available at the time of the GRADE assessment.  
 345

346 **Fig 1: Expected Serious Adverse Events (SAEs) and Grade  $\geq 3$  Reactogenicity Per Single**  
 347 **Hospitalisation Prevented with Universal Booster Vaccination on a Large University**  
 348 **Campus of 30,000 Students**

349



350

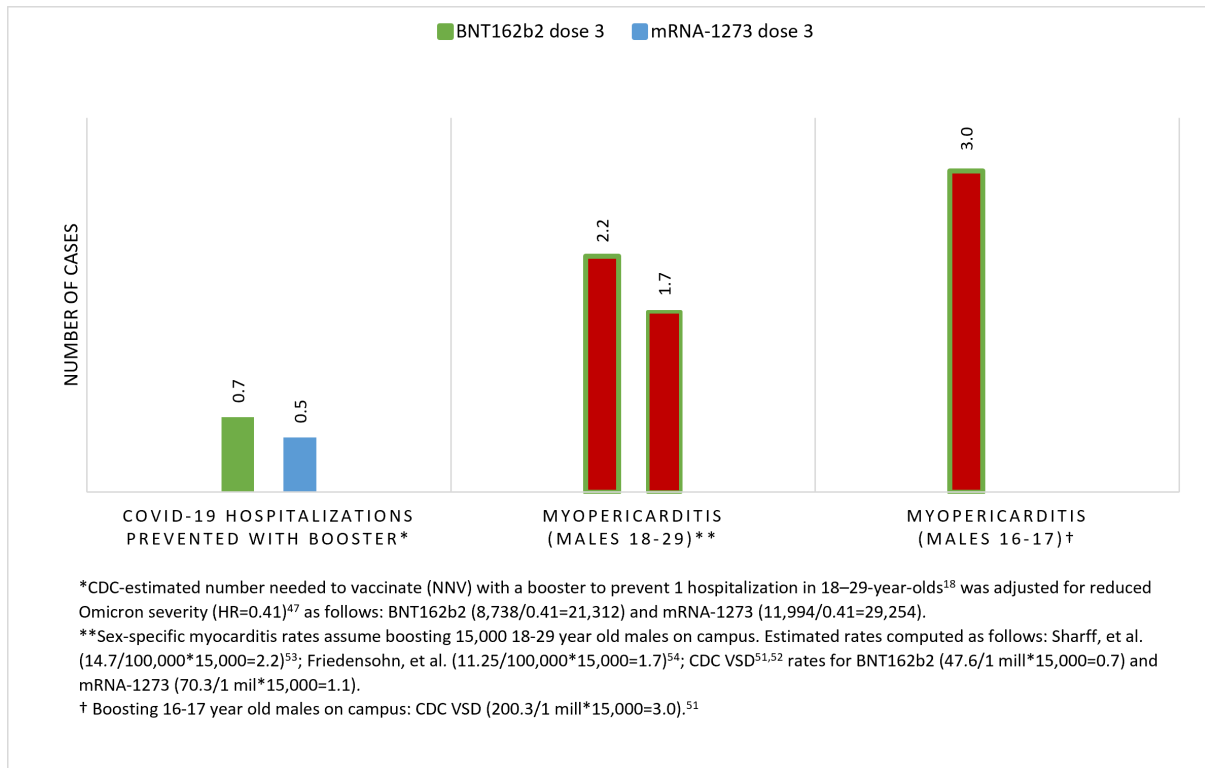
351

352



353 **Fig 2: Expected Myopericarditis Cases per Single Hospitalisation Prevented with**  
 354 **Universal Booster Vaccination on a Large University Campus with 30,000 Students**  
 355 **(15,000 Males)**

356



357

358

### 359 3.6. Limitations of analysis

360

361 These estimates have a number of limitations. First, our estimates rely on sponsor-reported and  
 362 CDC summaries of adverse events; we cannot account for failures to report or loss to follow-  
 363 up during the clinical trials. Second, we do not distinguish between specific types or clinical  
 364 significance of SAEs because of scarce data, including the small sample size of the original  
 365 booster clinical trials and the inability to verify reasons for participant loss to follow-up, which  
 366 may have been due to unreported SAEs. The Pfizer trial, for example, included only 78  
 367 individuals 16–17 years of age randomised to receive booster or placebo.<sup>71</sup> Nevertheless one

368 male in this age group was diagnosed with myocarditis. It is also possible that multiple severe  
369 side-effects were reported by the same participant and that the number of people impacted by  
370 such reactions is lower than our estimate. We are extrapolating SAE data to young adults (18–  
371 29 years old) that were originally generated in clinical trials involving all age groups. However,  
372 studies have shown that younger people have a greater likelihood of vaccine-related adverse  
373 events.<sup>72</sup> The three vaccine-associated SAEs reported by Pfizer were moderate persistent  
374 tachycardia, moderate transient elevated hepatic enzymes, and mild elevated hepatic  
375 enzymes.<sup>18</sup> Hence, the causal relationship between our estimated SAEs and the Covid-19  
376 vaccines needs to be approached with caution. Haas et al.<sup>73</sup> suggested that many systemic AEs  
377 in the RCTs (76% of systemic and 24% of local reactogenicity) may have been due to a nocebo  
378 effect—*anxiety, expectations and background symptoms*. It is very likely, however, that real-  
379 world severe or serious AEs may be greater than those reported in the RCT data because  
380 standard trials are underpowered to detect rare AEs and there may also be selection bias: those  
381 with greater expectation of harmful side effects are less likely to enrol in a trial. In fact, these  
382 data are usually collected after a drug has been approved and is on the market (phase IV clinical  
383 trial data). Such limitations show the need for more robust post-marketing data and ideally  
384 large, controlled trials to determine costs and benefits for any future booster doses, especially  
385 in younger age groups. Universities have not recorded cumulative adverse event rates on their  
386 Covid-19 dashboards, thus there is no way to validate our estimates with real-world data. Even  
387 with the residual uncertainties, our risk-benefit assessment shows that it is at least plausible  
388 that expected individual harms outweigh benefits for young healthy people (i.e., most young  
389 adults), and it is implausible that individual benefits significantly outweigh risks. Pfizer’s  
390 public data supports this inference.<sup>72</sup> In requesting the EUA for boosting adolescent males, the  
391 Pfizer’s risk-benefit analysis estimated 23-69 cases of myocarditis per one million booster  
392 doses administered and 29-69 hospitalizations averted, yet this estimate of 23-69 cases of

393 myocarditis per million third doses administered is now known to be an order of magnitude  
394 below the 200.3 per million reported by the US CDC among adolescents aged 16–17 years.<sup>51</sup>

395

#### 396 **4. Five ethical arguments against university booster mandates**

397

398 Below, we present five ethical arguments against university booster mandates informed by our  
399 risk-benefit assessment and ethical analysis of mandatory policies to date. These arguments  
400 relate to (1) the importance of transparency in policy (which has been lacking), (2) the potential  
401 for net individual harm, (3) the lack of a proportionate public health benefit, (4) the lack of  
402 reciprocity in terms of compensation for vaccine-related harms, and (5) the wider social harms  
403 of vaccine mandates.

404

##### 405 **4.1. Transparency**

406 Risk-benefit assessment is essential to the ethical acceptability of public health policy, and  
407 transparent assessments help maintain trust in public health, especially in the context of  
408 controversial policies. There is an even stronger rationale for thorough and transparent risk-  
409 benefit assessment when interventions are mandated or when (given uncertainty or relevant  
410 population differences) some people might face harms not outweighed by individual benefits.  
411 In such cases, risk-benefit assessments should be stratified by demographic factors and updated  
412 as new data become available to reduce uncertainty. At a minimum, if an intervention is  
413 implemented despite significant uncertainty (especially if it is mandated), there is a strong  
414 ethical rationale to collect (controlled) data to resolve relevant uncertainties.

415

416 It is arguably negligent that key institutions such as the CDC and FDA have not conducted a  
417 risk-benefit assessment either before or after recommending that all adults *should* receive a

418 booster dose. Without such a formal analysis, professional associations (such as the American  
419 College of Cardiology (ACC) expert panel<sup>61</sup>) have been forced to infer from the literature and  
420 CDC's own analyses. For example, the ACC expert panel produced a graphic displaying a  
421 favourable harms vs. benefits ratio for young adults ages 12-29.<sup>61</sup> The ACC's widely promoted  
422 graphic is tied to data presented by the CDC<sup>74</sup> and relies on four key assumptions which  
423 necessarily bias the findings in favour of vaccination: 1) vaccine effectiveness of 95% over 120  
424 days to prevent Covid-19 cases and hospitalizations; 2) myocarditis rates were derived from  
425 passive surveillance in VAERS instead of active surveillance available to the CDC (VSD)  
426 resulting in harms being underestimated by a factor of 10<sup>51,52</sup>; 3) harms and benefits were  
427 averaged across ages 12–29 when the risk may be highest among those aged 16–19<sup>51,52</sup>; and 4)  
428 hospitalisation rates were tied to May 2021 data, more than a year prior to the ACC's review  
429 and pre-Omicron. Nevertheless, for adolescent males ages 12–17, the CDC estimated 56-69  
430 myocarditis cases would be expected while 71 ICU admissions could be averted.<sup>74</sup>

431  
432 It was foreseeable that the decision to approve boosters (against the advice of the FDA panel)  
433 would be followed by booster mandates since pandemic vaccine mandates were already in  
434 place in many universities and colleges throughout the United States at the time.<sup>13</sup> Universities  
435 rely upon public health agencies such as the CDC for guidance. Thus, we maintain that if  
436 mandates remain then there is an ethical obligation for the agency (and independent scientists)  
437 to update public NNV estimates for boosters among adults younger than 40, stratified by sex,  
438 comorbidity status and history of infection to provide evidence that the intervention confers an  
439 expected net benefit to individuals younger than 40 years in the context of the prevailing SARS-  
440 CoV-2 variants and pre-existing immunity. Without this, it is problematic to simply claim that  
441 Covid-19 vaccines are “safe and effective” without specific risk-benefit analyses for different  
442 age categories and with consideration for individual health status, including evidence of prior

443 infection, because risks of both disease and vaccination are highly variable according to these  
444 factors.<sup>9,10</sup>

445

446 Since there has not been any RCT specific to evaluating boosters in young adults, the CDC  
447 relied on data from an older cohort with a median age of 51.<sup>71,75</sup> and perhaps assumed that the  
448 benefits would also outweigh risks for younger age groups. As we have shown, it is likely that  
449 this assumption is incorrect. Under such uncertainties, ethical vaccine policymaking arguably  
450 requires radical transparency about scientific knowledge and uncertainties regarding vaccine  
451 risks and benefits (i.e., even more transparency than where certainty is high).

452

453 Transparent policymaking can encounter a “trust paradox” in providing information about  
454 vaccine risks to the public. As noted by Petersen, et al.<sup>76</sup> governments have a perverse incentive  
455 to withhold negative information about vaccines since they are actively promoting such  
456 products and negative information about vaccines reduces vaccination uptake. And yet  
457 transparent disclosure about negative information (e.g., side effects) helps to sustain trust in  
458 health officials and reduces the politicisation of vaccines.<sup>77</sup> Transparency may reduce the  
459 uptake of vaccination in the short-term but will uphold trust in health authorities and vaccines  
460 in the longer-term—just as open disclosure regarding clinical harms promotes trust in  
461 medicine.<sup>78</sup> Conversely, efforts by the FDA to prevent the release of internal documents and  
462 communications with Pfizer when requested by a civil society group (<https://phmpt.org>)  
463 through a Freedom of Information Act (FOIA) reinforce the view that regulatory agencies are  
464 not being transparent with the public. To address the “trust paradox” in regulatory politics, and  
465 to maintain trust in government and scientific institutions, greater data accountability (in this  
466 case, a risk-benefit analysis) should precede mandates. Given concerns about pharmaceutical

467 influence on the political process<sup>78,79</sup> this should be facilitated by new mechanisms for  
468 independent scrutiny of regulatory science during emergencies.<sup>79</sup>

469

#### 470 **4.2. Potential Net Expected Individual Harm**

471 The reasonable possibility of a net harm to individuals (as presented in our risk-benefit  
472 assessment) should provide a strong basis to argue for the ethical case against booster mandates  
473 for young adults. Mandates at institutions of higher education serve the age group with one of  
474 the lowest public health burdens from Covid-19. Hence boosters provide a low impact on  
475 hospitalisation and a low impact on transmission for an age group with a low prospect of  
476 benefit. Arguably, this has been considered by most universities and colleges and is the reason  
477 why most do *not* have booster mandates for the fall of 2022. In fact, this is likely why European  
478 countries, including the UK, France, Germany and Norway, Sweden and Denmark (to our  
479 knowledge) never had university-implemented mandates.<sup>24</sup> When the European Centre for  
480 Disease Control and Prevention (ECDC) recommended boosters for all adults in November  
481 2021, priority was focused on those over age 40.<sup>80</sup> Taking a different view of the data, the US  
482 CDC recommended boosters for all adults and currently recommends a *second* booster for all  
483 Americans aged 50 years or more.<sup>81</sup> The ECDC, in contrast, recommended that first boosters  
484 be “offered” with prioritisation for those over 40 years, and second boosters only for those over  
485 age 60 and those with an immunocompromised status or high risk medical conditions.<sup>82</sup>

486

487 The UK’s *Joint Committee on Vaccination and Immunisation* (JCVI) provides an interesting  
488 example of using the potential for net harm to advise *against* the primary vaccination series for  
489 12–15-year-olds.<sup>83</sup> The JCVI argued that the potential benefit of vaccination in this age group  
490 was only “marginally greater than the potential known harms,” since healthy 12–15-year-olds  
491 are at very low risk of serious outcomes from Covid-19. Although it may (or may not) be the

492 case that the JCVI adopted worst-case estimates<sup>84</sup>, such an approach reinforces the need to act  
493 judiciously under conditions of uncertainty where the clear benefits of an intervention are not  
494 confidently above the potential harms. Note also that they mention “potential known harms”  
495 without taking into consideration potential long-term effects. The UK Health Ministers  
496 subsequently voted to offer a single dose of vaccination to adolescents ages 12-15 in  
497 consideration of: “...the health and wider social benefits to this cohort.”<sup>85</sup> A second dose was  
498 offered to those with underlying health conditions. There are important parallels between the  
499 JCVI decision and the outcome of the FDA panel that recommended against universal booster  
500 recommendations for adults in the US in the fall of 2021: in both cases, the US and UK  
501 governments went against these recommendations. A key ethical difference is that the UK has  
502 not implemented any Covid-19 vaccine mandates at schools or universities, and the mandate  
503 proposed for care home and healthcare workers was withdrawn.<sup>86</sup>

504

505 As noted above, blanket mandates ignore critical data, such as the benefits of prior infection  
506 and data on adverse effects. These factors make an expected net harm now even more likely  
507 than when mandates began and make it even more urgent to update Covid-19 vaccine policy.  
508 Policies for other vaccines have been updated following the accumulation of new data. For  
509 example, adult boosters for tetanus and diphtheria vaccines (though previously widely  
510 administered) have been shown to provide no benefit.<sup>87</sup> Vaccines for influenza, dengue, and  
511 rotavirus have been withdrawn or had strict limitations placed on their use in children due to  
512 unexpected harms.<sup>88</sup> Adenovirus-vectored Covid-19 vaccines have been limited in their use  
513 due to thrombosis (especially in younger women).<sup>89</sup> Uncertainties remain regarding mRNA  
514 vaccines, for example related to their effects on menstruation<sup>90</sup>, shingles<sup>91</sup>, or the overall safety  
515 of current formulations in younger adults and children as well as evidence in support of booster  
516 vaccination.<sup>92</sup>

517 There are two other theoretical problems that could be factored into mandatory programs from  
518 a precautionary standpoint: original antigenic sin and the non-specific effects of vaccines.  
519 Original antigenic sin refers to the decreased ability of an individual to respond to a new viral  
520 variant because the immune system has been “locked” onto the original immunogen.<sup>93</sup> While  
521 data has not shown this to be true with certainty for Covid-19 it cannot yet be ruled out as an  
522 important side effect of repeat vaccination including with the new bivalent booster. Non-  
523 specific effects of vaccination refers to the effects of a vaccine on overall health and all-cause  
524 mortality, which have been shown to differ based on the type of vaccine (live vs. non-live) and  
525 age/sex.<sup>94,95</sup> Both of these theoretical issues are at the frontiers of our current knowledge of  
526 vaccinology and are rarely considered in the media and by the lay public. We cite these  
527 examples to prove our main point: proportionality of mandates should account for the  
528 precautionary principle in the context of uncertain evidence that benefits outweigh risks and  
529 harms. The net effect of these uncertainties, combined with other factors such as the rising  
530 prevalence of post-infection immunity<sup>13</sup>, is that future risk-benefit assessments of mRNA  
531 vaccines may be even less favourable. Further, with vaccination mandates, young males in  
532 particular are being coerced into assuming a documented, albeit very small, risk of death related  
533 to vaccination<sup>69,70</sup> for, in most cases of booster vaccination, an uncertain individual and societal  
534 benefit.

535

#### 536 **4.3. Lack of proportionate public health benefit**

537 Proportionality, a key principle in public health ethics, requires that the benefits of a public  
538 health policy must be expected to outweigh harms, including harms arising from the restriction  
539 of individual liberty.<sup>1,5-8,86</sup> Where mass vaccination involves harm to a minority of individuals  
540 or coercion or undue inducements are used to increase vaccine uptake, proportionality requires



541 that these considerations be outweighed by public health benefits, typically in the form of  
542 reduced transmission from vaccinated individuals to others.<sup>96</sup>  
543  
544 Covid-19 booster mandates often involve a degree of coercion, including the threat of loss of  
545 access to education and free choice of occupation.<sup>96</sup> Contrary to those who restrict the concept  
546 of coercion to situations of a direct threat to something people should have access to as a matter  
547 of right<sup>97</sup>, we endorse here a broader concept of coercion that includes situations of structural  
548 pressure that deprive people of reasonable options.<sup>98</sup> To be ethically acceptable, such severe  
549 restrictions of individual liberty need to be justified not only by an individual benefit but by  
550 the expectation that vaccination reduces harm to others. Booster doses of Covid-19 vaccines  
551 provide no lasting reduction in the probability of infection or transmission<sup>27-29</sup> and extremely  
552 low expected benefits to young healthy individuals, especially those who have already been  
553 infected.<sup>31-33,100-102</sup> The net expected harms to individuals and the harms of coercive mandates  
554 themselves are not counterbalanced by a large public health benefit; such harms and restrictions  
555 of liberty are therefore disproportionate and ethically unjustifiable.

556

#### 557 **4.4. Failure of Reciprocity**

558 The use of booster mandates raises an additional ethical problem of *reciprocity* for institutions  
559 of higher education and public health authorities.<sup>103,104</sup> Most vaccines are covered in the US<sup>105</sup>,  
560 the Canadian province of Quebec<sup>106</sup>, and 18 other countries<sup>106</sup> by an injury compensation  
561 program based on fair (reciprocal) compensation for those who experience a vaccine-related  
562 harm. Mandatory vaccines arguably require even stronger protections for individuals who  
563 experience harmful consequences that lead to permanent harm<sup>107</sup> because their free choice  
564 regarding vaccination has been limited. While institutions of higher education are mandating  
565 boosters, the US and Canadian compensation programs have failed to uphold their social justice

566 responsibility to injured individuals. In the US, Covid-19 vaccines and therapeutics are  
567 processed by the Countermeasures Injury Compensation Program (CICP) which is designed to  
568 cover epidemics, pandemics and security threats as designated by the Secretary of Health and  
569 Human Services and as authorised by the PREP Act.<sup>105</sup> As of August 1, 2022, 37 claims have  
570 been denied compensation because “the standard of proof for causation was not met” or “a  
571 covered injury was not sustained.”<sup>108</sup> No claims have been paid out by the US CICP but one  
572 claim for anaphylaxis has been approved for compensation and pay-out is currently pending  
573 assessment of eligible expenses.<sup>108</sup>

574

575 It is highly problematic that young adults are being mandated to take a third dose—especially  
576 given the risk-benefit assessment—while the federal US vaccine injury program has failed to  
577 compensate but one Covid-19 vaccine-injured individual.<sup>108</sup> It is also important to note that  
578 boosters have been granted an EUA by the FDA, but are still not fully approved.<sup>109</sup> Universities  
579 and colleges that mandate Covid-19 boosters are pressuring young adults to receive a vaccine  
580 that, in case of injury, has no transparent legal route to adequate compensation. In sum, one  
581 core precondition for vaccine mandates is a functioning and fair compensation program, which  
582 has not been achieved for Covid-19 vaccines.

583

#### 584 **4.5. Wider Social Harms**

585 Strong coercion creates significant social harms. Covid-19 vaccine mandates have often  
586 involved a high degree of coercion, effectively ostracising unvaccinated individuals from  
587 society. University mandates involve significant coercion in that they exclude unvaccinated  
588 people from the benefits of university education (or employment) and thereby entail major  
589 infringements to free choice of occupation and freedom of association. When such mandates  
590 are not supported by a *compelling* public health justification and where exemptions are not

591 easily available, the likelihood of reactance and negative social effects are increased.<sup>1</sup> The  
592 social harms of university Covid-19 mandates have not been formally studied, but there is  
593 reason to think that they may be significant.<sup>1</sup> Policies can have wide-ranging consequences for  
594 non-compliance, such as loss of employment, loss of internet use, restriction to off-campus vs.  
595 on-campus housing, delays or refusal to process student housing requests, loss of enrolment, a  
596 hold placed on grades, inability to use recreational facilities to train for competitive sports or  
597 register for class, and delays in ability to repay student loans post-graduation. A number of  
598 young adults and professors affected by mandates have outlined publicly their perspectives and  
599 the social harms of these policies, such as loss of access to schooling and social services<sup>110</sup>,  
600 psychosocial stress, reputational damage and lost income, and threats of being disenrolled or  
601 deported.<sup>111</sup> This punitive public health approach may also provoke reactance in young adults<sup>1</sup>,  
602 with long-term negative consequences on trust in society and institutions and vaccine  
603 confidence in general, including vaccine hesitancy for routine paediatric and adult vaccines, a  
604 problem which predated the pandemic and is considered one of the World Health  
605 Organization’s top ten “threats to global health.”<sup>112</sup>

606

## 607 **5. Objections: possible rationales for mandates**

608 Despite the considerations above, proponents of university Covid-19 booster mandates might  
609 argue that such policies are justified (even if some individuals experience uncompensated  
610 harms) because they: (i) help *normalize* compliance with vaccination as a social duty (thereby  
611 promoting solidarity or pro-vaccine attitudes that undermine anti-vaccination sentiment) and/or  
612 (ii) help to increase the safety of the university environment or wider society. Mandates may  
613 help some people “feel better,” knowing that everyone in a crowd, dorm, or classroom is  
614 vaccinated, that they are among peers that have “done the right thing” and “care about the  
615 safety of others.” For instance, some faculty and staff may “feel protected” by the new booster

616 mandate introduced at Western University in Ontario, Canada, on August 22, 2022.<sup>113</sup> From  
617 this perspective, if a majority of university policymakers (whether clinical advisory group  
618 members, administrators and/or professors) or students *believe* that vaccination should be  
619 socialised to promote solidarity, counteract anti-vaccination sentiment, or create a safe  
620 environment, then such beliefs (and values) should guide policy.

621

622 However, even if many people hold such beliefs and even if such goals are valuable, policy  
623 must be responsive to facts. Risk-benefit assessments should remain objective and avoid the  
624 use of some people feeling better or safer to justify behavioural rules with sanctions for non-  
625 compliance in the absence of rational justification. While many vaccines do improve group  
626 safety by reducing transmission, the current generation of Covid-19 vaccines do not provide  
627 significant lasting effects of this kind, and repeated doses appear to provide diminishing  
628 benefits (in terms of reduced infection) per dose, especially among young adults.<sup>114</sup> It therefore  
629 makes little sense to claim that Covid-19 vaccination is a pro-social act (or that the  
630 unvaccinated are a disproportionate threat to others). Moreover, it is unclear whether  
631 *mandating* Covid-19 boosters will produce a net positive effect on pro-vaccine sentiment in  
632 society—in fact, booster mandates appear to be associated with an increase in anti-vaccination  
633 beliefs and reduced uptake of other (non-coronavirus) vaccines.<sup>1,86,96</sup> As highlighted above,  
634 there are also wider social harms of policies that purport to reduce transmission of a ubiquitous  
635 virus: such policies may create a fear of infection among young healthy people (out of  
636 proportion to the actual risks) and contribute to worsening mental health which predated the  
637 pandemic.<sup>115</sup>

638

639 Moreover, the claim that the *socialisation* of compliance with public health measures can  
640 justify those measures is problematic for three other reasons. First, such an argument is circular:

641 compliance is not an end itself; policy must be justified by the expectation of public health  
642 benefit. Second, people may have different attitudes to compliance depending on their values  
643 (e.g., the views regarding the importance of individual liberty) and experiences (e.g., those with  
644 low baseline levels of trust in public health due to negative experiences of health professionals  
645 or government agencies). Policies that require people to comply against their values and  
646 preferences require ethical justification, especially where voluntary compliance is likely to be  
647 lower among those who are disempowered (e.g., students) or marginalised for other  
648 reasons<sup>5,116</sup>, for example those from social groups which have been mistreated by government  
649 agencies or by the medical system in the past, including in the context of research.<sup>117</sup> Third, the  
650 socialisation argument is based, in part, on concepts of civic duty and responsibility to others.  
651 Pushing for boosters even when these will not contribute to overall risk reduction runs counter  
652 to the responsible use of public resources. Policies that encourage waste of valuable health care  
653 resources, to make some feel better, are sending a distorted message about important societal  
654 obligations.

655

656 The proclivity for university vaccine mandates may also reflect harmful trends toward  
657 intolerance in university bureaucracies that value compliance over individual freedoms.  
658 Mandates, by their nature, encourage conformity and acquiescence to authority, and exclude  
659 those with different views or values. Though universities might take pride in being places that  
660 permit the free exchange of ideas, mandates reduce the scope for reasoned debate regarding  
661 scientific uncertainties or conflicts of ethical values.<sup>118</sup> For example, how many universities  
662 have held public debates about mandatory Covid-19 vaccination? To our knowledge, very few  
663 such debates have taken place in North American institutions. We are aware of only one  
664 academic event<sup>119</sup> which some of us organised, in which booster mandates were critically  
665 debated. Sanctions for lack of full vaccination imposed on university professors who publicly

666 voiced their opposition against mandates could arguably also have been intended to suppress  
667 public debate or be interpreted as such.

668

669 **6. Implications for Broader Covid-19 Vaccine Mandates for Youth in**  
670 **Schools, and Other Institutions**  
671

672 The arguments presented above are relevant not only to 3<sup>rd</sup>, 4<sup>th</sup>, or 5<sup>th</sup> dose booster mandates  
673 but also to university or school policies that maintain primary two-dose Covid-19 vaccine  
674 mandates in 2022 in the face of high rates of previous SARS-CoV-2 infection. Two dose  
675 mandates are being upheld in at least 1000 universities and colleges across the United States,  
676 far more than the 300 or so maintaining booster mandates<sup>2</sup>, and also some primary and  
677 secondary schools<sup>120</sup> which instituted mandates then extended the deadline when it was  
678 apparent that serious inequities in access to education would result.<sup>121</sup> It is even harder to justify  
679 a two-dose primary vaccine mandate in late 2022 than when such policies began in mid-2021.<sup>46</sup>  
680 Consistent with our argument above, the now high prevalence of prior infection, data regarding  
681 the lack of sustained transmission reduction by current vaccines, and the age at peak risk for  
682 myo/pericarditis being college-bound students ages 17–19 all undermine the case for two-dose  
683 vaccine mandates. We would therefore urge universities and schools to rescind all Covid-19  
684 vaccine mandates. Strong statements in support of mandates made in 2021 by organisations  
685 such as the Association of Bioethics Program Directors in North America<sup>122</sup>, the American  
686 Civil Liberties Union<sup>123</sup>, and the Ontario Human Rights Commission<sup>124</sup> should be updated.  
687 Such organisations have an ethical obligation to revise these public statements and consider  
688 whether they are valid in light of current data.

689

690 The continued policy of two-dose mandates may represent status quo bias: when a rule is  
691 normalised it remains even when it has no (current) rational basis. The more rules, the more

692 paperwork and cumbersome “busy work” that administrators and young students and  
693 professionals need to jump through. Yet rules come with consequences: how much are  
694 universities, corporations, consulting firms and the military paying in staff time to monitor and  
695 maintain vaccine mandates? How much time and energy are young adults using to comply with  
696 these policies? How much frustration and psychosocial stress is this causing? What about  
697 attrition from institutions and the military at times when the labour market and recruitment is  
698 difficult? When vaccine mandates are unethical, individuals may have an ethical duty to oppose  
699 them, in part to promote tolerance and prevent further bureaucratic encroachment and  
700 disenfranchisement of individuals with reasoned arguments against such mandates. Finally, we  
701 argue that institutions have an ethical duty to evaluate the effectiveness of such programs if the  
702 status quo is to be maintained.

703

## 704 **7. Conclusion**

705 Based on public data provided by the CDC<sup>18</sup>, we estimate that approximately 22,000 to 30,000  
706 previous *uninfected* young adults ages 18–29 years must be boosted with an mRNA vaccine to  
707 prevent one Covid-19 hospitalisation. Given the fact that this estimate does not take into  
708 account the protection conferred by prior infection nor a risk-adjustment for comorbidity status,  
709 this should be considered a conservative and optimistic assessment of benefit. Our estimate  
710 shows that university Covid-19 vaccine mandates are likely to cause net expected harms to  
711 young healthy adults—between 18 and 98 serious adverse events requiring hospitalisation and  
712 1373 to 3234 disruptions of daily activities—that is not outweighed by a proportionate public  
713 health benefit. Serious Covid-19 vaccine-associated harms are not adequately compensated for  
714 by current US vaccine injury systems. As such, these severe infringements of individual liberty  
715 are ethically unjustifiable.

716

717 Worse still, mandates are associated with wider social harms. The fact that such policies were  
718 implemented despite controversy among experts and without updating the sole publicly  
719 available risk-benefit analysis to the current Omicron variants suggests a profound lack of  
720 transparency in scientific and regulatory policy making. These findings have implications for  
721 mandates in other settings such as schools, corporations, healthcare systems and the military.  
722 Policymakers should repeal booster mandates for young adults immediately, ensure pathways  
723 to compensation to those who have suffered negative consequences from these policies,  
724 provide open access to participant-level clinical trial data to allow risk- and age-stratified harm-  
725 benefit analyses of any new vaccines prior to issuing recommendations<sup>125</sup>, and begin what will  
726 be a long process of rebuilding trust in public health.

727

728

#### 729 **Conflicts of Interest**

730 We have no interests to declare.

731

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737

738



739 **References**

- 740 1. Bardosh K, de Figueiredo A, Gur-Arie R, Jamrozik E, Doidge JC, Lemmens T, et al. The  
741 Unintended Consequences of COVID-19 Vaccine Policy: Why Mandates, Passports, and  
742 Restrictions May Cause more Harm than Good. *BMJ Global Health* 7:e008684.
- 743 2. Golembeski D. These Are the Colleges Requiring Vaccine Boosters Now. Updated March 18,  
744 2022. Available at [What Colleges Require the COVID-19 Vaccine? | BestColleges](#) Accessed  
745 on August 30, 2022.
- 746 3. Burt C. Calls for end to COVID-19 vaccine booster mandates growing in higher ed. January 21,  
747 2022. Available at [https://universitybusiness.com/calls-for-end-to-covid-19-vaccine-booster-](https://universitybusiness.com/calls-for-end-to-covid-19-vaccine-booster-mandates-growing-in-higher-ed/)  
748 [mandates-growing-in-higher-ed/](https://universitybusiness.com/calls-for-end-to-covid-19-vaccine-booster-mandates-growing-in-higher-ed/) Accessed on March 28, 2022.
- 749 4. Block J. US college covid-19 vaccine mandates don't consider immunity or pregnancy, and  
750 may run foul of the law. *BMJ* 2021; 373:n1397 doi:10.1136/bmj.n1397
- 751 5. World Health Organization. COVID-19 and mandatory vaccination: Ethical considerations:  
752 policy brief. May 30, 2022. Available at [COVID-19 and mandatory vaccination: Ethical](#)  
753 [considerations \(who.int\)](#). Accessed on August 20, 2022.
- 754 6. Savulescu J. Good reasons to vaccinate: mandatory or payment for risk? *J Med Ethics* 2021  
755 Feb;47(2):78-85. doi: 10.1136/medethics-2020-106821. Epub 2020 Nov 5. PMID: 33154088;  
756 PMID: PMC7848060.
- 757 7. Giubilini, Alberto et al. "COVID-19 vaccine: vaccinate the young to protect the old?" *Journal*  
758 *of Law and the Biosciences* 2020(7).
- 759 8. Williams BM. The Ethics of Selective Mandatory Vaccination for COVID-19. *Public Health*  
760 *Ethics* 2021 Dec 15;15(1):74-86. doi: 10.1093/phe/phab028. PMID: 35702643; PMID:  
761 PMC9188377.

- 762 9. Romero Starke K, Reissig D, Petereit-Haack G, Schmauder S, Nienhaus A, Seidler A. The  
763 isolated effect of age on the risk of COVID-19 severe outcomes: a systematic review with  
764 meta-analysis. *BMJ Glob Health*. 2021 Dec;6(12):e006434. doi: 10.1136/bmjgh-2021-006434.  
765 PMID: 34916273; PMCID: PMC8678541.
- 766 10. Choi JH, Choi SH, Yun KW. Risk Factors for Severe COVID-19 in Children: A Systematic  
767 Review and Meta-Analysis. *J Korean Med Sci*. 2022 Feb 7;37(5):e35. doi:  
768 10.3346/jkms.2022.37.e35. PMID: 35132841; PMCID: PMC8822112.
- 769 11. Ughi N, Del Gaudio F, Dicuonzo A, Orso M, Micheloni G, Puoti M, Pani A, Scaglione F,  
770 Zoppini L, Rossetti C, Epis OM, Bellavia G, Girolodi S, Moreno M, Bosio M. Host factors and  
771 history of SARS-CoV-2 infection impact the reactogenicity of BNT162b2 mRNA vaccine:  
772 results from a cross-sectional survey on 7,014 workers in healthcare. *Eur Rev Med Pharmacol*  
773 *Sci*. 2021 Dec;25(24):7985-7996. doi: 10.26355/eurrev\_202112\_27649. PMID: 34982462.
- 774 12. Karlstad Ø, Hovi P, Husby A, Härkänen T, Selmer RM, Pihlström N, Hansen JV, Nohynek H,  
775 Gunnes N, Sundström A, Wohlfahrt J, Nieminen TA, Grünewald M, Gulseth HL, Hviid A,  
776 Ljung R. SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million  
777 Residents. *JAMA Cardiol*. 2022 Jun 1;7(6):600-612. doi: 10.1001/jamacardio.2022.0583.  
778 PMID: 35442390; PMCID: PMC9021987.
- 779 13. Clarke KE, Jones JM, Deng Y, et al. Seroprevalence of Infection-Induced SARS-CoV-2  
780 Antibodies — United States, September 2021–February 2022. *MMWR Morb Mortal Wkly Rep*  
781 2022;71:606-608. DOI: <http://dx.doi.org/10.15585/mmwr.mm7117e3external icon>
- 782 14. Centers for Disease Control and Prevention. Joint CDC and FDA Statement on Vaccine  
783 Boosters. July 8, 2021. Available at <https://www.cdc.gov/media/releases/2021/s-07082021.html>  
784 accessed on August 20, 2022.

- 785 15. Food and Drug Administration. Emergency Use Authorization (EUA) for an Unapproved  
786 Product. September 21, 2021. Available at <https://www.fda.gov/media/152432/download> page  
787 5. Accessed on March 28, 2022.
- 788 16. Krause PR, Fleming TR, Peto R, Longini IM, Figueroa JP, Sterne JAC, et al. Considerations in  
789 boosting COVID-19 vaccine immune responses. *The Lancet* 2021;398(10308): pp1377-1380.  
790 doi: [https://doi.org/10.1016/S0140-6736\(21\)02046-8](https://doi.org/10.1016/S0140-6736(21)02046-8)
- 791 17. Doshi P, Godlee F, Abbasi K. Covid-19 vaccines and treatments: we must have raw data, now.  
792 *BMJ*. 2022;376:o102. Available at <https://www.bmj.com/content/376/bmj.o102.short> Accessed  
793 March 28, 2022.
- 794 18. Oliver S. Updates to the Evidence to Recommendation Framework: Pfizer-BioNTech and  
795 Moderna COVID-19 vaccine booster doses. ACIP Meeting, November 19, 2021. (Slides 26, 29,  
796 30, 31, 37) Available at [https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-  
797 11-19/06-COVID-Oliver-508.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf) Accessed on March 28, 2022.
- 798 19. Andrews, N., Stowe, J., Kirsebom, F. et al. Effectiveness of COVID-19 booster vaccines  
799 against COVID-19-related symptoms, hospitalization and death in England. *Nat Med* (2022).  
800 <https://doi.org/10.1038/s41591-022-01699-1>
- 801 20. Bar-On YM, Goldberg Y, Mandel M, Bodenheimer O, Freedman L, Alroy-Preis S, et al.  
802 Protection against Covid-19 by BNT162b2 Booster across Age Groups. *N Eng J Med* 2021;  
803 385:2421-2430. doi: 10.1056/NEJMoa2115926.
- 804 21. Link-Gelles R, Levy ME, Gaglani M, et al. Effectiveness of 2, 3, and 4 COVID-19 mRNA  
805 Vaccine Doses Among Immunocompetent Adults During Periods when SARS-CoV-2 Omicron  
806 BA.1 and BA.2/BA.2.12.1 Sublineages Predominated — VISION Network, 10 States,  
807 December 2021–June 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:931–939. DOI:  
808 <http://dx.doi.org/10.15585/mmwr.mm7129e1>

- 809 22. Li X, Lai FTT, Chua GT, et al. Myocarditis Following COVID-19 BNT162b2 Vaccination  
810 Among Adolescents in Hong Kong. *JAMA Pediatr.* 2022;176(6):612–614.  
811 doi:10.1001/jamapediatrics.2022.0101.
- 812 23. Oliver S. Evidence to Recommendation Framework: Moderna COVID-19 vaccine in children  
813 ages 6 months – 5 years & Pfizer-BioNTech COVID-19 vaccine in children ages 6 months – 4  
814 years. (Slide 66) June 17, 2022. Available at  
815 [https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-covid-oliver-](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-covid-oliver-508.pdf)  
816 [508.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/03-covid-oliver-508.pdf) accessed on August 20, 2022.
- 817 24. Havergal C. No Plans to Require Vaccines at English Universities. *Inside Higher Ed* August 6,  
818 2021. Available at [https://www.insidehighered.com/news/2021/08/06/no-plans-require-](https://www.insidehighered.com/news/2021/08/06/no-plans-require-vaccines-english-universities)  
819 [vaccines-english-universities](https://www.insidehighered.com/news/2021/08/06/no-plans-require-vaccines-english-universities) Accessed on March 28, 2022.
- 820 25. Andrews N, Stowe J, Kirsebom F, Toffa S, Rickeard T, Gallagher E, et al. Covid-19 Vaccine  
821 Effectiveness against the Omicron (B.1.1.529) Variant. *N Eng J Med*  
822 doi: 10.1056/NEJMoa2119451
- 823 26. Accorsi EK, Britton A, Fleming-Dutra KE, Smith ZR, Shang N, Gordana D, et al. Association  
824 Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the  
825 SARS-CoV-2 Omicron and Delta Variants. *JAMA* 2022;327(7):639–651.  
826 doi:10.1001/jama.2022.0470.
- 827 27. Singanayagam A, Hakki S, Dunning J, Madon KJ, Crone MA, Koycheva A, et al. Community  
828 transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated  
829 and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. *The Lancet*  
830 2021;22(2):183-195. doi: [https://doi.org/10.1016/S1473-3099\(21\)00648-4](https://doi.org/10.1016/S1473-3099(21)00648-4)
- 831 28. Boucau J, Marino C, Regan J, Uddin R, Choudhary MC, Flynn JP, Chen G, Stuckwisch AM,  
832 Mathews J, Liew MY, Singh A, Lipiner T, Kittilson A, Melberg M, Li Y, Gilbert R, Reynolds  
833 Z, Iyer SL, Chamberlin GC, Vyas TD, Goldberg MB, Vyas JM, Li JZ, Lemieux JE, Siedner

- 834 MJ, Barczak AK. Duration of Shedding of Culturable Virus in SARS-CoV-2 Omicron (BA.1).  
835 *N Engl J Med* 2022; 387:275-277. DOI: 10.1056/NEJMc2202092
- 836 29. Centers for Disease Control and Prevention. Omicron Variant: What You Need to Know.  
837 Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html>  
838 Accessed on August 20, 2022.
- 839 30. Mulligan CB, Arnott RD. NON-COVID EXCESS DEATHS, 2020-21: COLLATERAL  
840 DAMAGE OF POLICY CHOICES? National Bureau of Economic Research. June 2022.  
841 Available at [https://www.nber.org/system/files/working\\_papers/w30104/w30104.pdf](https://www.nber.org/system/files/working_papers/w30104/w30104.pdf) Accessed  
842 on August 20, 2022.
- 843 31. Pilz S, Theiler-Schwetz V, Trummer C, Krause R, Ioannidis J.P.A. SARS-CoV-2 reinfections:  
844 Overview of efficacy and duration of natural and hybrid immunity, *Environmental Research*  
845 2022;209:112911. <https://doi.org/10.1016/j.envres.2022.112911>
- 846 32. Wei, J., Pouwels, K.B., Stoesser, N. et al. Antibody responses and correlates of protection in the  
847 general population after two doses of the ChAdOx1 or BNT162b2 vaccines. *Nat Med* 2022;28:  
848 1072–1082. <https://doi.org/10.1038/s41591-022-01721-6>
- 849 33. Nordström P, Ballin M, Nordström A. Risk of SARS-CoV-2 reinfection and COVID-19  
850 hospitalisation in individuals with natural and hybrid immunity: a retrospective, total  
851 population cohort study in Sweden. *The Lancet Infectious Diseases* 2022;22(6):p781-790.  
852 Available at [https://doi.org/10.1016/S1473-3099\(22\)00143-8](https://doi.org/10.1016/S1473-3099(22)00143-8) accessed on August 22, 2022.
- 853 34. Offit PA. Covid-19 Boosters - Where from Here? *N Engl J Med*. 2022 Apr 28;386(17):1661-  
854 1662. doi: 10.1056/NEJMe2203329. Epub 2022 Apr 13. PMID: 35417633; PMCID:  
855 PMC9020580.
- 856 35. Crist, C. Fauci: ‘Many, Many’ More Vaccine Mandates Needed to End Pandemic. WebMD.  
857 September 13, 2021. Available at [Fauci: ‘Many, Many’ More Vaccine Mandates Needed to](https://www.webmd.com/healthcare/news/2021/09/13/fauci-many-many-more-vaccine-mandates-needed-to-end-pandemic)  
858 [End Pandemic \(webmd.com\)](https://www.webmd.com/healthcare/news/2021/09/13/fauci-many-many-more-vaccine-mandates-needed-to-end-pandemic) Accessed on August 30, 2022.

- 859 36. Heriot GS, Jamrozik E. Imagination and remembrance: what role should historical  
860 epidemiology play in a world bewitched by mathematical modelling of COVID-19 and other  
861 epidemics? *Hist Philos Life Sci.* 2021 Jun 7;43(2):81. doi: 10.1007/s40656-021-00422-6.  
862 PMID: 34100155; PMCID: PMC8183318.
- 863 37. Set i bakspejlet fik vi ikke meget ud af at vaccinere børnene, erkender Brostrøm. TV2. June 22,  
864 2022. Available at [Set i bakspejlet fik vi ikke meget ud af at vaccinere børnene, erkender](#)  
865 [Brostrøm - TV 2](#) Accessed on August 30, 2022.
- 866 38. Vaccination mod covid-19. Sundhedsstyrelsen. Available at [Vaccination mod covid-19 -](#)  
867 [Sundhedsstyrelsen](#) Accessed on August 30, 2022.
- 868 39. COVID-19 Forecasting Team. Variation in the COVID-19 infection–fatality ratio by age, time,  
869 and geography during the pre-vaccine era: a systematic analysis. *The Lancet.* 2022;399(10334):  
870 1469-1488.
- 871 40. Centers for Disease Control and Prevention, COVID-19 Response. Rates of COVID-19 Cases  
872 or Deaths by Age Group and Vaccination Status Public Use Data (version date: August 19,  
873 2022).
- 874 41. JCVI statement on the COVID-19 booster vaccination programme for autumn 2022: update 15  
875 August 2022. Available at [JCVI statement on the COVID-19 booster vaccination programme](#)  
876 [for autumn 2022: update 15 August 2022 - GOV.UK \(www.gov.uk\)](#). Accessed on August 22,  
877 2022.
- 878 42. Kirsebom FJM, Andrews N, Stowe J, Toffa S, Sachdeva R, Gallagher E, et al. COVID-19  
879 vaccine effectiveness against the omicron (BA.2) variant in England. *The Lancet Infectious*  
880 *Diseases.* 2022;22(7): 931-933.
- 881 43. Altarawneh HN, Chemaitelly H, Ayoub HH, Tang P, Hasan MR, Yassine HM, et al. Effects of  
882 Previous Infection and Vaccination on Symptomatic Omicron Infections. *New Engl J Med*

883 2022; 387:21-34 DOI: 10.1056/NEJMoa2203965 Available at [Effects of Previous Infection](#)  
884 [and Vaccination on Symptomatic Omicron Infections | NEJM](#) Accessed on August 22, 2022.

885 44. Al-Aly, Z., Bowe, B. & Xie, Y. Long COVID after breakthrough SARS-CoV-2 infection. *Nat*  
886 *Med.* 2022;28:1461–1467. <https://doi.org/10.1038/s41591-022-01840-0>

887 45. Pham B, Rios P, Radhakrishnan A, et al Comparative-effectiveness research of COVID-19  
888 treatment: a rapid scoping review. *BMJ Open* 2022;12:e045115. doi: 10.1136/bmjopen-2020-  
889 045115

890 46. Krug A, Stevenson J, Høeg B. BNT162b2 Vaccine-Associated Myo/Pericarditis in  
891 Adolescents: A Stratified Risk-Benefit Analysis. *Eur J Clinical Inv* 2022;52(5).  
892 <https://doi.org/10.1111/eci.13759>

893 47. Ulloa AC, Buchan SA, Daneman N, Brown KA. Estimates of SARS-CoV-2 Omicron Variant  
894 Severity in Ontario, Canada. *JAMA* Published online February 17, 2022.  
895 doi:10.1001/jama.2022.2274.

896 48. Rosenblum HG, Gee J, Liu R, Marquez PL, Zhang B, Strid P, et al. Safety of mRNA vaccines  
897 administered during the initial 6 months of the US COVID-19 vaccination programme: an  
898 observational study of reports to the Vaccine Adverse Event Reporting System and v-safe, *The*  
899 *Lancet Infectious Diseases* 2022;22(6):802-812. [https://doi.org/10.1016/S1473-3099\(22\)00054-](https://doi.org/10.1016/S1473-3099(22)00054-8)  
900 [8](#)

901 49. National Institutes of Health. National Institute of Allergy and Infectious Diseases. Rules and  
902 Policies for Clinical Research: Safety Reporting and Pharmacovigilance. Available at [Safety](#)  
903 [Reporting and Pharmacovigilance | NIH: National Institute of Allergy and Infectious Diseases](#)  
904 Accessed on August 30, 2022.

905 50. CDC. Grading of Recommendations, Assessment, Development, and Evaluation (GRADE):  
906 Pfizer-BioNTech, Moderna, and Janssen COVID-19 booster doses. October 29, 2021. Available  
907 at <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-booster-doses.html#table-03a>

- 908 51. Shimabukuro T. Update on myocarditis following mRNA COVID-29 vaccination. Advisory  
909 Committee on Immunization Practices (ACIP). June 23, 2022. Available at: [Update on](#)  
910 [myocarditis following mRNA COVID-19 vaccination \(cdc.gov\)](#). Slides 10 and 23. Accessed on  
911 August 20, 2022.
- 912 52. Shimabukuro T. Myocarditis following mRNA COVID-19 vaccination. Advisory Committee  
913 on Immunization Practices (ACIP). July 19, 2022. Available at: [Myocarditis following mRNA](#)  
914 [COVID-19 vaccination \(cdc.gov\)](#). Slides 11 and 23. Accessed on August 20, 2022.
- 915 53. Sharff KA, Dancoes DM, Longueil JL, Lewis PF, Johnson ES. Myopericarditis after COVID-  
916 19 Booster Dose Vaccination. *Am J Card* 2022;172:165-166.  
917 <https://doi.org/10.1016/j.amjcard.2022.02.039>
- 918 54. Friedensohn L, Levin D, Fadlon-Derai M, et al. Myocarditis Following a Third BNT162b2  
919 Vaccination Dose in Military Recruits in Israel. *JAMA* Apr 26;327(16):1611-1612.  
920 doi:10.1001/jama.2022.4425.
- 921 55. Hause AM, Baggs J, Gee J, et al. Safety Monitoring of an Additional Dose of COVID-19  
922 Vaccine — United States, August 12–September 19, 2021. *MMWR Morb Mortal Wkly Rep*  
923 2021;70:1379–1384. DOI: <http://dx.doi.org/10.15585/mmwr.mm7039e4>
- 924 56. Beatty AL, Peyser ND, Butcher XE, et al. Analysis of COVID-19 Vaccine Type and Adverse  
925 Effects Following Vaccination. *JAMA Netw Open* 2021;4(12):e2140364.  
926 doi:10.1001/jamanetworkopen.2021.40364
- 927 57. Monforte A, Tavelli A, Perrone PM, Za A, Razzini K, Tomasoni D. Association between  
928 previous infection with SARS CoV-2 and the risk of self-reported symptoms after mRNA  
929 BNT162b2 vaccination: Data from 3,078 health care workers. *EClinicalMedicine*  
930 <https://doi.org/10.1016/j.eclinm.2021.100914> Accessed May 11, 2022.



- 931 58. Hause AM, Baggs J, Marquez P, et al. Safety Monitoring of COVID-19 Vaccine Booster Doses  
932 Among Adults — United States, September 22, 2021–February 6, 2022. *MMWR Morb Mortal*  
933 *Wkly Rep* 2022;71:249–254. DOI: <http://dx.doi.org/10.15585/mmwr.mm7107e1>
- 934 59. Sharff, KA, Dancoes, DM, Longueil, JL, Johnson, ES, Lewis, PF. Risk of myopericarditis  
935 following COVID-19 mRNA vaccination in a large integrated health system: A comparison of  
936 completeness and timeliness of two methods. *Pharmacoepidemiol Drug Saf.* 2022;31(8): 921-  
937 925. doi:10.1002/pds.5439
- 938 60. Morello R, Pepe M, Martino L, Lazzareschi I, Chiaretti A, Gatto A, Curatola A. COVID-19  
939 review shows that benefits of vaccinating children and adolescents appear to outweigh risks of  
940 post-vaccination myopericarditis. *Acta Paediatr.* 2022 Jun 23:10.1111/apa.16462. doi:  
941 10.1111/apa.16462. Epub ahead of print. PMID: 35735066; PMCID: PMC9350405.
- 942 61. Writing Committee, Gluckman, T. J., Bhavé, N. M., Allen, L. A., Chung, E. H., Spatz, E. S.,  
943 Verma, A. K, et al. 2022 ACC expert consensus decision pathway on cardiovascular sequelae  
944 of COVID-19 in adults: myocarditis and other myocardial involvement, post-acute sequelae of  
945 SARS-CoV-2 infection, and return to play: a report of the American College of cardiology  
946 solution set oversight Committee. *Journal of the American College of*  
947 *Cardiology* 2022;79(17):1717-1756.
- 948 62. Centers for Disease Control and Prevention. Estimated COVID-19 Burden. August 12, 2022.  
949 Available at [Estimated COVID-19 Burden | CDC](#). Accessed on August 24, 2022.
- 950 63. Buchan SA, Seo CY, Johnson C, et al. Epidemiology of Myocarditis and Pericarditis Following  
951 mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents  
952 and Adults in Ontario, Canada. *JAMA Netw Open.* 2022;5(6):e2218505.  
953 doi:10.1001/jamanetworkopen.2022.18505

- 954 64. Witberg G, Barda N, Hoss S, Richter I, Weissman M, Aviv Y, et al. Myocarditis after Covid-19  
955 Vaccination in a Large Health Care Organization. *N Engl J Med* 2021; 385:2132-2139.  
956 <https://www.nejm.org/doi/full/10.1056/NEJMoa2110737>
- 957 65. Shimabukuro T. Update on myocarditis following mRNA COVID-19 vaccination. Vaccines  
958 and Related Biologic Products Advisory Committee (VRBPAC). June 7, 2022. Available at:  
959 [Vaccines and Related Biological Products Advisory Committee June 7, 2022 Meeting](#)  
960 [Presentation- COVID19- Update on Myocarditis following mRNA vaccination \(fda.gov\)](#)  
961 Accessed on 12 July 2022
- 962 66. Schauer J, Buddhe S, Gulhane A, Chikkabyrappa SM, Law Y, Portman MA, et al. Persistent  
963 Cardiac MRI Findings in a Cohort of Adolescents with post COVID-19 mRNA vaccine  
964 myopericarditis. *The J of Pediatrics* 2022;245:233-237. Available at  
965 <https://doi.org/10.1016/j.jpeds.2022.03.032> Accessed on March 28, 2022.
- 966 67. Hadley, S.M., Prakash, A., Baker, A.L. et al. Follow-up cardiac magnetic resonance in children  
967 with vaccine-associated myocarditis. *Eur J Pediatr* 2022;181:2879–2883.  
968 <https://doi.org/10.1007/s00431-022-04482-z>
- 969 68. Patone M, Mei XW, Handunnetthi L, Dixon S, Zaccardi F, Shankar-Hari M, et al. Risk of  
970 myocarditis following sequential COVID-19 vaccinations by age and sex. *Circulation*  
971 Published August 22, 2022. Available at  
972 <https://doi.org/10.1161/CIRCULATIONAHA.122.059970> Accessed on August 24, 2022.
- 973 69. Mevorach D, Anis E, Cedar N, Bromberg M, Haas EJ, Nadir E, et al. Myocarditis after  
974 BNT162b2 mRNA Vaccine against Covid-19 in Israel. *N Engl J Med* 2021;385:2140-2149.  
975 DOI: 10.1056/NEJMoa2109730
- 976 70. Choi S, Lee S, Seo JW, Kim MJ, Jeon YH, Park JH, Lee JK, Yeo NS. Myocarditis-induced  
977 Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report

- 978 Focusing on Histopathological Findings. *J Korean Med Sci.* 2021;36(40):e286. doi:  
979 10.3346/jkms.2021.36.e286. PMID: 34664804; PMCID: PMC8524235.
- 980 71. CBER assessment of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3  
981 mL) administered to individuals 16 to 17 years of age after completion of a primary vaccination  
982 series with the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY. December 8, 2021.  
983 Available at [Pfizer-Biontech COVID-19 Vaccine Review Memorandum 12142021 \(fda.gov\)](#).  
984 Accessed on August 24, 2022.
- 985 72. Loosen, S. H., Bohlken, J., Weber, K., Konrad, M., Luedde, T., Roderburg, C., & Kostev, K.  
986 Factors Associated with Non-Severe Adverse Reactions after Vaccination against SARS-CoV-  
987 2: A Cohort Study of 908,869 Outpatient Vaccinations in Germany. *Vaccines* 2022;10(4):566.
- 988 73. Haas, J. W., Bender, F. L., Ballou, S., Kelley, J. M., Wilhelm, M., Miller, F. G., ... & Kaptchuk,  
989 T. J. Frequency of adverse events in the placebo arms of COVID-19 vaccine trials: A  
990 systematic review and meta-analysis. *JAMA Network Open.* 2022;5(1), e2143955-e2143955.
- 991 74. Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J,  
992 Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally  
993 VV, Romero JR, Talbot HK, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19  
994 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory  
995 Committee on Immunization Practices - United States, June 2021. *MMWR Morb Mortal Wkly*  
996 *Rep.* 2021 Jul 9;70(27):977-982. doi: 10.15585/mmwr.mm7027e2. PMID: 34237049; PMCID:  
997 PMC8312754.
- 998 75. Perez JL. Efficacy & Safety of BNT162b2 booster - C4591031 2 month interim analysis. ACIP.  
999 November 19, 2021. Available at  
1000 [https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf)  
1001 [508.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf) Accessed on August 24, 2022.

- 1002 76. Petersen, M. B., Bor, A., Jørgensen, F., & Lindholt, M. F. Transparent communication about  
1003 negative features of COVID-19 vaccines decreases acceptance but increases trust. *Proceedings*  
1004 *of the National Academy of Sciences* 2021;118(29). e2024597118.
- 1005 77. Witman AB, Park DM, Hardin SB. How do patients want physicians to handle mistakes? A  
1006 survey of internal medicine patients in an academic setting. *Arch Intern Med.* 1996;  
1007 156(22):2565-9. PMID: 8951299.
- 1008 78. Abraham J. The pharmaceutical industry as a political player. *The Lancet.*  
1009 2002;360(9344):1498-1502. [https://doi.org/10.1016/S0140-6736\(02\)11477-2](https://doi.org/10.1016/S0140-6736(02)11477-2)
- 1010 79. Jorgensen PD. Pharmaceuticals, political money, and public policy: a theoretical and empirical  
1011 agenda. *J Law Med Ethics.* 2013;41(3):561-70. doi: 10.1111/jlme.12065. PMID: 24088146.
- 1012 80. ECDC and EMA highlight considerations for additional and booster doses of COVID-19  
1013 vaccines. European Centre for Disease Prevention and Control. September 2, 2021.  
1014 [https://www.ecdc.europa.eu/en/news-events/ecdc-and-ema-considerations-additional-and-](https://www.ecdc.europa.eu/en/news-events/ecdc-and-ema-considerations-additional-and-booster-doses-covid-19-vaccines)  
1015 [booster-doses-covid-19-vaccines](https://www.ecdc.europa.eu/en/news-events/ecdc-and-ema-considerations-additional-and-booster-doses-covid-19-vaccines) .
- 1016 81. COVID-19 Vaccine Boosters. Centers for Disease Control and Prevention. July 20, 2022.  
1017 Available at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>. Accessed  
1018 on August 24, 2022.
- 1019 82. ECDC and EMA update recommendations on additional booster doses of COVID-19 vaccines.  
1020 European Centre for Disease Prevention and Control. July 11, 2022. Available at  
1021 [https://www.ecdc.europa.eu/en/news-events/ecdc-and-ema-update-recommendations-](https://www.ecdc.europa.eu/en/news-events/ecdc-and-ema-update-recommendations-additional-booster-doses-covid-19-vaccines)  
1022 [additional-booster-doses-covid-19-vaccines](https://www.ecdc.europa.eu/en/news-events/ecdc-and-ema-update-recommendations-additional-booster-doses-covid-19-vaccines). Accessed on August 24, 2022.
- 1023 83. JCVI statement on COVID-19 vaccination of children aged 12 to 15 years: 3 September 2021.  
1024 Joint Committee on Vaccination and Immunisation. Available at  
1025 <https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19->

- 1026 [vaccination-of-children-aged-12-to-15-years/jevi-statement-on-covid-19-vaccination-of-](#)  
1027 [children-aged-12-to-15-years-3-september-2021](#). Accessed on August 24, 2022.
- 1028 84. John SD. How low can you go? Justified hesitancy and the ethics of childhood vaccination  
1029 against COVID-19. *J Med Ethics*. 2022 Feb 25:medethics-2021-108097. doi:  
1030 10.1136/medethics-2021-108097. Epub ahead of print. PMID: 35217530; PMCID:  
1031 PMC8914403.
- 1032 85. Single dose of COVID-19 vaccine to be offered to 12-15 year olds. Department of Health and  
1033 Social Care. September 22, 2021. Available at [https://www.gov.gg/article/185637/Single-dose-](https://www.gov.gg/article/185637/Single-dose-of-COVID-19-vaccine-to-be-offered-to-12-15-year-olds)  
1034 [of-COVID-19-vaccine-to-be-offered-to-12-15-year-olds](https://www.gov.gg/article/185637/Single-dose-of-COVID-19-vaccine-to-be-offered-to-12-15-year-olds). Accessed on August 24, 2022.
- 1035 86. Vaccine Mandates. Institute for Government. March 31, 2022. Available at  
1036 <https://www.instituteforgovernment.org.uk/explainers/vaccine-mandates>. Accessed on August  
1037 24, 2022.
- 1038 87. Slifka, A. M., Park, B., Gao, L., & Slifka, M. K. Incidence of tetanus and diphtheria in relation  
1039 to adult vaccination schedules. *Clinical Infectious Diseases* 2021;72(2):285-292.
- 1040 88. Withdrawal of Rotavirus Vaccine Recommendation. Centers for Disease Control and  
1041 Prevention. *Morbidity and Mortality Weekly Report*. 1999;48(43):1007.  
1042 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm>
- 1043 89. Johnson & Johnson's Janssen COVID-19 Vaccine: Overview and Safety. Centers for Disease  
1044 Control and Prevention. Available at [https://www.cdc.gov/coronavirus/2019-](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html)  
1045 [ncov/vaccines/different-vaccines/janssen.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html). Accessed on August 24, 2022.
- 1046 90. Lee KMN, Junkis EJ, Luo C, Fatima UA, Cox ML, Clancy KBH. Investigating trends in those  
1047 who experience menstrual bleeding changes after SARS-CoV-2 vaccination. *Science Advances*  
1048 2022;8(28). <https://doi.org/10.1126/sciadv.abm7201>

- 1049 91. Aksu SB, Öztürk GZ. A rare case of shingles after COVID-19 vaccine: is it a possible adverse  
1050 effect? *Clin Exp Vaccine Res.* 2021;10(2):198-201. doi: 10.7774/cevr.2021.10.2.198. Epub  
1051 2021 May 31. PMID: 34222134; PMCID: PMC8217581.
- 1052 92. COVID-19 vaccine effectiveness in adolescents aged 12–17 years and interim public health  
1053 considerations for administration of a booster dose. European Centre for Disease Prevention  
1054 and Control. February 8, 2022. Available at [https://www.ecdc.europa.eu/en/publications-](https://www.ecdc.europa.eu/en/publications-data/covid-19-vaccine-effectiveness-adolescents-and-interim-considerations-for-booster-dose)  
1055 [data/covid-19-vaccine-effectiveness-adolescents-and-interim-considerations-for-booster-dose](https://www.ecdc.europa.eu/en/publications-data/covid-19-vaccine-effectiveness-adolescents-and-interim-considerations-for-booster-dose)  
1056 Accessed on August 24, 2022.
- 1057 93. Vatti A, Monsalve DM, Pacheco Y, Chang C, Anaya JM, Gershwin ME. Original antigenic sin:  
1058 A comprehensive review. *J Autoimmun.* 2017;83:12-21. doi: 10.1016/j.jaut.2017.04.008. Epub  
1059 2017 May 5. PMID: 28479213.
- 1060 94. Aaby P, Benn CS, Flanagan KL, Klein SL, Kollmann TR, Lynn DJ, Shann F. The non-specific  
1061 and sex-differential effects of vaccines. *Nat Rev Immunol.* 2020;20(8):464-470. doi:  
1062 10.1038/s41577-020-0338-x. Epub 2020 May 27. PMID: 32461674; PMCID: PMC7252419.
- 1063 95. Aaby P, Netea MG, Benn CS. Beneficial non-specific effects of live vaccines against COVID-  
1064 19 and other unrelated infections. *The Lancet Infectious Diseases.* Online first. August 26,  
1065 2022. [https://doi.org/10.1016/S1473-3099\(22\)00498-4](https://doi.org/10.1016/S1473-3099(22)00498-4)
- 1066 96. Attwell K, C Navin M. Childhood Vaccination Mandates: Scope, Sanctions, Severity,  
1067 Selectivity, and Salience. *Milbank Q.* 2019;97(4):978–1014. doi: 10.1111/1468-0009.12417.  
1068 Epub ahead of print. PMID: 31529546; PMCID: PMC6904257.
- 1069 97. Wertheimer A & Miller FG, “Payment for research participation: A coercive offer?” *J Med*  
1070 *Ethics* 2008;34:389–392. doi:10.1136/jme.2007.021857
- 1071 98. Fisher JA. Expanding the Frame of Voluntariness in Informed Consent: Structural Coercion and  
1072 the Power of Social and Economic Context. *Kennedy Institute of Ethics Journal*, 2013;23: 355-  
1073 379. <http://muse.jhu.edu/journal/107> <https://doi.org/10.1353/ken.2013.0018>

- 1074 99. Bambery B, Douglas T, Selgelid MJ, Maslen H, Giubilini A, Pollard AJ, Savulescu J. Influenza  
1075 Vaccination Strategies Should Target Children. *Public Health Ethics*. 2017;11(2):221-234. doi:  
1076 10.1093/phe/phx021. PMID: 30135702; PMCID: PMC6093440.
- 1077 100. Gazit S, Saciuk Y, Perez G, Peretz A, Pitzer V E, Patalon T et al. Short term, relative  
1078 effectiveness of four doses versus three doses of BNT162b2 vaccine in people aged 60 years  
1079 and older in Israel: retrospective, test negative, case-control study. *BMJ* 2022; 377:e071113  
1080 doi:10.1136/bmj-2022-071113.
- 1081 101. SARS-CoV-2 variants of concern and variants under investigation in England Technical  
1082 briefing: Update on hospitalisation and vaccine effectiveness for Omicron VOC-21NOV-01  
1083 (B.1.1.529). UK Health Security Agency. December 31, 2021. Available at  
1084 [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/fi](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1045619/Technical-Briefing-31-Dec-2021-Omicron_severity_update.pdf)  
1085 [le/1045619/Technical-Briefing-31-Dec-2021-Omicron\\_severity\\_update.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1045619/Technical-Briefing-31-Dec-2021-Omicron_severity_update.pdf) Accessed on  
1086 August 24, 2022.
- 1087 102. Wilder-Smith A. What is the vaccine effect on reducing transmission in the context of the  
1088 SARS-CoV-2 delta variant? *The Lancet Infect Dis*. 2022;22(2):152-153.  
1089 [https://doi.org/10.1016/S1473-3099\(21\)00690-3](https://doi.org/10.1016/S1473-3099(21)00690-3)
- 1090 103. Holm S. A general approach to compensation for losses incurred due to public health  
1091 interventions in the infectious disease context. *Monash Bioeth Rev*. 2020 Dec;38(Suppl 1):32-  
1092 46. doi: 10.1007/s40592-020-00104-2. PMID: 32130682; PMCID: PMC7095444.
- 1093 104. Benn CS, Fisker AB, Rieckmann A, Sørup S, Aaby P. Vaccinology: time to change the  
1094 paradigm? *Lancet Infect Dis*. 2020 Oct;20(10):e274-e283. doi: 10.1016/S1473-3099(19)30742-  
1095 X. Epub 2020 Jul 6. PMID: 32645296.
- 1096 105. Countermeasures Injury Compensation Program (CICP). Health Resources and Services  
1097 Administration. Available at <https://www.hrsa.gov/cicp>. Accessed on August 24, 2022.

- 1098 106. Vaccine Injury Support Program. Government of Canada. Available at  
1099 <https://vaccineinjurysupport.ca/en>. Accessed on August 24, 2022.
- 1100 107. Gill JR, Tashjian R, Duncanson E. Autopsy Histopathologic Cardiac Findings in 2 Adolescents  
1101 Following the Second COVID-19 Vaccine Dose. *Arch Pathol Lab Med.* 2022;146(8):925-929.  
1102 doi: 10.5858/arpa.2021-0435-SA. PMID: 35157759.
- 1103 108. Countermeasures Injury Compensation Program (CICP). Health Resources and Services  
1104 Administration. Data on CICP. Available at [Countermeasures Injury Compensation Program](#)  
1105 [\(CICP\) Data | HRSA](#) Accessed on August 24, 2022.
- 1106 109. Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Food and Drug Administration.  
1107 Available at [https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty)  
1108 [2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty) Accessed on  
1109 August 24, 2022.
- 1110 110. Olivier, M. Emory restricts WiFi for students noncompliant with booster requirements, sees  
1111 slight increase in COVID-19 cases. *The Emory Wheel.* 2022; 4: 6. Available from  
1112 [https://emorywheel.com/emory-restricts-wifi-for-students-noncompliant-with-booster-](https://emorywheel.com/emory-restricts-wifi-for-students-noncompliant-with-booster-requirements-sees-slight-increase-in-covid-19-cases/)  
1113 [requirements-sees-slight-increase-in-covid-19-cases/](https://emorywheel.com/emory-restricts-wifi-for-students-noncompliant-with-booster-requirements-sees-slight-increase-in-covid-19-cases/)
- 1114 111. Braganca, D. Stanford to International Students: Get the Booster or Face Deportation | Opinion.  
1115 Newsweek March 31, 2022. Available at [https://www.newsweek.com/stanford-international-](https://www.newsweek.com/stanford-international-students-get-booster-face-deportation-opinion-1693073)  
1116 [students-get-booster-face-deportation-opinion-1693073](https://www.newsweek.com/stanford-international-students-get-booster-face-deportation-opinion-1693073)
- 1117 112. Godlee F. What should we do about vaccine hesitancy? *BMJ.* 2019;365:l4044  
1118 <https://doi.org/10.1136/bmj.l4044>
- 1119 113. Bhargava I. Some Western students confused why university mandated a 3rd COVID-19 shot  
1120 after they'd paid tuition. CBC. August 24, 2022. Available at  
1121 <https://www.cbc.ca/news/canada/london/western-students-covid-mandates-1.6560239>  
1122 Accessed on August 24, 2022.



- 1123 114. Regev-Yochay G, Mandelboim M, Amit S, Nemet I, Joseph G, Mendelson E, et al. Efficacy of  
1124 a Fourth Dose of Covid-19 mRNA Vaccine against Omicron. *N Engl J Med* 2022;386:1377-  
1125 1380 DOI: 10.1056/NEJMc2202542
- 1126 115. Lipson SK, Zhou S, Abelson S, Heinze J, Jirsa M, Morigney J, et al. Trends in college student  
1127 mental health and help-seeking by race/ethnicity: Findings from the national healthy minds  
1128 study, 2013–2021. *Journal of Affective Disorders*. 2022;306:138-147.  
1129 <https://doi.org/10.1016/j.jad.2022.03.038>
- 1130 116. Selgelid MJ. A Moderate Pluralist Approach to Public Health Policy and Ethics. *Public Health*  
1131 *Ethics* 2009;2(2):195–205, <https://doi.org/10.1093/phe/php018>.
- 1132 117. Mosby I. Administering colonial science: Nutrition research and human biomedical  
1133 experimentation in Aboriginal communities and residential schools, 1942–1952. *Social History*.  
1134 2013;46:145–72.
- 1135 118. Haidt, J. *The righteous mind: Why good people are divided by politics and religion*. Vintage.  
1136 2013
- 1137 119. The Unintended Consequences of COVID-19 Vaccine Mandates: Why They May Cause More  
1138 Harm than Good. Available at [\(1047\) The Unintended Consequences of COVID-19 Vaccine](#)  
1139 [Mandates: Why They May Cause More Harm than Good - YouTube](#) Accessed on August 30,  
1140 2022.
- 1141 120.. Bonk, V. DC schools require COVID-19 vaccine for students 12 and up. July 19, 2022. *WTOP*  
1142 *News* [https://wtop.com/dc/2022/07/dc-schools-require-covid-19-vaccine-for-students-12-and-](https://wtop.com/dc/2022/07/dc-schools-require-covid-19-vaccine-for-students-12-and-up/)  
1143 [up/](#)
- 1144 121. Segraves N. DC Extends Deadlines for Student COVID-19 Vaccination, Routine  
1145 Immunizations. August 26, 2022. Available at [DC Extends Deadlines for Student COVID-19](#)  
1146 [Vaccination, Routine Immunizations – NBC4 Washington \(nbcwashington.com\)](#) Accessed on  
1147 August 30, 2022.
- 1148 122. ABPD Statement in Support of COVID-19 Vaccine Mandates For All Eligible Americans.  
1149 Association of Bioethics Program Directors. September 22, 2021. Available at

- 1150 <https://www.bioethicsdirectors.net/wp-content/uploads/2021/09/ABPD-Statement-in-Support->  
1151 [of-COVID-19-Vaccine-Mandates\\_FINAL9.22.2021.pdf](https://www.bioethicsdirectors.net/wp-content/uploads/2021/09/ABPD-Statement-in-Support-). Accessed on August 24, 2022.
- 1152 123. Mach D, Cole D. Civil Liberties and Vaccine Mandates: Here's Our Take. American Civil  
1153 Liberties Union. September 2, 2021. Available at <https://www.aclu.org/news/civil->  
1154 [liberties/civil-liberties-and-vaccine-mandates-heres-our-take](https://www.aclu.org/news/civil-liberties/civil-liberties-and-vaccine-mandates-heres-our-take). Accessed on August 24, 2022.
- 1155 124. OHRC Policy statement on COVID-19 vaccine mandates and proof of vaccine certificates.  
1156 Ontario Human Rights Commission. September 22, 2021. Available at [OHRC Policy statement](#)  
1157 [on COVID-19 vaccine mandates and proof of vaccine certificates | Ontario Human Rights](#)  
1158 [Commission](#) Accessed on August 30, 2022.
- 1159 125. Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, Doshi P. Serious adverse  
1160 events of special interest following mRNA COVID-19 vaccination in randomized trials in  
1161 adults. *Vaccine* 2022 <https://doi.org/10.1016/j.vaccine.2022.08.036>.
- 1162