

1 ***Vaccination – is there a place for penalties for non-compliance?***

2

3 **Running title: The ethics of compulsory vaccination**

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23 **Abstract**

24 The introduction of the punitive measures to control outbreaks of measles in Europe has sparked debate
25 and public protest about the ethical justification of penalties and exclusionary processes for non-
26 immunization. This article advances an ethics framework related to compulsory vaccination policies,
27 which we use to analyse three case studies, of mandatory policies that are enforced by fines; of policies
28 that require vaccination for the provision of social goods; and of community-led policies in which
29 communities themselves decide how to enforce vaccination compliance. We report on contemporary,
30 ongoing and past measures that have been used to increase vaccine uptake, consider their rational and
31 the related public responses, elaborate on socio-cultural and contextual influences and discuss the
32 ethical justification for mandatory vaccination. We argue for a measured approach that protects
33 fundamental human rights to evidence-based information and medical counsel to support health
34 decision-making and simultaneously raises awareness about the role of immunization in protecting the
35 wider community. We think more emphasis needs to be placed on immunization as a means of
36 promoting social good, reducing harm and protecting vulnerable groups.

37

38 **Key points for decision-makers**

- 39 • More emphasis needs to be placed on immunization as a moral duty; a means to promote
40 social good, to reduce harm and protect vulnerable groups.
- 41 • It is reasonable to restrict access to public institutions (e.g. schools) with appropriate recourse
42 for medical, philosophical and religious exemptions in contexts where vaccination coverage is
43 low and outbreaks likely.
- 44 • Vaccine mandates must be undergirded by tailored and socio-cultural appropriate
45 immunization information materials, counsel and complemented by strategies to augment trust
46 in immunisation.

47 **Introduction**

48 The recent introduction of the punitive measures to control outbreaks of measles in Europe and similar
49 action in other parts of the world has sparked debate and public protest about the ethical justification of
50 penalties and exclusionary processes for non-immunization. It remains to be seen if mandatory
51 measures will sufficiently boost vaccination coverage and it would be unwise to assume the measures
52 will achieve the desired outcomes seamlessly(1). For example, Italy saw sizable public protests in 2017
53 against mandatory vaccination(2). Public resistance to mandatory vaccination has a long history. The
54 enforcement of smallpox vaccination in 1854 in England backfired initially, resulting in a decrease of
55 uptake and increase in smallpox related mortality. Uptake rates improved over time however and other
56 European countries with compulsory smallpox immunization had lower associated mortality rates by the
57 1870s (3). However, the legal enforcement of smallpox vaccination in England provided significant
58 impetus for the birth of the anti-vaccination movement in England which was influential in the 19th and
59 start of the 20th century (4, 5).

60

61 This article advances an ethics framework related to compulsory vaccination policies, which we use to
62 analyse three case studies, of mandatory policies that are enforced by fines; of policies that require
63 vaccination for the provision of social goods; and of community led policies in which communities
64 themselves decide how to enforce vaccination compliance.

65

66 **Ethics framework**

67

68 It is widely accepted that the State has a duty to take measures to curb the spread of communicable
69 diseases, especially where these are diseases of high morbidity and mortality. Such duties can be
70 justified both via the human right to health, and by the more general consideration that the State has a
71 duty to protect the common good (6-8). In discharging the duty to protect the common good, States

72 need to be mindful of other rights that individuals have. Rights to liberty, to privacy, and to autonomy
73 can all potentially be violated by public health policies that are too single-minded in their protection of
74 public health (9).

75

76 Population level vaccination policies present a particularly challenging combination of opportunities and
77 challenges from the perspective of the State. Vaccination is an important opportunity, because it is
78 generally very cost-effective. Where herd immunity can be ensured, it also provides effective ways of
79 protecting the most vulnerable. Vaccination also presents an important challenge, because population
80 level vaccination programmes target those who are asymptomatic and include in their coverage those
81 who would be at low risk. Moreover, there is a persistent minority in many States with philosophical or
82 religious objections to vaccination.

83

84 Different vaccination programmes will have different profiles of risk and benefit. Where a disease is
85 non-communicable (such as tetanus), the benefits of vaccination accrue only to the vaccinated
86 individual; whereas in cases of communicable diseases establishing herd immunity can be vital,
87 especially when some people are not able to be vaccinated. This means that ethical arguments that
88 might support mandatory measles vaccination will often not support mandatory tetanus vaccination:
89 something that raises interesting ethical questions given that tetanus is often bundled together into a
90 pentavalent vaccine with vaccines for Diphtheria, Hepatitis B, Pertussis, and haemophilus influenzae
91 B(10).

92

93 The reasons for inadequate vaccine coverage rates which increases the risk of contracting diseases are
94 manifold. They include the “three Cs” of complacency, confidence and convenience. Complacency exists
95 where perceived risks of vaccine-preventable diseases are low, and immunisation is not deemed a

96 necessary preventative action. Confidence relates to levels of public confidence in the vaccine, providers
97 as well as other actors and the politics surrounding vaccination programmes. Convenience encompasses
98 the physical availability, geographic accessibility and affordability of vaccines as well as people's health
99 literacy and ability to understand the value of immunisation services(11). These factors are viewed as
100 core to vaccine decision-making and related behaviours and are used to help understand why vaccine
101 uptake might be low in some contexts, as such they are constituents of a model of vaccine hesitancy.
102 The continuum of vaccine hesitancy between full acceptance of vaccines and outright refusal of all
103 vaccines is actually quite broad(11), and as indicated by the three 'Cs' is not only attributable to
104 concerns about vaccination but can also be explained by difficulties in being able to access vaccines.
105
106 The requirement to ensure herd immunity and maintain high vaccine coverage rates interacts in
107 problematic ways with vaccine hesitancy. If vaccine hesitancy is widespread, this may be perceived to
108 make policies of mandatory vaccination necessary; but the fact of widespread vaccine hesitancy may
109 itself undermine the perceived political legitimacy of so doing. What is required is an approach that
110 adequately reconciles the goals of public health with the diverse other goals of citizens and of States
111 (12).
112
113 We argue that the best way to do this is to pursue a synergistic and proportionate approach. First,
114 synergistic, that public health policy should aim, where possible, to enhance and strengthen other goals
115 that citizens have reason to value; for example, aiming at promoting upstream determinants of health
116 such as education that empower citizens to make healthy choices. Second, policies should be
117 proportionate insofar as where the protection and promotion of health does come into conflict with
118 other goals, it should do so in a way that these conflicts are minimised.
119

120 In dealing with conflicts, we argue for the following principles.

121

122 1. The size of benefit to be gained or size of harm to be avoided by a given vaccination policy
123 matters. Other things being equal, the greater the expected benefit and the greater the
124 expected harm to be avoided, the stronger the argument in favour of an intervention(10).

125 2. The extent to which the population endorses or consents to the policy matters. Other things
126 being equal, the greater percentage of the affected population who endorse an intervention
127 (and the more enthusiastically they do so) the stronger the reason in favour of the policy.

128 3. The ability to make autonomous choices matters. Other things being equal, the more significant
129 a choice is, the more important it is that a person has the opportunity to make a genuine or
130 authentic choice and the more problematic it is to interfere with their choice.

131 4. Liberty matters. Other things being equal, the more coercive a policy is, the more problematic it
132 is (13).

133

134 Some cases of vaccination policies will be clear cut: where a policy that will bring a great benefit, which
135 is supported by a majority, and involves only a mild interference with choices which are not generally
136 thought to be significant, the intervention will be easy to justify. Where a policy will bring only a small
137 benefit and is opposed the majority, and involves a coercive interference with significant choices, then
138 the intervention will definitely not be justified.

139

140 The more interesting cases—which this article focuses on—will be those within the middle. Ethical
141 reasoning alone will not be able to give universal answers to these questions, because which
142 interferences are justifiable depends (among other things) on the level of general consent to the policy,
143 and the significance of the choices interfered with. The level of consent will obviously vary relative to

144 culture and time; and we will also have to take account of local differences in which choices are believed
145 by particular communities to be significant. Because of the importance of contextual factors, the body of
146 this article examines several country case studies, which each raise different questions of culture,
147 political organisation, and level of consent.

148

149 **Case studies**

150 *Italy and France: reinforcing mandatory policies in response to disease outbreaks*

151 Italy and France reinforced mandatory vaccination in September 2017 and January 2018, respectively.

152 However, Italy reversed changes following an election in August 2018. The reasons for strengthening

153 mandatory policies were that both countries had struggled with stagnating and declining uptake of

154 childhood vaccines, with coverage remaining below WHO targets for some of them (14, 15). This

155 transpired through an increase in the number of measles cases and an amplification of the magnitude of

156 measles outbreaks across Europe, which led both countries to increase the number of mandatory

157 vaccines to 11 in France and 10 in Italy (including measles).

158

159 Italy has a history of mandatory vaccination and the decision to widen the existing mandate in 2017

160 came from the Ministry of Health and the Constitutional Court of the Italian Republic to “safeguard

161 health as a fundamental right of the individual and as a collective interest” (16). This top-down approach

162 meant that mandatory vaccination became a central argument in the latest political elections, with

163 populist parties the Five-Star Movement and the Northern League promising the people that it would

164 scrap the law once in power. This promise was fulfilled at the beginning of August 2018 (17), but not in

165 time for the start of the school year which left many parents unclear about their obligations to vaccinate

166 their children in relation to school entry. Italian vaccine policy decision-making assumed a political

167 dimension with politicians seeking to seek the approval of those with diverse views concerning
168 immunisation.

169

170 In France, public health law has typically emphasised individual autonomy. The decision to increase the
171 number of mandatory vaccines (until coverage rates reach satisfactory targets) came from a citizen
172 consultation and an approach of participatory politics (15, 18). It was also aimed at addressing vaccine
173 hesitancy by sending a signal to the wider population that vaccination is a social good and a vital part of
174 public health. Previous confidence crises around Hepatitis B and A, H1N1 vaccination highlighted the
175 need for more transparency and engagement of both the general public and healthcare workers in
176 decision-making around vaccination. The report from the citizen consultation states that the 11 vaccines
177 should remain mandatory only until coverage and confidence have increased and are back to acceptable
178 levels.

179

180 In both countries, the new mandatory policies required children to be vaccinated to attend school,
181 unless they have a medical contraindication. In France, children can be denied entry if they are not
182 vaccinated within three months of admission and parents might face a fine or imprisonment (19). In Italy
183 however, children could still attend school provided their parents pay a fine and speak to their local
184 vaccine providers (20).

185

186 The impact of the laws has been different in both countries. In Italy, large 'Vaccine Freedom Marches'
187 took place in the summer of 2017 in response to the introduction of the new law, which had initially
188 made 12 vaccinations mandatory. This public protest was as much a defiant vocal defence of civil
189 liberties as a demonstration of vaccine hesitancy, although the anti-vaccine movement in Italy has a
190 strong foothold. As a result of the marches the Italian government relaxed its planned laws, dropped

191 the rates of proposed fines, reduced the number of mandatory vaccines to 10 and scrapped the
192 obligation to report parents who don't comply with the law to authorities - a move which could, in
193 extreme cases, have left parents at risk of losing custody (21). However, the mandatory policies (which
194 have now been reversed) did result in increases of vaccine coverage (20). In France, experts have raised
195 concerns that the new law could polarize opinions on vaccination but the impact remains to be seen
196 (15).

197

198 ***USA: Mandating with exemptions***

199 The United States of America (USA) has a longer history of applying different measures for encouraging
200 and enforcing immunization and since vaccines fall under the public health jurisdiction of individual
201 States, there is some variation in immunization laws and requirements (22-24). Mandatory vaccination
202 dates from 1809 when Massachusetts legislated compulsory smallpox vaccination and the Supreme
203 Court upheld individuals' rights to pass compulsory immunization laws in 1905 and 1922. Compulsory
204 vaccination became more commonplace from the 1960s/70s when it was associated with efforts to
205 eliminate measles transmission in school settings(25).

206

207 All States require children to be fully immunized before starting school but most States allow for
208 medical, religious or philosophical exemptions(26). Almost all States grant religious exemptions for
209 persons who have deeply held religious beliefs in opposition to immunization. Eighteen States allow
210 philosophical exemptions, which allow parents to decline immunization for their children because of
211 personal, moral or other beliefs. However, in the case of Virginia this exemption applies only to the
212 Human Papilloma Virus Vaccine, and in Missouri this exemption only applies to child care facilities and
213 not to public schools. In some States, for example, Mississippi, West Virginia and California, only medical

214 exemptions have been allowed(27). The process for obtaining exemptions also varies from State to
215 State. Some States require special paper-work, and others allow simple parental declarations(22).

216
217 The ease by which you can obtain exemptions in individual States has been shown to have a correlation
218 with disease prevalence rates, which suggests that making it more difficult for parents to opt out
219 increases vaccine uptake (28). Recent research also indicates that children who are exempted from
220 immunisation are 22 times more likely to acquire measles and 6 times more likely to acquire pertussis
221 than immunised children (29). The incidence rates of measles and pertussis in vaccinated children who
222 live in areas with higher numbers of exempted children are also higher, which raises questions about
223 how granting exemptions for some children can place others at increased risk of contracting disease
224 (29).

225

226 ***Rural area in Ethiopia: Promoting shared responsibility for immunization***

227 Significant emphasis is placed on promoting shared individual, community and governmental
228 responsibility for immunization against vaccine preventable diseases in the Global Vaccine Action Plan
229 (30). Projects that seek to engender shared responsibility for vaccination can however result in
230 unexpected by-products, as was the case in a community engagement immunization project in north-west
231 Ethiopia (31). Active engagement of health development army members and *kebele* (smallest
232 administrative unit in Ethiopia) leaders in promoting immunization resulted in action that was not planned
233 by the project implementers. This was a community self-regulation strategy which involved sanctions for
234 non-immunization that were agreed by *kebele* members and applied by the *kebele* leadership without
235 input from district health officers or the project implementers. They were issued where there was
236 evidence of complete disregard of guidance provided by health workers and were not limited to vaccine
237 default but also covered health facility non-attendance for childbirth. The latter was the only instance

238 cited where a monetary penalty of 500 Ethiopian Birr (approximately US\$18) had been issued. With
239 regards to vaccination, sanctions mainly served as a deterrent, a last resort for persistent non-immunisers.
240 This self-regulation strategy provided evidence that the community engagement project had fostered
241 shared responsibility for immunization, but it also raised questions about: i) who is qualified to determine
242 the type of sanctions that should be applied, ii) if monetary, who collects fines and how should they be
243 invested, iii) at what level of the health system should these types of measures be ratified?

244 This community action is interesting in that it is decided at a more local level rather than imposed by
245 higher levels of the health ministry or government. To what extent it was completely democratic is up for
246 question, but the research findings suggested that the sanctions were endorsed by a variety of community
247 members and suggested by members of the health development army who work closely with mothers in
248 neighbouring households (31). Hence, although this community self-regulating exercise did give rise to
249 questions about the coercion and individual rights, it encroached less on civil liberties in that the sanctions
250 were agreed in keeping with pre-existing community accountability mechanisms, which involve
251 community members and representatives.

252

253 **Discussion**

254 The recent move towards tougher vaccination policies is indicative that health professionals and
255 government leaders feel that they have not succeeded at communicating the public health value of
256 immunization and have to resort to more coercive action to prevent further measles outbreaks and
257 enable programmes to achieve WHO vaccine coverage recommendations. There is also a sense of
258 fatigue over stagnating uptake rates in countries that pioneered early vaccines and where the
259 population level benefits of vaccination seem to have obscured individuals' perceptions of need for
260 protection.

261

262 As the three case studies reveal, there are different tools that can be used by authorities wishing to
263 ensure adequate levels of vaccine coverage to ensure herd immunity. These include building trust in
264 immunization as a social good, mobilising social norms to express social disapproval of vaccine hesitancy
265 which are implicit goals of the French mandates, making access to some public services (e.g. schools and
266 kindergarten) dependent on vaccination as is the case in the USA, community designed sanctions as
267 documented in the Ethiopian case study, and the use of fines as instigated in the 2017 Italian vaccine
268 mandates.

269

270 Where it is feasible to maintain adequate rates of vaccination without resorting to mandatory measures,
271 then this is to be preferred. This follows both from our ethical framework, and from more general policy
272 considerations. Any ethics approach needs to take seriously the need to justify to individuals who are
273 coerced why the State is acting as it is. Given that enforced vaccination will (a) infringe on the bodily
274 integrity of individuals and (b) will be strongly resisted by some for reasons of religion or personal belief
275 (these reasons correspond to liberty and to autonomy in our ethics framework) the authority would
276 need to be able to show that the interference was not disproportionate. Where herd immunity would
277 be achievable without such measures it seems very likely that it would be judged disproportionate. So
278 we would agree with Verweij and Dawson (32) that participation in vaccination programmes “should,
279 generally, be voluntary unless compulsory vaccination is essential to prevent a concrete and serious
280 harm.”

281

282 From a policy perspective, it is important to reflect on the experiences in Italy and elsewhere, which
283 should remind us that introducing a coercive policy without the relevant social licence to enforce it can
284 undermine the public trust necessary to ensure high vaccination rates. So, the best situation is one
285 where mandatory vaccination is not required; and where even if mandatory measures are required, the

286 policy should be undergirded by a commitment to building trust in immunisation and understanding of
287 immunization as a social good.

288

289 However, it would be wrong to draw the conclusion that mandating vaccination is always unethical.

290 Where there are specific contexts in which there is no other way of controlling outbreaks, then

291 mandating vaccination can be proportionate. Justifying policies of mandated vaccination requires

292 balancing the health benefit to be achieved against the reduction in liberty and autonomy and doing so

293 in a way that can be seen to be fair. Given the ideal of social trust, we would recommend that

294 mandatory systems of vaccinations (e.g. French case study) should be temporary and kept under review.

295 As Colgrove (10) argues, there is case to be made for mandatory policies to be closely aligned with

296 persuasive action that encourages parents to immunise their children.

297

298 An important prerequisite for mandatory vaccination campaigns is an adequate scheme of vaccine

299 surveillance and compensation for vaccine-caused harms. Although some claims of harms from

300 vaccination made by anti-vaccination campaigners are clearly unsubstantiated it is widely accepted that

301 vaccines can have side effects, most of which are mild and time limited, however more severe and rare

302 and unexpected side-effects can occur. A documented example of the latter is the increase in incidence

303 of intussusception in infants following the administration of a rotavirus vaccine (RotaShield®, Wyeth)

304 which led to the withdrawal of this vaccine from the market (33). This withdrawal happened very

305 quickly due to the effective post-licensure vaccine safety monitoring administered by the US Centers for

306 Disease Control and Prevention. Such monitoring, which is core to vaccine surveillance is a critical aspect

307 of immunization programme management. If vaccination is to be enforced there is a clear case for a

308 national vaccination injury compensation programme. All G8 countries apart from Canada and Russia

309 have a national vaccine injury compensation program (34).

310

311 Mandatory vaccination policies also need to take a stance on exemptions. Navin and Largent (35)
312 helpfully distinguish three types of strategies for managing objections: Eliminationism (not allowing non-
313 medical exemptions), Prioritizing Religion (allowing only religious based exemptions, and not ones based
314 on other personal beliefs), and Inconvenience (allowing both religious and personal belief based
315 exemptions, but making it inconvenient enough to receive such an exemption that those whose
316 objection is not strongly-held are likely to be deterred).

317

318 Where a policy is one to which someone has a genuine objection of conscience, it is a serious matter to
319 mandate overriding this objection; as in the Italian case, the perception of State over-reach may have
320 made the mandatory policy (that has now been reversed) counterproductive. So, we think that there are
321 reasons to allow some non-medical exemptions in most cases. It is difficult to articulate what makes an
322 objection a religious one, and within the context of a secular State it is also difficult to justify why
323 religious objections should be afforded a special status. So, we think it is difficult to justify prioritising
324 religion. To the extent that there is a worry about too many people claiming exemptions, it would be
325 better to keep a cap on numbers in a way that is neutral between religious and nonreligious reasons,
326 perhaps by making exemption less convenient. An example of a religious reason for declining an
327 immunisation or seeking an exemption from participating in a vaccine programme is the intranasal
328 influenza vaccine, which contains porcine gelatine as a stabilizer. When the primary school age influenza
329 vaccine programme was piloted and introduced in England it was met by resistance from Muslim and
330 Jewish population groups(36). Not all members of these groups refused the vaccine for their child, but
331 many did choose to forgo the vaccine, and some questioned why they were not offered the inactivated
332 vaccine (which does not contain porcine gelatine) which is used in the Flu programme for other age and
333 risk groups. Some were also precluded from making an active decision for their children when religious

334 schools refused to support this school-based immunisation programme. From a public health
335 perspective, the health agency responsible for the vaccination programme was assured that children
336 who did not receive the vaccine would benefit from herd immunity achieved as part of the programme.
337 Especially since this programme did not require high levels of uptake to achieve herd immunity. At an
338 individual level Muslim parents weighed up whether they thought that influenza was serious enough for
339 them to contravene religious ordinances, or whether they were sufficiently concerned to obtain the
340 inactivated vaccine privately for their child. This example raises several issues regarding equity and
341 health protection and State responsibility to provide immunisations that are acceptable for all groups,
342 and parents' individual rights to decide whether their child should receive a vaccine. It could be argued
343 that schools which refused to support the programme were restricting access to public health
344 interventions and should have signposted parents to this programme and how they could access an
345 influenza vaccine for their child even if they were unwilling to host immunisation teams at their schools.

346
347 The main reasoning given for the sanctions in the Ethiopian case study was to maintain and secure
348 respect for valuable health resources which were recently established at *kebele* level as part of the
349 Ethiopian Health Extension Programme. This is pertinent since it matches an approach proposed by
350 Patryn and Zagaya (37), who discuss questions of coercion and enforcement in a review of vaccine
351 related sanctions (welfare cuts, fines, exclusion from schools and theme parks and restrictions on
352 freedom) applied in different countries. They suggest an approach, whereby individuals are required to
353 contribute to treatment costs if they contract the illness for which they refused immunization. This
354 argument corresponds with the desire to protect and respect health resources observed in the
355 community self-regulation applied in Ethiopia, and provides an alternative approach to sanctions, which
356 are hard to apply fairly and not always effective (38). However, this approach may be problematic to
357 apply across different health systems, specifically the NHS in England, which offers free care at the point

358 of access to its citizens. It could also be difficult to administer for example, in cases where the cause of
359 illness is not easy to define, the patient is seriously ill and not in a position to provide a financial
360 contribution, and where someone is responsible for infecting others.

361

362 **Conclusion: the need for a measured approach and further debate**

363 So, what is the answer? Is there a place for penalties for non-compliance? We have argued for a measured
364 approach that protects fundamental human rights to evidence-based information and medical counsel to
365 support health decision-making and raise awareness about the role of immunization in protecting the
366 wider community. We think more emphasis needs to be placed on immunization as a means of promoting
367 social good, reducing harm and protecting vulnerable groups. This is of importance with reference to
368 highly infectious diseases such as measles which can have serious sequelae for susceptible populations,
369 especially those who cannot be immunized due to underlying medical conditions. There needs to be a
370 franker discussion about the moral duty to prevent harm by being vaccinated and the consequences of
371 refusing vaccination both for individuals and their social networks. We feel less comfortable about the
372 introduction of fines, and laws that require intermediaries to report vaccine refusers to health authorities.
373 There could however be a case for mandating immunization as an entrance requirement to educational
374 establishments with appropriate recourse for medical, philosophical and religious exemptions. Any type
375 of exclusionary mechanisms must however be undergirded by tailored and socio-cultural appropriate
376 immunization information materials, counsel and vaccination services. The immunization experience
377 needs to be positive and potential vaccine beneficiaries need the opportunity to voice hesitation and
378 receive appropriate and sensitive guidance. While there is a place for mandatory measures, these need
379 to be proportionate, and where feasible allow exemptions and to occur on a temporary basis.

380

381

382 **Compliance with Ethical Standards**

383 **Conflicts of interest**

384 Tracey Chantler, Emilie Karafillakis and James Wilson have no conflicts of interests to report.

385

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393

394 **Author Contributions**

395 Tracey Chantler wrote the first draft of this paper. Emilie Karafillakis and James Wilson commented on
396 the first draft and contributed to writing the final draft.

397

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