

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

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

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## **Abstract**

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

## **Key points for decision-makers**

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

## **Introduction**

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

for the birth of the anti-vaccination movement in England which was influential in the 19th and start of the 20th century (4, 5).

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

### **Ethics framework**

It is widely accepted that the State has a duty to take measures to curb the spread of communicable diseases, especially where these are diseases of high morbidity and mortality. Such duties can be justified both via the human right to health, and also by the more general consideration that the State has a duty to protect the common good (6-8). In discharging the duty to protect the common good, states need to be mindful of other rights that individuals have. Rights to liberty, to privacy, and to autonomy can all potentially be violated by public health policies that are too single-minded in their protection of public health (9).

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

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

The reasons for inadequate vaccine coverage rates which increases the risk of contracting diseases are manifold. They include the “three C’sCs” of complacency, confidence and convenience. (the three ‘Cs’; complacencyComplacency exists where perceived risks of vaccine-preventable diseases are low and immunisation is not deemed a necessary preventative action. Confidence relates to levels of public confidence in the vaccine, providers as well as other actors and the politics surrounding vaccination programmes. , convenienceConvenience encompasses the physical availability, geographic accessibility and affordability of vaccines as well as people’s health literacy and ability to understand the value of

immunisation services(11). These factors are viewed as core to vaccine decision-making and related behaviours and are used to help understand why vaccine uptake might be low in some contexts, as such they are constituents of a model of vaccine hesitancy. The continuumspectrum of vaccine hesitancy between full acceptance of vaccines and outright refusal of all vaccines is actually quite broad(11), and as indicated by the three 'Cs' is not only attributable to concerns about vaccination but can also be explained by difficulties in being able to access vaccines. is

The requirement to ensure herd immunity and maintain high vaccine coverage rates interacts in problematic ways with vaccine hesitancy. If vaccine hesitancy is widespread, this may be perceived to make policies of mandatory vaccination necessary; but the fact of widespread vaccine hesitancy may itself undermine the perceived political legitimacy of so doing. What is required is an approach that adequately reconciles the goals of public health with the diverse other goals of citizens and of States (12).

We argue that the best way to do this is to pursue a synergistic and proportionate approach. First, synergistic, that public health policy should aim, where possible, to enhance and strengthen other goals that citizens have reason to value; for example, aiming at promoting upstream determinants of health such as education that empower citizens to make healthy choices. Second, policies should be proportionate insofar as where the protection and promotion of health does come into conflict with other goals, it should do so in a way that these conflicts are minimised.

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

1. The size of benefit to be gained or size of harm to be avoided by a given vaccination policy matters. Other things being equal, the greater the expected benefit and the greater the expected harm to be avoided, the stronger the argument in favour of an intervention(10).
2. The extent to which the population endorses or consents to the policy matters. Other things being equal, the greater percentage of the affected population who endorse an intervention (and the more enthusiastically they do so) the stronger the reason in favour of the policy.
3. The ability to make autonomous choices matters. Other things being equal, the more significant a choice is, the more important it is that a person has the opportunity to make a genuine or authentic choice and the more problematic it is to interfere with their choice.
4. Liberty matters. Other things being equal, the more coercive a policy is, the more problematic it is (13).

Some cases of vaccination policies will be clear cut: where a policy that will bring a great benefit, which is supported by the vast majority of people, and involves only a mild interference with choices which are not generally thought to be significant, the intervention will be easy to

justify. Where a policy will bring only a small benefit, and is opposed by the vast majority of the population, and involves a coercive interference with significant choices, then the intervention will definitely not be justified.

The more interesting cases—which this article focuses on—will be those within the middle. Ethical reasoning alone will not be able to give universal answers to these questions, because which interferences are justifiable depends (among other things) on the level of general consent to the policy, and the significance of the choices interfered with. The level of consent will obviously vary relative to culture and time; and we will also have to take account of local differences in which choices are believed by particular communities to be significant. Because of the importance of contextual factors, the body of this article examines a number of country case studies, which each raise different questions of culture, political organisation, and level of consent.

### **Case studies**

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

Italy and France reinforced mandatory vaccination in September 2017 and January 2018, respectively. However, Italy reversed changes following an election in August 2018. The reasons for strengthening mandatory policies were that both countries had struggled with stagnating and declining uptake of childhood vaccines, with coverage remaining below WHO targets for some of them (14, 15). This transpired through an increase in the number of measles cases and an amplification of the magnitude of measles outbreaks across Europe, which led both countries to increase the number of mandatory vaccines to 11 in France and 10 in Italy (including measles).

Italy has a history of mandatory vaccination and the decision to widen the existing mandate in 2017 came from the Ministry of Health and the Constitutional Court of the Italian Republic to “safeguard health as a fundamental right of the individual and as a collective interest” (16). This top-down approach meant that mandatory vaccination became a central argument in the latest political elections, with populist parties the Five-Star Movement and the Northern League promising the people that it would scrap the law once in power. This promise was fulfilled at the beginning of August 2018 (17), but not in time for the start of the school year which left many parents unclear about their obligations to vaccinate their children in relation to school entry. Italian vaccine policy decision-making assumed a political dimension with politicians seeking to seek the approval of those with diverse views concerning immunisation.

In France, public health law has typically emphasised individual autonomy. The decision to increase the number of mandatory vaccines (until coverage rates reach satisfactory targets) came from a citizen consultation and an approach of participatory politics (15). It was also aimed at addressing vaccine hesitancy by sending a signal to the wider population that vaccination is a social good and a vital part of public health. Previous confidence crises around Hepatitis B and A, H1N1 vaccination highlighted the need for more transparency and engagement of both the general public and healthcare workers in decision-making around

vaccination. The report from the citizen consultation states that the 11 vaccines should remain mandatory only until coverage and confidence have increased and are back to acceptable levels.

In both countries, the new mandatory policies required children to be vaccinated to attend school, unless they have a medical contraindication. In France, children can be denied entry if they are not vaccinated within three months of admission and parents might face a fine or imprisonment (18). In Italy however, children could still attend school provided their parents pay a fine and speak to their local vaccine providers (19).

The impact of the laws has been different in both countries. In Italy, large 'Vaccine Freedom Marches' took place in the summer of 2017 in response to the introduction of the new law, which had initially made 12 vaccinations mandatory. This public protest was as much a defiant vocal defence of civil liberties as a demonstration of vaccine hesitancy, although the anti-vaccine movement in Italy has a strong foothold. As a result of the marches the Italian government relaxed its planned laws, dropped the rates of proposed fines, reduced the number of mandatory vaccines to 10 and scrapped the obligation to report parents who don't comply with the law to authorities - a move which could, in extreme cases, have left parents at risk of losing custody (20). However, the mandatory policies (which have now been reversed) did result in increases of vaccine coverage (19). In France, experts have raised concerns that the new law could polarize opinions on vaccination but the impact remains to be seen (15).

### ***USA: Mandating with exemptions***

The United States of America (USA) has a longer history of applying different measures for encouraging and enforcing immunization and since vaccines fall under the public health jurisdiction of individual States, there is some variation in immunization laws and requirements (21-23). Mandatory vaccination dates from 1809 when Massachusetts legislated compulsory smallpox vaccination and the Supreme Court upheld individuals' rights to pass compulsory immunization laws in 1905 and 1922. Compulsory vaccination became more commonplace from the 1960s/70s when it was associated with efforts to eliminate measles transmission in school settings(24).

All States require children to be fully immunized before starting school but most States allow for medical, religious or philosophical exemptions(25). Almost all States grant religious exemptions for persons who have deeply held religious beliefs in opposition to immunization. Eighteen States allow philosophical exemptions, which allow parents to decline immunization for their children because of personal, moral or other beliefs. However, in the case of Virginia this exemption applies only to the Human Papilloma Virus Vaccine, and in Missouri this exemption only applies to child care facilities and not to public schools. In some States, for example, Mississippi, West Virginia and California, only medical exemptions have been allowed(26). The process for obtaining exemptions also varies from State to State. Some States require special paper-work, and others allow simple parental declarations(21).

The ease by which you can obtain exemptions in individual States has been shown to have a correlation with disease prevalence rates, which suggests that making it more difficult for parents to opt out increases vaccine uptake (27). Recent research also indicates that children who are exempted from immunisation are 22 times more likely to acquire measles and 6 times more likely to acquire pertussis than immunised children (28). The incidence rates of measles and pertussis in vaccinated children who live in areas with higher numbers of exempted children are also higher, which raises questions about how granting exemptions for some children can place others at increased risk of contracting disease (28).

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

Significant emphasis is placed on promoting shared individual, community and governmental responsibility for immunization against vaccine preventable diseases in the Global Vaccine Action Plan (29). Projects that seek to engender shared responsibility for vaccination can however result in unexpected by-products, as was the case in a community engagement immunization project in north-west Ethiopia (30). Active engagement of health development army members and *kebele* (smallest administrative unit in Ethiopia) leaders in promoting immunization resulted in action that was not planned by the project implementers. This was a community self-regulation strategy which involved sanctions for non-immunization that were agreed by *kebele* members and applied by the *kebele* leadership without input from district health officers or the project implementers. They were issued where there was evidence of complete disregard of guidance provided by health workers and were not limited to vaccine default but also covered health facility non-attendance for childbirth. The latter was actually the only instance cited where a monetary penalty of 500 Ethiopian Birr (approximately US\$18) had been issued. With regards to vaccination, sanctions mainly served as a deterrent, a last resort for persistent non-immunisers. This self-regulation strategy provided evidence that the community engagement project had fostered shared responsibility for immunization, but it also raised questions about: i) who is qualified to determine the type of sanctions that should be applied, ii) if monetary, who collects fines and how should they be invested, iii) at what level of the health system should these types of measures be ratified?

This community action is interesting in that it is decided at a more local level rather than imposed by higher levels of the health ministry or government. To what extent it was completely democratic is up for question, but the research findings suggested that the sanctions were endorsed by a variety of community members and suggested by members of the health development army who work closely with mothers in neighbouring households (30). Hence, although this community self-regulating exercise did give rise to questions about the coercion and individual rights, it encroached less on civil liberties in that the sanctions were agreed in keeping with pre-existing community accountability mechanisms, which involve community members and representatives.

## **Discussion**

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

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

Where it is feasible to maintain adequate rates of vaccination without resorting to mandatory measures, then this is to be preferred. This follows both from our ethical framework, and from more general policy considerations. Any ethics approach needs to take seriously the need to justify to individuals who are coerced why the State is acting as it is. Given that enforced vaccination will (a) infringe on the bodily integrity of individuals and (b) will be strongly resisted by some for reasons of religion or personal belief (these reasons correspond to liberty and to autonomy in our ethics framework) the authority would need to be able to show that the interference was not disproportionate. Where herd immunity would be achievable without such measures it seems very likely that it would be judged disproportionate. So we would agree with Verweij and Dawson (31) that participation in vaccination programmes "should, generally, be voluntary unless compulsory vaccination is essential to prevent a concrete and serious harm."

From a policy perspective, it is important to reflect on the experiences in Italy and elsewhere, which should remind us that introducing a coercive policy without the relevant social licence to enforce it can undermine the public trust necessary to ensure high vaccination rates. So the best situation is one where mandatory vaccination is not required; and where even if mandatory measures are required, the policy should be undergirded by a commitment to building trust in immunisation, and understanding of immunization as a social good.

However, it would be wrong to draw the conclusion that mandating vaccination is always unethical. Where there are specific contexts in which there is no other way of controlling outbreaks, then mandating vaccination can be proportionate. Justifying policies of mandated vaccination requires balancing the health benefit to be achieved against the reduction in liberty and autonomy, and doing so in a way that can be seen to be fair. Given the ideal of social trust, we would recommend that mandatory systems of vaccinations (e.g. French case study) should be temporary and kept under review. As Colgrove (10) argues, there is case to be made for

mandatory policies to be closely aligned with persuasive action that encourages parents to immunise their children.

An important prerequisite for mandatory vaccination campaigns is an adequate scheme of vaccine surveillance and compensation for vaccine-caused harms. Although some claims of harms from vaccination made by anti-vaccination campaigners are clearly unsubstantiated it is widely accepted that vaccines can have side effects, most of which are mild and time limited, however more severe and rare and unexpected side-effects can occur. A documented example of the latter is the increase in incidence of intussusception in infants following the administration of a rotavirus vaccine (RotaShield©, Wyeth) which led to the withdrawal of this vaccine from the market (32). This withdrawal happened very quickly due to the effective post-licensure vaccine safety monitoring administered by the US Centers for Disease Control and Prevention. Such monitoring, which is core to vaccine surveillance is a critical aspect of immunization programme management. If vaccination is to be enforced there is a clear case for a national vaccination injury compensation programme. All G8 countries apart from Canada and Russia have a national vaccine injury compensation program (33).

Mandatory vaccination policies also need to take a stance on exemptions. Navin and Largent (34) helpfully distinguish three types of strategies for managing objections: Eliminationism (not allowing non-medical exemptions), Prioritizing Religion (allowing only religious based exemptions, and not ones based on other personal beliefs), and Inconvenience (allowing both religious and personal belief based exemptions, but making it inconvenient enough to receive such an exemption that those whose objection is not strongly-held are likely to be deterred).

Where a policy is one to which someone has a genuine objection of conscience, it is a serious matter to mandate overriding this objection; as in the Italian case, the perception of State over-reach may have made the mandatory policy (that has now been reversed) counterproductive. So we think that there are reasons to allow some non-medical exemptions in most cases. It is difficult to articulate what makes an objection a religious one, and within the context of a secular State it is also difficult to justify why religious objections should be afforded a special status. So, we think it is difficult to justify prioritising religion. To the extent that there is a worry about too many people claiming exemptions, it would be better to keep a cap on numbers in a way that is neutral between religious and nonreligious reasons, perhaps by making exemption less convenient. An example of a religious reason for declining an immunisation or seeking an exemption from participating in a vaccine programme is the intranasal influenza vaccine, which contains porcine gelatine as a stabilizer. When the primary school age influenza vaccine programme was piloted and introduced in England it was met by resistance from Muslim and Jewish population groups(35). Not all members of these groups refused the vaccine for their child, but many did choose to forgo the vaccine, and some questioned why they were not offered the inactivated vaccine (which does not contain porcine gelatine) which is used in the Flu programme for other age and risk groups. Some were also precluded from making an active decision for their children when religious schools refused to support this school-based

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

The main reasoning given for the sanctions in the Ethiopian case study was to maintain and secure respect for valuable health resources which were recently established at *kebele* level as part of the Ethiopian Health Extension Programme. This is pertinent since it matches an approach proposed by Patryn and Zagaya (36), who discuss questions of coercion and enforcement in a review of vaccine related sanctions (welfare cuts, fines, exclusion from schools and theme parks and restrictions on freedom) applied in different countries. They suggest an approach, whereby individuals are required to contribute to treatment costs if they contract the illness for which they refused immunization. This argument corresponds with the desire to protect and respect health resources observed in the community self-regulation applied in Ethiopia, and provides an alternative approach to sanctions, which are hard to apply fairly and not always effective (37). However, this approach may be problematic to apply across different health systems, specifically the NHS in England, which offers free care at the point of access to its citizens. It could also be difficult to administer for example, in cases where the cause of illness is not easy to define, the patient is seriously ill and not in a position to provide a financial contribution, and where someone is responsible for infecting others.

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

So, what is the answer? Is there a place for penalties for non-compliance? We have argued for a measured approach that protects fundamental human rights to evidence-based information and medical counsel to support health decision-making and raise awareness about the role of immunization in protecting the wider community. We think more emphasis needs to be placed on immunization as a means to promote social good, to reduce harm and protect vulnerable groups. This is of particular importance with reference to highly infectious diseases such as measles which can have serious sequelae for susceptible populations, especially those who cannot be immunized due to underlying medical conditions. There needs to be a franker discussion about the moral duty to prevent harm by being vaccinated and the consequences of refusing vaccination both for individuals and their social networks. We feel less comfortable

about the introduction of fines, and laws that require intermediaries to report vaccine refusers to health authorities. There could however be a case for mandating immunization as an entrance requirement to educational establishments with appropriate recourse for medical, philosophical and religious exemptions. Any type of exclusionary mechanisms must however be undergirded by tailored and socio-cultural appropriate immunization information materials, counsel and vaccination services. The immunization experience needs to be positive and potential vaccine beneficiaries need the opportunity to voice hesitation and receive appropriate and sensitive guidance. While there is a place for mandatory measures, these need to be proportionate, and where feasible allow exemptions and to occur on a temporary basis.

## **Compliance with Ethical Standards**

### **Conflicts of interest**

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

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### **Author Contributions**

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

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