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Global Ethical Considerations Regarding Mandatory Vaccination in Children

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Whether children should be vaccinated against coronavirus disease-2019 (COVID-19) (or other infectious diseases such as influenza) and whether some degree of coercion should be exercised by the state to ensure high uptake depends, among other things, on the safety and efficacy of the vaccine. For COVID-19, these factors are currently unknown for children, with unanswered questions also on children's role in the transmission of the virus, the extent to which the vaccine will decrease transmission, and the expected benefit (if any) to the child. Ultimately, deciding whether to recommend that children receive a novel vaccine for a disease that is not a major threat to them, or to mandate the vaccine, requires precise information on the risks, including disease severity and vaccine safety and effectiveness, a comparative evaluation of the alternatives, and the levels of coercion associated with each. However, the decision also requires balancing self-interest with duty to others, and liberty with usefulness. Separate to ensuring vaccine supply and access, we outline 3 requirements for mandatory vaccination from an ethical perspective: (1) whether the disease is a grave threat to the health of children and to public health, (2) positive comparative expected usefulness of mandatory vaccination, and (3) proportionate coercion. We also suggest that the case for mandatory vaccine in children may be strong in the case of influenza vaccination during the COVID-19 pandemic. (*J Pediatr* 2021;231:10-6).

We are in the midst of a global pandemic. Many countries are pinning their hopes on a coronavirus disease-2019 (COVID-19) vaccine as the solution. There are 247 vaccine candidates being tested at the moment, 10 of which are in phases II or III.¹ When a safe and effective vaccine becomes available, the focus will be on who should receive it and how it will be rolled out both nationally and internationally.²⁻⁵ One issue that will be hotly debated is whether the vaccine should be mandatory and whether it should be mandated for children. Some ethicists have already made a general case for mandatory COVID-19 vaccination, without arguing specifically for child vaccination, given certain assumptions about availability and risk profile of the vaccine, and suggested that there would be very few legal barriers to it in the US.⁶ Mandatory vaccination for children might be required if vaccine uptake will not be high enough or if governments have reasonable grounds to believe so. Because the timely implementation of effective vaccination policies save lives, there might be a case for considering mandatory vaccination, including for children, before less coercive policies.

We provide an ethical assessment of possible mandatory COVID-19 vaccination policies targeting children, focusing on COVID-19 and influenza vaccines. We use a comparison with influenza vaccination policies to emphasize the risks and benefits of the 2 vaccines, both for children and for the public, and to assess the ethics of mandatory child vaccination. The public health importance of both the influenza vaccine and future COVID-19 vaccines cannot be underestimated, considering the number of deaths both vaccines will be able to prevent. With many countries having to face the influenza season in the midst of the COVID-19 pandemic and without a COVID-19 vaccine, adequate influenza vaccine uptake is going to be particularly important for public health this year. We first define what is meant by "mandatory" vaccination. We then provide an ethical assessment of mandatory vaccination policies, on the basis of considerations about risks of a vaccine for the targeted group, in this case, the COVID-19 vaccine for children. We identify 3 ethically relevant criteria: (1) whether the diseases are a grave threat to public health, (2) the positive comparative expected usefulness of mandatory vaccination, and (3) proportionate coercion. We examine how these concepts apply to influenza vaccination and to future COVID-19 vaccination policies.

What Is Mandatory Vaccination?

With the escalation in antivaccination activity, misinformation and conspiracy theories, COVID-19 vaccines may not achieve high enough uptake, with between

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60% and 80% coverage needed to reach the herd immunity threshold. To date, low adult intention to refuse COVID-19 vaccines has been reported in Australia (7.6%), compared with data from the US (20%-27%)⁷ and France (27%).⁸ These estimates will fluctuate over time with the phases of the pandemic, with 49% of adults in the US stating that they would refuse a COVID-19 vaccine in September 2020.⁹ Those refusing vaccination for themselves are of course very likely to refuse it for their children as well. Mandatory vaccination is already being discussed in Australia to facilitate high COVID-19 vaccine uptake amongst the key target groups, that is, frontline healthcare workers and people with medical risk factors. Children will not be initial targets of a COVID-19 vaccination program, but will be offered the vaccine according to the prioritization schedule over time. However, ensuring public confidence in vaccine safety and effectiveness will be crucial to facilitate uptake and introducing mandatory vaccination too early may threaten this. But what does “mandatory” mean and what needs to be considered before it is introduced?

Mandatory vaccination means that some form of coercion is used to get people to vaccinate themselves and/or their children. Vaccine mandates are fundamentally about restricting individual or parental liberty for the public good or for a child’s own good. Coercion means that threats of penalties are used to restrict a person’s options, by making certain options (eg, vaccine refusal for oneself or for one’s child) significantly more costly. Note that religious or ideological exemptions from vaccination requirements do not necessarily mean a policy is not mandatory. If, as is often the case for example with military conscription, the “conscientious objector” is required to provide some alternative and sufficiently burdensome contribution to the collective good, then the policy would still count as mandatory.¹⁰ What conscientious objectors often want, though, is to costlessly refuse vaccination for themselves or their children in the name of freedom of choice or of conscience. Vaccination mandates with opt-out procedures might be seen as a form of mere nudging policy (which is not coercive) or as a form of coercion, depending on the cost of the exemption procedure.

Mandatory vaccination for children is already employed in some parts of the world. In the US, for instance, children cannot be enrolled in state schools if their vaccination schedule is not up to date, unless they have a valid medical exemption. Many states allow nonmedical exemptions for personal moral or religious reasons, but some states have started to remove nonmedical exemptions (eg, California with the SB277 bill) or to make them particularly burdensome to obtain (eg, Michigan), for example by requesting objecting parents to attend immunization education courses.¹¹ In Australia, financial assistance payments, including the childcare benefit, a childcare rebate, and family tax benefit Part A end-of-year supplement, are withheld when families do not fully vaccinate their children according to the National Immunization Program schedule (“No Jab, No Pay”) or access to early childhood education including Kinder-

garten is withheld (“No Jab, No Play”). Italy introduced a form of mandatory vaccination in 2017 that includes fines up to 500 euros for the parents of unvaccinated children who attend school.¹²

Coercion or the severity of the penalty can take a number of different forms from relatively mild (making a parent go through an education program) to moderate (fines, withholding financial or childcare, Kindergarten, or school exclusion), or severe (large fines or imprisonment). We call all these measures mandatory, although terms like mandatory and compulsory are used inconsistently or interchangeably in the vaccination debate; some reserve the term mandatory for policies that threaten to withdraw valuable social goods or services and compulsory for policies that consider vaccine refusal as a crime, with legal sanctions.¹¹

It is important to distinguish between coercion, which is based on some kind of disincentive (threats of some penalty), from incentivization programs. Coercion restricts liberty by narrowing the range of options reasonably available to people. Incentivization, in contrast, increases liberty, providing a person with a new option, typically one that is made more desirable to the person because of the incentive.

Incentives could be financial or nonfinancial. Incentives make a person significantly better off with reference to a certain baseline. What constitutes the baseline is context dependent. In a pandemic context, where confinement or limitation of social interactions have become the norm, the offer of enhanced freedom of movement or association for those who do vaccinate can represent an incentive. “Immunity passports” could in this sense become the incentive that lets the immunized enjoy their freedoms (almost) at a pre-pandemic level.^{13,14}

Incentives do raise some ethical concerns. If not properly implemented, they can be exploitative or constitute undue inducement. Exploitation involves taking advantage of a person choosing an option that they would not choose if it were not for their vulnerable position, typically the result of some injustice. Undue inducement involves choosing an option when one’s judgement is somehow distorted by the offer and therefore judgement is not fully autonomous or rational. Exploitation can occur when an incentive is too small, and a person only accepts it because she desperately needs even a small amount of whatever good is offered. Inducement can be undue when an incentive is too large and therefore its appeal leads someone to disregard risks.

Mandatory or Voluntary?

The typical justification offered for mandatory vaccination is the same justification given for coercion in infectious disease management in the case of quarantine, isolation, and surveillance: a person who carries or is presumed to carry an infectious agent represents a risk of harm to others. This justification builds on John Stuart Mill’s Harm-Principle: each individual should be free unless they pose a risk of significant harm to others. The only justification for the use of

state coercion is prevention of serious harm to others, including when harm is caused by inaction. Harm to self is never a sufficient warrant, as long as the agent is competent to make autonomous, self-harming decisions.¹⁵

The principle does not apply to younger children, who are not competent to make fully autonomous decisions. Thus, there is a duty of parents or the state to protect their welfare. But there remains a duty to prevent 1 child harming other children.

The problem with the Millian principle is that it typically deals with clear harm. In the cases we are considering, however, the risk of harm varies significantly across infectious diseases, across groups, across individuals, and with the level of immunity in a community. We are entitled to risk harming others up to a certain point; otherwise, liberty would be an empty concept, because almost everything we do entails at least some remote risk of harm to others. For example, we can drive a car provided we exercise certain care and stay within certain rules. Moreover, if we are going to restrict liberty once we are beyond this acceptable threshold, the Millian principle is silent on how much coercion is justified.

In the case of vaccine-preventable diseases, there are 3 requirements that must be met for mandatory vaccination to be justified.¹⁶

Serious Threat to Public Health

The restriction of liberty should only be considered when the problem is significant and there is a large expected harm of not intervening. This happens, for instance, when a life-threatening virus like COVID-19 is circulating at high levels in the community. Expected harm is the probability of the harm multiplied by the magnitude of the harm. The greater the chances of harm (without mandatory vaccination) or the greater the extent of the harm, the more mandatory vaccination should be considered. In the case of infectious diseases, the magnitude of the harm is typically measured either by the number of lives threatened by the disease or the long-term morbidity.

In the case of children, there are also paternalistic reasons to vaccinate. We should also consider the risk the disease poses to the child whom we are considering vaccinating. The greater the chance the child will be harmed by the disease, or the greater the extent of the harm, the stronger the justification for intervention.

Influenza. Influenza is a significant public health threat. Each year, the Centers for Disease Control and Prevention estimates that between 12 000 and 61 000 people die in the US of influenza.¹⁷ Worldwide, influenza kills between 290 000 and 650 000 people each year, which means it is among the deadliest infectious diseases.¹⁸ The elderly are at a significantly higher risk of death from influenza. During the 2018-2019 influenza season there were 34 200 deaths from influenza in the US, and people aged 65 or older accounted for 75% of such deaths.¹⁷ Erosion of the immune system during old age explains not only why the elderly are more

subject to severe complications from influenza, such as pneumonia, but also why they tend to mount poor immune response to the vaccine.¹⁹ As a consequence, elderly people can die as a consequence of influenza, even when they are vaccinated.²⁰

The broader economic effects of influenza are equally significant. According to the estimates used by Centers for Disease Control and Prevention, influenza costs the US around US\$10.4 billion only for direct costs for hospitalizations and outpatient visits for adult, but when we consider loss of earning caused by illness, the estimated cost is US\$87.1 billion.²¹ In Australia, influenza is the most common vaccine-preventable disease, with children under 5 years of age (especially those with medical comorbidities) and adults more than 65 years of age having the highest risk of influenza-related hospitalization.²²⁻²⁴ However, the risks to children are lower than to adults, with a case/fatality rate estimated at less than 1 in 1 000 000 in unvaccinated children.²⁰

COVID-19. Children are at low risk of dying of COVID-19. The mortality rate in children is estimated to be low, at 0.0016%, which is comparable with the mortality rate of chickenpox, or slightly higher, at 0.10-0.05 in 100 000, according to some other estimates.^{25,26} However, there is the possibility of long-term neurologic sequelae or chronic fatigue.²⁷ It does not seem that children play a major role in COVID-19 transmission as they do in the case of influenza.²⁸

It is reasonable to conclude that both influenza and COVID are serious threats to public health, but that children, apart from infants less than 6 months of age in the case of influenza who are among the highest risk age groups, are at lower risk than adults in both cases.

Comparative Expected Usefulness of Mandatory Vaccination Is High

To be a candidate even for voluntary administration, a vaccine must be proven to be safe and effective. Of course, "proven" is a value-laden concept. What this means is that we have a very high confidence based on sound extensive research that it is both safe and effective.

However, for mandatory vaccination, it is not enough that a vaccine is safe and effective. The vaccination policy itself must be significantly better than the alternatives, including voluntary vaccination, in addressing the serious threat to public health.

Expected usefulness is a concept from decision theory. The expected usefulness of an intervention is the expected benefits minus the expected harms. Expected benefit is the value of all the benefits multiplied by the probability of them occurring. Comparative expected usefulness is the expected usefulness of mandatory vaccination compared with that of the next best alternative.

In the case of children, we need to consider both the expected usefulness to society and the expected usefulness to the child of vaccination.

Influenza. The comparative expected usefulness to society of vaccinating children for influenza is high. Children are primarily responsible for spreading influenza. Vaccinating the elderly (and health care workers) is less effective than vaccinating children. Targeting children to increase herd immunity and limit transmission of influenza in the community is a more effective strategy.²⁰

Many countries are confident that voluntary vaccination programs can achieve sufficient coverage to protect the elderly, either directly if they voluntarily vaccinate, or indirectly if enough young people voluntarily vaccinate. For example, in the UK a program of making a nasal spray freely available in schools has led to an increase in vaccination uptake, with decreases in disease incidence in both targeted and nontargeted age groups.²⁹

If a voluntary program can achieve herd immunity, then mandatory vaccination is not required. It is important to point out that there are 2 ways in which mandatory policies can realize herd immunity: first, by inducing more people to vaccinate to avoid whatever penalty is attached to nonvaccination; and second, by addressing the so-called “problem of assurance,” whereby hesitant individuals are more likely to make their contribution to certain public goods (eg, herd immunity) if given enough reassurance that enough other people are making the same “sacrifice.”¹⁰

The comparative expected usefulness of vaccination for children appears positive. Even though more children less than 5 of age years are hospitalized with influenza than any other vaccine-preventable disease, very few children die from influenza. Thus, it seems to be in a child’s interests to have influenza vaccination. The case fatality rate for unvaccinated children from influenza is approximately 1 in 1 000 000, and the case/fatality rate of vaccination in children is less than 1 in 25 000 000.²⁰

In the 2018-2019, season at least 138 children died from influenza-related disease in the US.³⁰ We do not know how many of these were unvaccinated, but it is plausible to assume that a significant number were unvaccinated. For example, during the 2017-2018 influenza season, there were 186 influenza-related pediatric deaths in the US, and approximately 80% of the children who died had not received an influenza vaccination.³¹

Mandatory policies in children are most justifiable when they have both positive expected usefulness for society and for the child.

The case for mandatory influenza vaccination in children will be even stronger during the COVID-19 pandemic because of pressure on hospital resources. By preventing spread to vulnerable patients who may require hospitalization for influenza, vaccination for children can free up limited resources for use by patients with COVID-19. Not only will direct mortality (resulting from children infecting vulnerable elderly) be decreased, but indirect mortality will be decreased by decreasing the number of elderly hospitalizations.

COVID-19. The development of a COVID-19 vaccine is ongoing and we have never had a vaccine against any coronavirus. There are a variety of different vaccines being tested.³² Each of these will have different risk profiles. Although the testing is extensive, there cannot be same level of confidence in the safety and efficacy of first human use of COVID-19 vaccines as there is in the case of influenza vaccination. Some side effects may be very rare and only emerge once the vaccine is rolled out and assessed during post-marketing surveillance. The Oxford vaccine is the only one that included children aged 5-12 in phase II studies.¹ Thus, the expected harm of a COVID-19 vaccine for children, however small, might be greater than for an influenza vaccine. While phase III trials are awaited, the level of certainty in safety will inevitably be lower than with a vaccine like that for influenza, which has been used for decades.

The expected usefulness to society of a COVID-19 vaccine, however, is likely to be enormous. The mortality rate of COVID-19 is greater than that of influenza; some estimated it to be 10 times greater.³³

What about the usefulness to children? Children are at a low risk of death from COVID-19.²⁶ Although they may experience complications from COVID-19, it is less clear that a vaccine is overall beneficial to them. Considering the greater expected harm of a COVID-19 vaccine compared with the influenza vaccine, it seems that a COVID-19 vaccine is less beneficial to a young child than influenza vaccine.

This conclusion does not rule out mandatory vaccination for COVID-19 for children, if not initially, at least at some point according to the prioritization schedule. The relevant question is whether the expected public health benefit of vaccinating children is large enough to justify an intervention on children that might not be overall beneficial for them.

Peter Singer gives the famous example of “duty of easy rescue” of a child drowning in a pond.³⁴ If I can save a child whom I see drowning in a pond near me, and the only cost to me would be to ruin my new expensive pair of shoes, then I ought to do it. The benefit to the third party significantly outweighs the cost to me. If COVID-19 vaccination entails a sufficiently small risk for children, then there could be a duty to vaccinate children.

We have previously argued that there can be a collective duty of easy rescue, which can be enforced when the good at stake is sufficiently important.^{35,36} Thus, if the public health threat were grave and if mandatory vaccination were more likely to be successful than any other strategy, and the cost to children was sufficiently small, it might be justified.

However, on the basis of this principle, it is far harder to justify mandatory vaccination of children for COVID-19 than it is for influenza. We should be prepared to coercively impose some risk on children, but not significant risks. Given the relative uncertainties around the COVID-19 vaccine, it will be difficult to justify mandatory vaccination in children, at least initially.

Coercion Should Be Proportionate

Even if the public health threat is serious and the comparative expected usefulness is high, a third requirement for an ethical justification of mandatory vaccination policies is that the restriction of liberty should be as minimal as necessary to achieve the goal.

Sometimes this idea is expressed in public health ethics by appealing to a principle of the least restrictive alternative.^{37,38} This formulation, in practice, is often of not much use. Usually, greater restrictions of individual liberties will yield larger collective benefits with regard to any specific goal; for example, if no one were allowed to drive a car, no one would be killed by being run over by a car. So the question is, should we use more coercion to achieve greater expected usefulness or less coercion and achieve less expected usefulness? We need a criterion to strike a reasonable balance between respect of individual liberty and expected usefulness. The greater the public health threat, the more liberty can be restricted.

For example, a reasonably onerous “opt out” scheme for school vaccination of children for influenza might be justifiable ethically and acceptable to the public.³⁹ Liberty would be substantially preserved, but the onerous procedure would represent a modest disincentive to opting out. Nonetheless, individual autonomy would be respected, because people who strongly valued not vaccinating could do so. More coercive measures would be justified if such a form of hard nudging was not enough. In fact, vaccination for the world’s greatest infectious scourge against small pox was in some places compulsory, for example, in the UK for more than 100 years before it was discontinued in 1971.⁴⁰

The Role of Incentives in Vaccination of Children

One of us has argued that, in cases where the conditions are less clearly met, incentivization may be better than coercion if voluntary vaccination is not sufficient.¹⁶ Incentivizing vaccination would require full disclosure of the risks and benefits and of the limitations of knowledge and confidence in vaccine safety.

However, incentivization of vaccination under these conditions in children is problematic if the vaccine is primarily of benefit to achieving or maintaining herd immunity and not primarily of benefit to the child, and the benefit accrues to the parent. In that case, the parent benefits from vaccinating the child and the child cannot consent to the risk. This creates a conflict of interest for the parent: minimizing the risks for the child vs benefitting from the incentive.

Ideally, at least part of the incentive should accrue to the child. If the child benefits from the incentive, for example, is allowed greater freedom of movement or association, then it may be acceptable to authorize vaccination. Because influenza vaccination is in the interest of the child, as well as of society, incentives may permissibly be used. The justification is more difficult to make in the case of COVID-19, where the net benefit to the child is less clear.

Objection

There is some concern that mandatory vaccination programs could backfire by increasing people’s hesitancy or distrust toward vaccines, and more generally that with effective communication, transparency, and adequate information, voluntary vaccination schemes would be sufficient to realize herd immunity.⁴¹ Confidence in the COVID-19 vaccine will probably be different from confidence in influenza or MMR vaccine. First, mandatory programs are not incompatible with campaigns to foster trust in vaccines, and even with mandatory policies in place, it remains preferable that people vaccinate out of an autonomous choice and because they trust vaccines than merely because they are coerced. If a mandatory vaccination policy is shown to be effective, that is itself a way in which trust could be built. Second, if properly implemented (eg, if penalties are appropriate and there is adequate enforcement), mandatory vaccination programs can work. In Italy, mandatory vaccination for school-age children was introduced in 2017 for 10 vaccines, including the MMR vaccine; as a result of the new mandatory scheme and related information campaigns, MMR vaccination coverage at 24 months increased by 4.4%.¹²

If mandatory vaccination is considered, sufficient vaccine supply and access to vaccination without financial or logistic barriers needs to be ensured.⁴² Furthermore, adequate compensation systems need to be established alongside comprehensive and real-time surveillance of vaccine side effects or vaccine safety surveillance platforms. Compensation schemes for vaccine injuries already exist in many countries.⁴³ They are ethically required as a matter of fairness and solidarity toward those who experience significant complications from vaccines for which they are not responsible, considering that by getting vaccinated they often make a contribution to public health and not only to their own health.⁴⁴

Conclusion

Mandatory vaccination of children for influenza with mild to moderate coercion could be justified. This practice might include reasonably onerous opt-out procedures or perhaps modest fines. Alternatively, incentive schemes could be justified. Mandatory vaccination of children (or incentive schemes) for COVID-19 is more difficult to justify, given the lower disease severity compared with adults and uncertainty around the effectiveness and risk profile for children.

However, the combination of COVID-19 and influenza poses a much greater threat to public health than either disease considered in isolation. Thus, if the case for mandatory COVID-19 vaccination for children is not strong, then the case for mandatory influenza vaccination for children is probably stronger than usual, because the need of vulnerable individuals to be protected from influenza is greater, as is the need to preserve hospital capacity.

Even if there is some risk to the child, if that risk is sufficiently small, then parents may be free to impose that risk for the sake of others, and if necessary to protect the vulnerable, the state may justifiably impose some degree of coercion on parents.

We need to make sure that the public health benefit is actually large enough to justify the imposition of the small risk. For instance, if children do not spread the virus to a significant degree, then the benefit to others of vaccinating children would also be reduced. And, if there are other policies, such as case identification and contact tracing, that decrease the need to vaccinate children, then these may be preferable.

Ultimately, whether volunteering children for a novel vaccine for a disease that is not a major threat to them, or mandating a vaccine, or incentivizing it, depends on very precise information about the nature of the disease, its severity, spread, and the vaccine itself. But it also requires balancing self-interest and duty to others, and liberty with usefulness. ■

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