The ethical impact of mandating childhood vaccination: The importance of the clinical encounter

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Abstract

Health ethics can justify the use of vaccination mandates. However, policies that pressurize parents to vaccinate their children can undermine traditional clinical ethics standards (e.g. autonomy and informed consent). The aim of this paper is to argue that the ethical impact of vaccination mandates can only be determined in the context of the clinical encounter. Public debate on the topic tends to be general in nature and, as a result, issues that require clarification to help sustain the trust of service users are underexamined. In addition, ethical debates are hampered by a toxic dichotomy in the public sphere between those (anti-vaccinators) who claim a move away from parental choice is necessarily a serious ethical violation; and others (often health scientists) who neglect serious consideration of ethical issues. This predicament permits flawed ethical claims to be made, and to remain unchallenged. Despite this, ethical concerns – including those relating to trust and individual freedom – are fundamental to sustaining confidence in vaccination. This has recently been highlighted by the Covid-19 pandemic which made accessing childhood vaccinations harder, leading to a further decline in uptake. The pandemic has also revealed the strength of public feeling towards infection control measures that restrict peoples’ freedoms. In this paper I argue that to minimize the ethical disruption associated with the use of vaccination mandates, it is essential to focus more attention on their impact in the clinic and to accurately identify the drivers of such tensions.

Keywords

Vaccination, informed consent, clinical ethics, public health, Covid-19

Introduction

Rates of childhood immunization remain high across developed nations. However, there is clustering of low, delayed or selective uptake and, as a result, outbreaks of preventable diseases. In October 2019, in the United States (US) the Center for Disease Control (CDC) reported the highest annual rate of measles since 1992 (1,249). Included in this number were two outbreaks in New York. Similarly, in 2019 the World Health Organization (WHO) reported across the European region 34,300 cases of measles in 42 countries. The outbreak of Covid-19 and the public health social distancing measures requiring people to stay home has had a significant impact on the uptake of childhood vaccinations. The Health Care Cost Institute in the US reported that in April 2020 the uptake of childhood vaccinations reduced by 60% on average compared to the same time point in 2019. Some recovery in uptake was achieved in the months that followed, but it is still lower than required for herd immunity.

Sub-optimal uptake of vaccination is driven by a variety of factors: difficulty accessing vaccinations; parental hesitancy (those who are indecisive or unsure about vaccination) and those who reject some or all vaccinations (anti-vaccinators). The reasons for hesitancy and vaccine rejection are complex but include: religious and philosophical objections; concerns about vaccine safety; parents feeling they need more information to make an informed decision; and a perception of cost. The ethical impact of these factors is not limited to the individual. In addition to the adverse impact on individual health, serious health consequences for the community also occur, particularly when vaccines are targeted at children and adolescents. The ethical impact of these considerations is significant and requires careful consideration.
information,\textsuperscript{11} the belief that vaccines don’t work, are unnecessary or that too many are required.\textsuperscript{12,13} Also problematic for immunization uptake is the spread of misinformation via social media;\textsuperscript{14} and the rise of democratization in health contexts that can lead to the prioritizing of service user opinion or ‘expertise’ at the expense of professional knowledge and scientific evidence.\textsuperscript{15}

As a response to disease outbreaks, countries are increasingly deciding to use some form of top-down pressure to urge parents to immunize their children. The US has long required parents to have their children vaccinated to attend school – though individual states allow different exemptions.\textsuperscript{16} In addition, a growing number of nations – for example, France, Italy and Australia – now employ measures that pressure parents to vaccinate their children. This includes utilizing financial sanctions or fines (e.g. ‘no jab no pay’) or social exclusion (e.g. ‘no jab no play’) to push parents to vaccinate.\textsuperscript{17} There has been much debate at a policy level over the ethical acceptability and value of using mandates to increase vaccination.\textsuperscript{18} However, the ethical focus of such analysis is outdated in environments where mandates are already in use. In such situations, attention needs to focus on the ethical challenges raised by individual cases in the clinic.

Mandates are intended to influence people to undertake a particular course of action (e.g., to vaccinate their children, or wear a face mask on public transport). Associated with such top-down directives is some form of sanction. The types of sanction used to gain compliance in the uptake of childhood vaccination are diverse (e.g., complex measures being required to achieve exemptions, fines, other financial penalties, criminal sanction, restrictions on movement or exclusion from participation).\textsuperscript{18,19} Equally diverse is the level or severity of each sanction. This can, for example, vary between small financial penalty ($20), or a more severe financial ($20,000 fine) or criminal (jail sentence) sanction.\textsuperscript{18} As a result, the impact mandates have on people is variable.

The aim of this paper is to argue that the ethical impact of vaccination mandates can only be determined in the context of the clinical encounter. Currently, much public debate on the topic is general in nature and, as a result, issues that require clarification to help sustain the trust of service users are underestimated. Initially, I will identify features of the ethical culture surrounding immunization that make it important to address values-based challenges, alongside initiatives to provide people with information. The importance of this approach is heightened by the challenging ethical climate that currently surrounds public health initiatives, difficulties which have been revealed and, arguably, exacerbated by the Covid-19 pandemic. I will then contend that a dichotomy exists within debates around vaccination that undermines the quality of much needed examinations of ethical issues in the context of mandates. The remaining sections of the paper then point to a number of issues that influence the ethical impact vaccination mandates actually have and which require more dedicated attention.

**Ethical culture: Individual autonomy and informed consent**

Health ethics plays a critical role in helping to ensure service users have confidence in healthcare services. Foundational in this are assurances that people will have their choices and privacy respected. The primary ethical principles that help to protect individuals and sustain trust include autonomy, informed consent and confidentiality.\textsuperscript{20} Important for the focus of this paper, informed consent requires that people are: informed, mentally competent, able to understand information, and voluntarily able to decide. The final part of the process is the actual giving of consent or authorization for an intervention.\textsuperscript{21} The American Academy of Pediatrics (AAP) has argued, parental authorization or permission for vaccination should be respected unless a child is placed at ‘risk of serious harm’.\textsuperscript{22} Given the prominence of freely given authorization in clinical contexts, vaccination mandates are particularly ethically challenging for informed consent because the pressure they can exert has the potential to undermine its voluntariness.\textsuperscript{23} This predicament is exacerbated by a wider political turn to democratization which also prioritizes individual preferences. In health contexts, this focus is evident in commitments to person centered care and citizen participation.\textsuperscript{15} The development of less individually focused public health ethics arguably has little impact in the public sphere. As a result, when people engage with health issues their focus is often on individual concerns. If policies or health ethics run counter to this prioritizing, for example to protect public health, they require careful, transparent explanation to limit their negative impact on service user trust.

Evidence of the challenging ethical climate that surrounds public health and vaccination has recently been emphasized by the responses of some citizens to public health measures aimed at controlling the Covid-19 pandemic. More specifically, this global crisis has illustrated the strength of public commitments to individual freedoms and of anti-public health sentiments. In this respect, protests about lockdowns, mask-wearing and social distancing have highlighted that disputes between the public and health professionals around infectious disease control and vaccination are not
only disputes about facts or risks. For example, anti-mask and anti-lockdown protests across the United Kingdom, Europe, and the United States demonstrate public objections to mandatory measures that seek to limit freedom. 24–26 It was easy to assume that the outbreak of a deadly new infectious disease might shake and reverse the tide of anti-vaccination sentiment. But the protests and sometimes violent scenes when people are confronted about breaching public health measures in public spaces,27 have arguably reinvigorated efforts to block public health initiatives. Added to this is the negative impact that the rush to create a vaccine for Covid-19 has had on vaccine confidence. 28,29 In this respect, before a vaccine became available, research for the Pew Research Foundation found that 49% of Americans would not take a Covid-19 vaccine.30 More recently, the Foundation has reported that, as confidence has grown amongst the public that the ‘research and development process will yield a safe and effective vaccine for COVID-19’, 60% of Americans now say they will get vaccinated.31 But particularly concerning for the promotion and maintenance of public trust in vaccination are data that suggest healthcare professionals are amongst the vaccine hesitant.32 The strong public reactions to the impact on freedom of different types of public health mandates or restrictions, that have been so visible in the context of Covid-19, show the importance of taking values-based challenges seriously.

Despite the importance of ethics in gaining and sustaining service user confidence, and values-based challenges around vaccination and policies that mandate it, public discourse is marked by a toxic dichotomy which impedes serious consideration of such issues. More specifically, there is a division between those who claim any move away from parental choice is a serious ethical breach; and those whose commitment to the health sciences can mean ethical challenges do not receive the rigorous attention they warrant. To illustrate the impact of this in the public sphere some examples will now be outlined.

**Limited, quality ethical debate**

One of the main sources for information on vaccination and certainly a key driver of public policy is research in the health sciences. But the ethical messages that are deliberately or inadvertently transmitted by this work are a cause for concern. For example, in 2019 Nature, a journal with one of the highest impact factors in the world, published a Comment piece which urged caution over the use of vaccine mandates. The authors argued that imposing sanctions on people for failing to vaccinate their children could worsen health inequalities, obstruct vaccine uptake and ‘fuel anti-vaccine activism’.33 These points are important and well made. However, although the Comment focused on the challenges associated with vaccination mandates, and claimed to propose a ‘smart and ethical’ approach, the authors failed to address the challenges presented for informed consent or parental authorization. 33 Instead they suggested only that clinical environments need to be ‘welcoming’. As the historical drivers of health ethics reveal, a reliance on ‘welcoming’ environments has not prevented abuse. 34 Thus, this approach is ethically insufficient to win and sustain service user trust.

Also problematic is work in the health sciences that focuses on informed consent in countries that already mandate vaccination (e.g. Australia) which does not engage with questions concerning the possibility of autonomous consent in such systems. 35-36 This is partly because the work focuses too narrowly on information provision within informed consent, at the expense of the other aspects of the five-part process. This does a disservice to the ethical complexity of the issues and, importantly, to the value-based preferences of parents – which are only partly determined by information. Underplaying the potential for mandates to disrupt traditional clinical ethics guidance risks undermining trust and confidence amongst parents who require ethical support and not only factual information on issues like vaccination and disease risks.

Finally, there is disagreement in the literature on whether ‘nudging’ - or efforts to control the options with which service users are presented in order to influence their decisions - is compatible with traditional clinical ethics standards. 37,38 Ploug and Holm contend that the legitimacy of general claims that ‘nudging’ is ethically acceptable are unsound. This is because the ethical status of nudging can only be determined in the context of the clinical encounters that show its actual impact.39 Elsewhere I have argued that in the context of vaccination, the use of ‘nudging’ lacks the transparency needed to engage parents and communities as equal partners; a predicament that could be counterproductive to efforts to promote trust and uptake.15 This concern has largely been ignored in health science literature.40 Indeed, it has been argued that policies ‘which merely nudge’ people to vaccinate allow for voluntary immunization.41 Not acknowledging legitimate ethical concerns about the impact nudging has on autonomy or parents’ capacity to freely authorize vaccination again has the potential to undermine trust. This is particularly the case in ethical cultures committed to individual choice. There are good ethical reasons for limiting autonomy, but arguments need to be made for such measures, they should not be smuggled through to avoid legitimate scrutiny.
'Anti-Vaccinators' and parental rights

A prominent, alternative source of ethical messaging about vaccination and policies that mandate it comes from those who can be identified as holding an ‘anti-vaccine’ position. This includes some sections of the popular press that have been responsible for ‘cynically, irrationally, and willfully...’ fanning public fears around vaccination and specifically the Measles, Mumps and Rubella (MMR) vaccine.\textsuperscript{42} One claim of ‘anti-vaccinators’ has been to emphasize that mandates impede the ‘right’ of parents to give informed consent, on behalf of their children, for vaccination.\textsuperscript{43,44} Fisher states: ‘Implicit in the concept of informed consent is the right to refuse consent or, in the case of vaccination laws, the right to exercise conscientious, personal belief or philosophical exemption to mandatory use of one or more vaccines.’\textsuperscript{43} Informed consent is a central principle within biomedical ethics; and arguments about the impact of mandates on it appear in peer-reviewed academic literature.\textsuperscript{23} However, anti-vaccination statements leave a number of points needing clarification. This includes the claims that: vaccine mandates necessarily disrupt parental ‘rights’; and the implication that the capacity to freely consent to vaccination is the only part of the informed consent or authorization process of relevance. Just as it is important to correct flawed ‘anti-vaccination’ rhetoric relating to the science of vaccination, it important to flag ethical inaccuracies that can influence people who are hesitant about immunization. Failures to offer a more adequate ethical response to the impact of mandates leaves ‘anti-vaccination’ rhetoric on the issue unchallenged and, arguably, emboldened. The paper now turns to identify issues that influence the impact of vaccination mandates.

The impact of vaccination mandates

In order to move beyond the dichotomy that hampers an inclusive examination of vaccination mandates, it is ethically necessary to identify issues that influence their impact on parental decisions about immunization. As noted above, the enforcement of mandates and the types or levels of sanctions used are variable. Families also have differing abilities to resist the intended influence of mandates. They may, for example, have the financial resources to minimize the impact of possible penalties for non-vaccination, or to provide home schooling or private play activities. For such families, mandates are likely to be largely toothless. Thus, while some parents might have their decision influenced by the intended impact of mandates, this assumption cannot be generalized to individual cases. More specifically, there are a number of factors which influence the legitimacy of ‘anti-vaccine’ claims that vaccination mandates are necessarily responsible for influencing parental freedoms in ways that are ethically problematic. These points also underline the importance of resisting the temptation to think a reliance on facts is sufficient, in the context of an issue littered with values-based challenges.

The influence of clinical encounters

Mandates could certainly lead to some parents, perhaps many, feeling pressurized to attend a vaccination appointment for their child. However, it is reasonable to suggest that as a result of their interaction with healthcare professionals when they attend a vaccination consultation, these parents come to freely authorize immunization. Similarly, the existence of mandates might be of no concern to many pro-vaccine parents, but a poor experience at a vaccination consultation – perhaps due to underhand ‘nudging’ - could lead to them feeling suddenly uncomfortable with the authorization process. This suggests that genuine concerns about the ability of parents to make informed, free decisions about vaccinations for their children should focus attention on what happens in clinical contexts. It is easy to stoke public fears about the ethical implications of top-down policies that mandate vaccination with claims they impede parental freedom. But this misrepresents the decision-making process which needs to take place, even when mandates exist. Most often, even with mandates in place, parents do give some form of authorization – vaccinations are very rarely literately physically forced.\textsuperscript{18} This makes it necessary to consider the type of authorization provided, and to identify the factors that influence this classification.

Informed consent: Autonomous or procedural?

To be more transparent about the impact mandates can have in clinical encounters it is important to distinguish between different forms of informed consent. Faden and Beauchamp identify two understandings of the concept. The first is traditional ‘autonomous’ consent, the second ‘effective’ consent which is ‘legally or institutionally effective’.\textsuperscript{45} ‘Effective’ consent satisfies the ‘rules and requirements’ of institutions, but is not necessarily freely given or autonomous. I have argued that, for a number of reasons, some parents will still be able to give autonomous authorization in the context of mandates. However, ‘effective’ consent represents the type of authorization that will be given by some parents who feel unable to give autonomous permission, but go along with vaccination. In such circumstances, authorization essentially operates as a waiver for
autonomous authorization and the acceptance of associated risks. In this way, it primarily protects the institutions and professionals providing the vaccination and falls short of traditional autonomous authorization. A number of points raised by this issue require attention.

Firstly, in liberal democracies and ethical cultures based on individualism, parents might reasonably assume informed consent aligns with autonomy. If this is not so, requiring parents to sign informed consent forms could mean they only give procedural authorization, not autonomous permission. This could lead to concerns that double-standards are operating – informed consent is required, but providing it might not feel autonomous. A lack of transparency on this point risks stoking fears around vaccination ‘conspiracies’ and ethical abuses. The need to explain and even record on the form the type of authorization that is actually given by parents requires consideration to help ensure clinical contexts remain ethically credible.

Secondly, it is also necessary to debate whether informed consent is downgraded to a procedural act solely as a result of top-down policies, like public health mandates. It has, for example, been argued that the prominence of procedural consent is influenced by the growing tendency to focus too much attention to consumer preference, due to the democratization or engagement turn in health. In this respect, O’Neill contends prioritizing consumer choice can be at the expense of quality health interventions and based on ‘a breathtaking simplification of ethical justification in and beyond medicine’. Individual and citizen views have a central role to play in health policy and practice. But this involvement should not be reduced to simple, unreflective, poorly informed choice. When parents don’t engage adequately with professional expertise to help inform their vaccination decisions, this can also play a role in undermining their capacity for making sound values-based decisions. Similarly, placing an unmoderated emphasis on individual choice in health systems that are actually profoundly impacted by interdependence, risks undermining, rather than supporting, the efforts of citizens to be autonomous. These issues emphasize the need to cultivate more sophisticated ethical decision-making skills in discussions of vaccination.

The synergy of facts and values

I have argued that the health sciences can give too little attention to the role of values-based preferences and the wider ethical culture that determines parental preferences. ‘Anti-vaccination’ claims regarding the impact of mandates on parental choice tend to emphasize parental ‘rights’ at the expense of sound understanding, reasoning and quality information. As authorization is the final part of a five-part consent process. It is critical for the legitimacy of informed consent, or parental permission that all steps in the process are respected, not only the need for lack of coercion, or the importance of information. Legitimate authorization for vaccination is dependent on respecting the synergy between facts and values that underpins sound ethical decision-making. Living in an era in which misinformation is spread instantly and widely via social media, makes claims that parents are necessarily well-informed and able to reason soundly questionable. Relying on poor quality information can undermine a person’s ability to give autonomous permission, regardless of any use of mandates. Indeed, it is such circumstances that have led to Government’s using mandates to endeavor to fulfill their ethical obligation to protect children because parents can fail to exercise their duty of care responsibly and in a manner that protects the best interests of their children. However, while this general policy can be justifiable, its legitimate operation and ethical impact can ultimately only be determined and minimized to help promote confidence in vaccination in the context of specific cases.

Conclusion

Ethical debates on the use of vaccination mandates tend to take place at a policy level and focus on the age-old tension between individual freedoms and public interests. The impact of mandates in clinical environments has not received the attention it merits, yet it is this level of debate that ultimately determines the ethical burden of such policies. Expanding debates on this issue is essential to ensure healthcare professionals and parents are equipped to steer a course through the ethical inertia of the health sciences, and the inaccurate anti-vaccination claims they encounter regarding vaccination and mandates. The issues examined in this paper are not only of relevance for childhood vaccination, but also for other efforts to use mandates to protect public and individual health. If public confidence in vaccinations for Covid-19 remains low, Government’s may feel compelled to mandate them. This will give added urgency to the appropriate ethical treatment of the issue.

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