REVIEW

Acquiescence and submission to COVID-19 vaccination: ethics considerations [version 1; peer review: awaiting peer review]

Jerome Amir Singh[1,2], Sunita S. Bandewar[3], Ana Palmero[4], Anant Bhan[5,6]

[1]Howard College School of Law, University of KwaZulu Natal, Durban, 4001, South Africa
[2]Dalla Lana School of Public Health, University of Toronto, Toronto, Canada
[3]Health, Ethics and Law Institute for Training Research and Advocacy (HEaL Institute), Forum for Medical Ethics Society, Mumbai-Pune, India
[4]Directorate of Health Research, Ministry of Health, Buenos Aires, Argentina
[5]Department of Community Medicine, Yenepoya Medical College, Mangalore, India
[6]Centre for Ethics, Yenepoya University, Mangalore, India

v1 **First published:** 27 Apr 2021, **6**:91
https://doi.org/10.12688/wellcomeopenres.16745.1
Latest published: 27 Apr 2021, **6**:91
https://doi.org/10.12688/wellcomeopenres.16745.1

Abstract

Compelling individuals to be vaccinated with candidate vaccines that have been granted emergency use approval based on limited data, and penalising non-compliance, raises challenging ethics issues. For instance, some individuals may wish to be vaccinated, but may be hesitant to be vaccinated with particular vaccine candidates. On the other hand, some individuals may be averse to vaccination of any sort but may find themselves being forced to submit to vaccination in certain situational contexts to gain access to benefits or services. In all such instances, acquiescence and submission runs counter to the notion of voluntariness, which is a central pillar of the doctrine of informed consent.

Keywords

COVID-19 vaccinations, mandatory vaccination, ethics

Open Peer Review

Reviewer Status *AWAITING PEER REVIEW*

Any reports and responses or comments on the article can be found at the end of the article.

Corresponding author: Jerome Amir Singh (singhj9@ukzn.ac.za)

Author roles: Singh JA: Conceptualization, Formal Analysis, Funding Acquisition, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Bandewar SS**: Writing – Review & Editing; **Palmero A**: Writing – Review & Editing; **Bhan A**: Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This manuscript is part of an Epidemic Ethics/WHO initiative which has been supported by FCDO/Wellcome Grant [214711/Z/18/Z].
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: Singh JA, Bandewar SS, Palmero A and Bhan A. **Acquiescence and submission to COVID-19 vaccination: ethics considerations [version 1; peer review: awaiting peer review]** Wellcome Open Research 2021, **6**:91 https://doi.org/10.12688/wellcomeopenres.16745.1

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Introduction

Since December 2020, several COVID-19 candidate vaccines have demonstrated efficacy and been granted emergency use designation by major drug regulators and the WHO[1]. As a result, tens of millions of people globally have now been vaccinated against COVID-19, with the number of vaccinees growing daily[2]. The accelerated pace of COVID-19 vaccine development, vaccine trials, and public deployment of candidate vaccines under emergency use regulatory frameworks merits praise. However, some health systems, such as the United Kingdom's National Health Service (NHS), are contemplating mandating COVID-19 vaccinations for health workers in the interests of patient safety[3]. Moreover, in some settings, access to essential services, employment, study, and travel could become conditional upon COVID-19 vaccination[4]. The adoption of such measures will effectively mean that individuals will be indirectly compelled to undergo COVID-19 vaccination, even in the absence of laws mandating such vaccination. As the pace of COVID-19 vaccine deployment gathers pace globally, the ethical issues implicit in indirect compulsion merit urgent attention.

Discussion

The public health and moral imperative of vaccination

Vaccines form the backbone of modern medicine and have transformed the lives of people, globally. Vaccination not only provides a benefit to the individual being vaccinated, but also confers a significant public health benefit by facilitating population immunity. To underscore this argument, in settings such as Argentina, vaccination is deemed by law to be of 'national interest'[5]. Some have argued that refusal of vaccination when offered a vaccine not only puts the individual at risk, but also increases public health risk by adding to a population of unimmunized individuals within which vaccine-preventable disease may spread[6]. Given such factors, some have argued that individuals who have access to vaccines and for whom vaccination is not medically contraindicated, have a collective moral obligation to realize population immunity by being vaccinated[7]. Such a position holds that vaccination should be viewed as an altruistic medical procedure because some vaccines are of more good to society than to the vaccinee, who runs associated health risks[8]. Such a position prioritizes public health over individual liberty and holds that vaccination at the individual level is a fair burden to bear to realize population immunity.

In 2019, the WHO identified vaccine hesitancy as one of the top 10 threats to global health[9]. Such hesitancy could be predicated by safety and/or efficacy concerns, and religious, moral, or philosophical objections. Perhaps mindful that mandating COVID-19 vaccinations based on limited safety and efficacy could further spur vaccine hesitancy and scepticism, officials in countries such as Argentina, India, and South Africa have issued assurances that COVID-19 vaccination will not be made mandatory[10–12]. However, voluntary vaccination campaigns could threaten the goal of attaining population immunity. Such concerns have been underscored in settings such as India, where some healthcare workers are avoiding COVID-19 vaccination, despite being at high risk of infection and being prioritised for vaccination[13–15].

Given the primacy of public health over individual autonomy, vaccination campaigns raise important ethics issues, even under ordinary circumstances. These issues are accentuated in the context of a rapidly evolving Public Health Emergency of International Concern, such as the COVID-19 pandemic. Target populations for vaccines fall into a broad spectrum, ranging from those who may be willing to be vaccinated at any cost, to those who will refuse any type of vaccination, regardless of potential benefit to self or others. Compelling individuals to be vaccinated with candidate vaccines that have been granted emergency use approval based on limited data, and penalising non-compliance, raises particularly challenging ethics issues. For instance, some individuals may wish to be vaccinated, but may be hesitant to be vaccinated with particular vaccine candidates. Such a situation is playing out in settings such as the European Union[16] and India[17]. If individuals are offered a vaccine and have no other alternative, such individuals could be left with no other choice but to accept a vaccine candidate they may ordinarily have declined. Such a situation is playing out in settings such as Argentina[18]. On the other hand, some individuals may be averse to vaccination of any sort, but may find themselves being forced to submit to vaccination in certain situational contexts. In all such instances, acquiescence and submission runs counter to the notion of voluntariness, which is a central pillar of the doctrine of informed consent.

Informed decision-making and vaccination

Various forms of informed consent are recognized. The notion of *express consent* is generally taken to mean that an individual should only be subject to a procedure or intervention if he or she has expressly agreed to it. In the context of vaccination, the doctrine requires that the potential risks and benefits of the vaccine, including the nature, frequency, and duration of any known or potential side effects, should be disclosed to an individual; the individual must appreciate the information; and they must affirmatively and prospectively agree to assume such risks. This process may occur verbally or be documented in writing through a formal, written informed consent process. *Implicit* or *implied consent* is a form of consent that is inferred from actions. For example, if the potential risks inherent in a vaccine are disclosed by the vaccinator, and understood by the vaccinee, and that individual voluntarily presents their exposed arm for vaccination without saying a word, the provision of their consent may be deemed to be implied. Some settings recognize the notion of *presumed consent*, which holds that every member of society is presumed to have agreed and consented to a procedure or the administration of an intervention, unless he or she specifically takes action to be excluded from the process. In some settings, presumed consent applies in the context of organ donation, where individuals who die are automatically presumed to be organ donors, unless they have explicitly opted out of the system[19]. Some settings recognize a mix of presumed and implied consent processes. For example, in the case of childhood vaccinations administered

in schools, parents may be informed that the vaccination program is imminent (for example, through letters or other forms of communications). Subsequently, the physical presence of the child with or without an accompanying parent at the vaccination session, is considered to imply the provision of parental consent. This is based on the opt-out principle: parents who do not consent to vaccination are expected implicitly to take steps to ensure that their child does not participate in the vaccination session (for example, by not letting the child attend school on a vaccination day)[20]. Under certain conditions, nonobjection or non-dissent constitutes valid *tacit consent*, which may be described as "consent that is expressed silently or passively by omissions or by failures to indicate or signify dissent"[21]. But the notion of tacit consent can sometimes be problematic when undue influence, coercion, mistake, or fraud applies. Such factors nullify the notion of informed consent[22]. Such factors are amplified in many low- and middle-income settings, where, for instance, illiteracy and/or low social standing may underpin deferral to authority and confound the apparent provision of tacit consent. In such instances, silence and/or passively accepting vaccine administration may be a sign of deferral, submission, and acquiescence to authority, rather than a sign of willing, affirmative, autonomous choice. In such instances autonomy and informed consent are not realized. Tacit consent is open to interpretation and should not be regarded as a valid form of consent in relation to vaccination, especially in relation to candidate vaccines that have not been granted full licensure.

Modalities of compulsion and penalization

Globally, a broad spectrum of vaccination modalities, compulsions, and penalizations apply. In countries such as South Africa, immunization is governed at a national level, while in countries such as Canada and the United States, immunization is governed at the subnational level (state or provincial level), which results in heterogeneity in both immunization programs and mandates[23]. Countries also differ in respect of vaccine schedules and type of vaccine that is mandated. For example, Belgium mandates just a single childhood vaccination (polio), whereas Argentina mandates 16 childhood vaccinations[23]. Countries also differ in relation to penalties for non-compliance with vaccination mandates. For example, in Argentina, non-compliance with a vaccination mandate can result in a fine while in Uganda, non-compliance can result in a fine or imprisonment up to six months[23].

The nature of disease may also determine a compulsion order. Some settings compel vaccination only against contagious diseases, but not against diseases which only threaten the individual[24]. As COVID-19 is a contagious disease, some settings may consider mandating vaccination against COVID-19, even if the candidate vaccine has only been granted emergency use designation, not full licensure. The United Kingdom government, for instance, which is in the midst of deploying COVID-19 candidate vaccines through a domestic emergency use regulatory framework, is not ruling out mandating COVID-19 vaccination[25]. Concerns of such a stance on the part of political leaders have prompted legislators in the US state of Connecticut to propose prohibiting the state of Connecticut from mandating a vaccine that has only been granted emergency use authorization, not full licensure[26]. On the other hand, in settings such as Chile, legislators have presented a Bill before the country's Congress that proposes adding COVID-19 to the country's list of mandatory immunisation schedule[27]. In some settings that mandate vaccination, vaccinators are required to screen patients for contraindications and precautions prior to vaccine administration (for example, where vaccination could seriously impair health or cause death due to specific pre-existing medical conditions)[28]. Some settings also require health service providers to certify or recertify that a patient should be medically exempt from vaccination[29]. Some settings have implicit vaccine mandates. In South Africa, for instance, an individual confirmed to be infected with a notifiable disease "must comply, to the best extent possible, with all infection control measures given, including but not limited to prophylaxis, treatment, isolation or quarantine measures"[30]. As vaccines are prophylactic by nature, this provision seems to suggest that only those confirmed to be infected with COVID-19 must comply with a vaccine mandate order. However, the law is silent on whether those whose infection status is unknown must also comply with a prophylactic vaccine mandate. Settings heavily affected by COVID-19, such as Argentina and India, have legislative frameworks that could be used to mandate the involuntary vaccination of individuals on public health grounds[31,32], mirroring the stance of settings, elsewhere[23,33].

How situational vulnerabilities can underpin acquiescence, deferral, and submission to COVID-19 vaccination

Even in the absence of a country mandating COVID-19 vaccinations, individuals who elect not to be vaccinated despite being eligible for vaccination and vaccine availability, could find themselves being forced be accept vaccination in certain situational contexts. In December 2020, Brazil's Federal Supreme Court was asked to determine whether States and Municipalities could compel the vaccination of their populations. The court held that there is a distinction between compulsory vaccination and enforced vaccination. Mandatory vaccination was deemed to be constitutional, as long as the State does not adopt invasive, distressing or coercive measures. The court held that while no one should be forcefully vaccinated, individuals could face other restrictions in their rights if they do not comply with a vaccination mandate. The adoption of indirect restrictive measures could include the restriction of certain activities or the prohibition of attending certain places for those who choose not to be vaccinated[34]. However, while such measures may pass legal muster in settings such as Brazil, they have could yield dire ethical implications. For instance, penalizing non-compliance could exacerbate inequalities as penalties such as financial repercussions for non-compliance, could disproportionately affect disadvantaged groups[23].

Employment contexts. International labour law stipulates that employers have the overall responsibility of ensuring that all practicable preventive and protective measures are taken to

minimize occupational risks[35]. Employers are responsible for providing, where necessary and so far as is reasonably practicable, adequate protective clothing and protective equipment, at no cost to the worker[36]. International labour advisories also hold that, taking into account the organisation of preventive medicine at the national level, occupational health services might, where possible and appropriate, carry out immunisations in respect of biological hazards in the working environment[37]. Such standards have been codified in many domestic occupational health and safety regulatory frameworks. In such settings, some employers may mandate COVID-19 vaccination as a precondition to employment, or a precondition for returning to the workplace, under the pretext of ensuring occupational health and safety. In such instances, if individuals cannot engage in remote or off-site work (for example, working from home) because of the inherent requirements of their job (for example, if they are employed as bus drivers or air stewards), or because their employer does not permit such an arrangement even if such a work arrangement is feasible, an employee or prospective employee may have no choice but to submit to COVID-19 vaccination if they want to secure or retain employment. In settings such as Brazil, employers are empowered to develop internal vaccination policies that require employees to be vaccinated against preventable diseases. Non-compliance could render such employees liable to disciplinary measures. While authorities in settings such as the Philippines have announced that private sector employers could face administrative penalties if they require their workers to receive COVID-19 vaccines before they are allowed to enter the workplace[38], some employers in settings such as the United States have indicated that they will mandate workplace vaccination[39].

In settings such as the United Arab Emirates, COVID-19 measures include the requirement that all employees attending the workplace are required to undertake a Nasal Swab Test once every 14 days, the cost of which is to be borne by the employee. Employees who have received the COVID-19 vaccine are exempt from such requirement[40]. Such penalising measures will effectively drive employees to submit to vaccination to avoid personal costs. Even if a setting lacks public health laws that compel vaccination, the power differential inherent in employer-employee relationships may vitiate the element of voluntariness if an employer mandates workplace vaccination. Such power imbalances have been amplified during the COVID-19 pandemic, where infection control measures such as lockdowns have spurred unprecedented job losses and high rates of job insecurity, globally[41]. Given such factors, some employees or aspiring work-seekers may feel unduly pressured into acquiescing to vaccination to keep their jobs or gain employment, when they ordinarily may elect not to do so.

Some workplace contexts are particularly challenging in regard to exercising autonomy. For example, obedience to orders is central to chain of command in law enforcement, the military, and, to some extent, the private security industry. In such contexts, disobeying an order could result in a charge of insubordination or non-deployment. In France, for instance, mandatory vaccination applies to the military and determines an individual's medical aptitude to serve or to be deployed in theatres of operation[42]. While informed consent is usually a precondition to vaccine administration in most settings, in setting such as the United States, the country's President may waive the requirement that members of the armed forces be informed that they can accept or refuse the administration of an intervention if such a requirement is deemed not to be in the interests of national security[43]. However, in the US, such waiver arguably does not apply if the use of the intervention has been authorised under an emergency use regulatory framework. It is thus questionable whether settings such as the US will mandate the vaccination of members of the armed forces on the basis of an emergency use authorisation, despite potential vaccine hesitancy amongst members of the armed forces. Once COVID-19 vaccines are licensed, members of the armed forces in many settings may be compelled to be vaccinated.

Engagement with organised labour will be key to any COVID-19 workplace vaccination program. However, engagement may be challenging in the context of COVID-19 infection control measures, such as lockdowns and physical distancing. Moreover, in some settings and in some workplace contexts, there may be no presence of organised labour, or individuals may not be eligible to join labour unions. While labour unions in some part of the world are advocating for COVID-19 workforce vaccination[44], and some are also challenging exclusive government procurement of COVID-19 vaccines[45], some unions are concurrently mindful that they may have to defend members who refuse vaccination[46]. Even where vaccine administration is not made mandatory for state employees such as health workers and teachers, such employees could feel unduly pressured into accepting vaccination if the government is sponsoring the vaccination drive and expects its personnel to set an example for the general population. In such instances, subordinates may find themselves acquiescing or submitting to vaccination, regardless of their personal preference.

Educational contexts. Some settings mandate the vaccination of all children against certain diseases[33], unless exceptions apply. In other settings, educational institutions sometimes deny admission to children who fail to provide a certification of vaccination, and, moreover, require an updated immunization record for all incoming and returning students[47]. In such settings, educational institutions (including those that enrol adults) could add vaccination against COVID-19 to the list of diseases they require their students to be vaccinated against, as a pre-condition to enrolment or admission. Such a requirement could be enforced by authorities in settings where mandatory vaccination laws apply and where exemptions are not applicable. To counter such measures, legislators in the US State of New Jersey have introduced a Bill prohibiting State, county and local government entities, as well as public and private childcare centres, preschool programs, elementary and secondary schools, and higher education institutions from mandating that any person receive the COVID-19 vaccine[48]. In the absence of such legislative prohibitions, if individuals do not, or cannot, engage in distance learning programmes, or be home-schooled (in the case of children), they may be forced to submit to COVID-19 vaccination to gain access to educational opportunities, even if they (or their parents, should

the target population be minors who lack autonomy) would ordinarily elect not to do so.

Insurance and travel contexts. In a bid to improve immunisation rates, some settings tie access to certain social benefits to vaccination. In Australia, for instance, children of all ages must be up-to-date with their childhood immunisations or they lose eligibility for child care payments[49], with exemptions granted only for medical reasons[50]. In a bid to improve adult vaccination rates, Australian officials have also mooted the feasibility of introducing a 'whole-of-life' register, to track adult vaccinations[51]. Should such proposals come to pass, whole-of life-registers could be used to track COVID-19 vaccinations. In some settings, life insurers could make life insurance cover conditional upon COVID-19 vaccination[52], or use a client's lack of COVID-19 vaccination as a rating factor in life insurance underwriting to determine risk exclusions and premiums[53]. In yet other settings, some have mooted permitting insurance companies to discriminately charge higher premiums to those who choose to not vaccinate[54].

Vaccination against COVID-19 may also impact on travel and travel-related insurance. Currently, yellow fever is the only disease specified in the International Health Regulations (2005) for which countries may require proof of vaccination from travellers as a condition of entry under certain circumstances and may take certain measures if an arriving traveller is not in possession of such a certificate (for example, requiring the individual to be vaccinated at the port of entry as a condition to entry into that country)[55]. Accordingly, several nations make border entry of travellers from regions with certain endemic diseases (such as yellow fever), conditional upon showing proof of vaccination against those diseases[56,57]. Once COVID-19 vaccines become more widely available, some regions, such as the European Union, have indicated that they may make visa issuance conditional upon applicants proving they have been vaccinated against COVID-19[58]. In March 2021, China announced that the country would facilitate visa applications if applicants had been vaccinated with Chinese vaccines[59]. This, despite Chinese COVID-19 vaccines not being authorised and/or accessible in many of the settings that visa applicants hailed from[60]. Settings such as Cyprus, Romania, and the Seychelles have lifted quarantine requirements to visitors who can prove they have been vaccinated against COVID-19[61]. Such measures have been described as akin to 'immunity passports' or 'vaccine passports[62]. If such policies become more common, travel insurers could refuse to provide coverage to those who decline vaccination against COVID-19[63]. Similar restrictions may apply in regard to the transport sector. For instance, some stakeholders in the airline[64] and cruise ship[65] industry have indicated that they will make access to modes of transport they control conditional upon COVID-19 vaccination. Countries such as the UK have even mooted making 'vaccine passports' / immunisation certificates / COVID status certification a precondition to entering venues on the premise that doing so would allow businesses to relax social distancing measures inside venues[66,67]. Such measures pose an indirect barrier to domestic and international travel for those who wish not to be vaccinated against COVID-19.

In all the above instances, even if a country lacks a legislative framework that compels vaccination, individuals could be pressured into being vaccinated, regardless of their preference regarding a candidate vaccine, or their willingness to be vaccinated. In such instances, acquiescence, deferral, and submission to vaccination would nullify the element of voluntariness, thereby invalidating the notion of personal autonomy.

Conclusion

While an increasing number of settings are taking the position that COVID-19 vaccinations will not be made mandatory, individuals could, nevertheless, be deprived of their right to insist on a vaccine of their choice, and, moreover, face indirect compulsion to be vaccinated even if they prefer otherwise. Penalisation for non-compliance will further undermine the notion of voluntariness. Stakeholder engagement and transparency could facilitate public trust. As COVID-19 vaccine deployment gathers pace globally – both in the context of emergency use designation and full licensure – the ethical issues implicit in indirect mandatory vaccination merit urgent attention. A failure to address the ethical issues implicit in indirect mandatory vaccination could fuel anti-vaccine sentiment and undermine the fight against the COVID-19 pandemic.

Data availability

No data are associated with this article.

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