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When Are Vaccine Mandates Appropriate?

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Abstract

Vaccine refusal is a serious public health problem, especially in the context of diseases with potential to spark global pandemics, such as Ebola virus disease in the Democratic Republic of the Congo. This article examines whether and when compelling vaccination through mandates and criminalization, for example, are appropriate. It argues that some legal approaches are ethical when they preserve social stability, trust in government, therapeutic research opportunities, or when they diminish disease severity.

Introduction

Nowhere is Ebola virus disease (EVD) a more serious global public health concern than in the Democratic Republic of the Congo (DRC), where the world's second largest outbreak resulted in 3200 cases and 2100 deaths from August 1, 2018 through September 24, 2019.¹ Fortunately, experimental Ebola vaccines have been rapidly developed and are being tested,² and many hope that they will be useful in time to help respond to the most recent outbreak. According to data released by the World Health Organization (WHO), one of the vaccines is 97.5% effective.³ Among more than 90 000 vaccinated individuals, only 71 developed Ebola, with only 15 developing the disease more than 10 days after vaccination when vaccines are assumed to be fully protective, while the remaining 56 developed EVD during the initial 10 day period in which the vaccine is thought to confer only partial protection at best.³ The new Ebola vaccine represents an important opportunity to combat a potentially pandemic disease.

Vaccines, however, are only effective when enough people receive them within a given population. Due to serious repression and human rights violations,⁴ the Congolese might be rightfully wary of coercive measures taken by their government, no matter how well intentioned. Another challenge to vaccine uptake is that, in the DRC, people in EVD outbreak regions also face military and paramilitary violence and political turmoil. The cities of Katwa and Butembo, for example, are too dangerous for WHO personnel to visit to administer vaccines.⁵ Attacks on Ebola treatment centers in both cities⁵ demonstrate not only perpetrators' violence but also their distrust of international health interventions and Ebola vaccine campaigns. Although no attacks have been reported in South Kivu province, where another outbreak has occurred,⁶ it is possible that they will spread. This article examines whether and when legal approaches to Ebola vaccine refusal and reluctance, such as mandates and criminalization, are appropriate.

Legal Frameworks for Vaccination

Legal approaches to increasing vaccination rates range from the most coercive—actual physical force, eg, police coming to people’s houses to forcefully vaccinate them—to least coercive, eg, educational modules.⁷ Because the United States considers public health to be largely governed by states, it has a diverse and robust set of legal standards concerning this issue that provide a range of options to draw on; we therefore can learn from the US legal framework. Vaccine mandates, when backed by criminal sanctions (rare in the United States⁷) or by limiting access to schools, services, and jobs are on the coercive side of this continuum, although they are not as coercive as physical force. Mandates can also differ with respect to populations to which they apply, such as children, professionals, or adults; in strength of penalties levied when violated; in rigor of enforcement; and in the nature and scope of exemptions they allow. Exemptions are generally allowed—appropriately—for persons with health conditions that might be exacerbated by vaccine administration. For example, although all US states have vaccine requirements for [children attending school](#), they all also have medical exemptions.⁸

Governments, even liberal democratic ones, limit individuals’ autonomy, and one question is whether and when restrictions are justified. In 1905, in *Jacobson v Massachusetts*,⁹ the US Supreme Court concluded that states may require vaccination via mandate accompanied by a criminal fine, as long as the mandate is reasonable. The Court explained:

[T]he liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis, organized society could not exist with safety to its members.⁹

Since *Jacobson*, the value courts and society place on individual bodily autonomy has increased, and autonomy has even been raised to the level of a fundamental right. US adults today have a right to decline even life-saving treatment, for example.¹⁰ Extrapolating this right to the DRC, we would permit DRC citizens to refuse an Ebola vaccination even though it might save lives. However, it is also recognized that the state can act to protect persons other than the affected person, even at the cost of limiting fundamental individual liberties. For example, the state’s power to limit individual freedom to protect communities is exercised when quarantining or isolating—even by force—individuals who pose risk (of infection, perhaps) to others; the legitimacy of this exercise of state power is settled legal doctrine.¹¹ Not vaccinating also has implications beyond an individual, and the state can step in to regulate vaccine administration under this same authority. In the right circumstances, this authority justifies vaccine mandates with criminal sanctions or by limiting mandate violators’ access to schools, services, and jobs.⁷ In the DRC context, we might reject an objector’s [refusal of vaccination](#) on the basis that refusing places not only his or her life at risk, but also the lives of other members of the community, especially considering the highly infectious nature of EVD.

The state's authority to impose mandates with consequences is even more extensive when applied to children, who are not legally regarded as autonomous, as adults are.⁷ The United States is one of many countries with a long history of using school mandates to increase vaccination rates^{7,12}; these mandates have been consistently upheld by US courts against claims that they violate individual rights.¹³ Although all states provide medical exemptions,⁸ they vary in nonmedical (eg, religious or personal belief) exemptions. Adults who violate these mandates may not be able to send their child to school.⁸ Internationally, Italy and France impose fines on parents who do not vaccinate their children¹²; in France, jail time (though we are unaware of any cases of parents actually jailed) is a potential consequence of vaccine mandate violation.¹⁴

States are understandably more reluctant to mandate experimental vaccines, such as the current Ebola vaccines, but there is some precedent for widespread administration of novel vaccines when the public health threat is significant enough. In 1954, for example, 623 972 US children were injected with the then-experimental polio vaccine or a placebo and more than a million other children received the vaccine in an observed control design at the direction of state public health officials.¹⁵

Ethical Justification of Legal Approaches

Because no society protects individual freedom to an absolute degree, when is it ethical and reasonable to limit individual freedom? The following criteria are used by the courts to assess the reasonableness of limits on individual freedom: (1) proportionality, (2) precedent, (3) context, and (4) sufficiency of access to the good or service being mandated. Here, we apply these criteria to limits on individual freedom with regard to vaccination.

1. *Proportionality.* Higher levels of risk justify more restrictive limitations on individual freedom, where risk is construed as a combination of risks posed by a disease and the ease of transmission of that disease in relevant local circumstances.
2. *Precedent.* Precedent set by prior limitations on individual freedom matters: more coercive or restrictive approaches should generally only follow failures of less coercive or restrictive approaches. That is, unless there is an immediate, severe risk, adults should be free to exercise their autonomy to the extent that vaccination rates afford sufficient public protection.
3. *Context.* Social and cultural context of liberty restrictions must also be considered. In areas where government is unstable or in societies in which trust is fragile, coercive measures could undermine what's left of a state's stability or a society's trust. Liberty restriction and coercion can exacerbate distrust, suggesting the appeal of less restrictive and less coercive **education-based approaches**. Two drawbacks of education-based approaches, however, are that they might not be trusted by some or might not be sufficiently protective of public safety.

4. *Sufficiency of access.* Restrictive, coercive legal approaches require sufficient access to the good or service being mandated. That is, it is patently unfair and nonsensical to demand compliance with vaccination policies without making vaccines sufficiently available to those subject to a mandate. This reasoning suggests the importance of the state's capacity to provide adequate supply for the vaccine for which a mandate creates demand.

Implementing Mandates

Assuming a vaccine mandate is justifiable according to the 4 criteria just described, when and how should a vaccine mandate be enforced? It's worth noting that vaccine mandates tend to fail when they do not or cannot account for plurality among perceptions, values, and beliefs that drive individuals' vaccination choices. In the United States, for example, ignoring a legacy of maltreatment of African-Americans by the medical establishment (eg, the US Public Health Service Syphilis Study at Tuskegee^{16,17}) can undermine understanding of why some African-American parents might not be motivated to comply with a government mandate to vaccinate their children. Opponents of vaccination can be categorized in a variety of ways—for example, as religious objectors, political libertarians, and self-interest maximizers—that help explain how mandates affect vaccination choices.¹⁸ A religious objector might require a mandate with a harsh penalty in order to comply with a mandate, while that same penalty could strengthen a political libertarian's reluctance to vaccinate. Before implementing a broad vaccine mandate in the DRC, then, public health officials would be wise to consider the most common reasons for vaccine refusal and work to address those concerns. This precaution is especially relevant considering the experimental nature of the current vaccines, which could arouse concerns that vaccine acceptance is tantamount to agreeing to participate in experimentation.

Paradoxically, in some contexts, a vaccine mandate could undermine public confidence in the vaccine, resulting in fewer people being vaccinated. For example, in 1853, England passed the National Vaccination Act, which imposed heavy fines for noncompliance.¹⁹ Riots erupted across the country, leading to the act's repeal and replacement with a much less restrictive, less coercive mandate. In the context of known violence against EVD clinics in the DRC,⁵ potential backlash against a harsh mandate requiring an experimental vaccine must be considered seriously.

Although mandates work well in some countries, they can also cause backlash, resistance, and resentment. When enforcement capacity is limited or nonexistent, mandates cannot be properly implemented and are thus unlikely to promote public health and safety. Moreover, mandates can backfire if a population resents being coerced and has not received sufficient education about the safety, efficacy, and public health importance of vaccinations. The WHO's Strategic Advisory Group of Experts correctly recognized the value of public education, especially in the DRC, when it included the implementation of a mass communications campaign as one of its key recommendations on Ebola vaccination in the region.²⁰ Thus coercive mandates are not substitutes for educational campaigns²¹; any promotion of

the Ebola vaccine in the DRC should be sure to include education as a key centerpiece, even when more coercive initiatives are utilized.

Conclusion

Evidence suggests that the recently developed Ebola vaccine is an effective and important tool for controlling outbreaks and future pandemics. But resistance to vaccines is also pervasive in some regions, including in the DRC, as suggested by a pattern of violence against vaccine providers.⁵ Legal approaches to compelling vaccination are well established and globally widespread, so restricting individual liberty by mandating vaccination in this context would not be ethically inappropriate or novel. Policymakers, however, should apply the criteria outlined above to assess whether and when a mandate is ethically justified.

References

1. Concern Worldwide US. Ebola outbreak in DRC: second largest outbreak in history ranges in Congo. <https://www.concernusa.org/story/ebola-outbreak-in-drc/>. Accessed October 7, 2019.
2. National Institute of Allergy and Infectious Diseases, National Institutes of Health. Ebola vaccines. <https://www.niaid.nih.gov/diseases-conditions/ebola-vaccines>. Updated February 26, 2016. Accessed September 2, 2019.
3. World Health Organization. Preliminary results on the efficacy of rVSV-ZEBOV-GP Ebola vaccine using the ring vaccination strategy in the control of an Ebola outbreak in the Democratic Republic of the Congo: an example of integration of research into epidemic response. <https://www.who.int/csr/resources/publications/ebola/ebola-ring-vaccination-results-12-april-2019.pdf?ua=1>. Updated April 12, 2019. Accessed June 20, 2019.
4. Human Rights Watch. Democratic Republic of Congo: events of 2018. <https://www.hrw.org/world-report/2019/country-chapters/democratic-republic-congo>. Accessed September 2, 2019.
5. Branswell H. Ebola response teams scrambling to care for patients after attacks set back efforts. *STAT*. March 1, 2019. <https://www.statnews.com/2019/03/01/ebola-response-teams-scrambling-to-care-for-patients-after-attacks-set-back-efforts/>. Accessed June 20, 2019.
6. Winsor M. Ebola outbreak spreads to 3rd province in eastern Democratic Republic of Congo. *ABC News*. August 19, 2019. <https://abcnews.go.com/International/ebola-outbreak-spreads-3rd-province-eastern-democratic-republic/story?id=65051770>. Accessed October 7, 2019.
7. Weithorn LA, Reiss DR. Legal approaches to promoting parental compliance with childhood immunization recommendations. *Hum Vaccines Immunother*. 2018;14(12):1610-1617.
8. National Conference of State Legislatures. States with religious and philosophical exemptions from school immunization requirements. <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>. Updated June 14, 2019. Accessed September 2, 2019.

9. *Jacobson v Massachusetts*, 197 US 11 (1905).
10. Annas GJ. *The Rights of Patients*. 3rd ed. Carbondale, Ill: Southern Illinois University Press; 2004.
11. Jobe KM. The constitutionality of quarantine and isolation orders in an Ebola epidemic and beyond. *Wake Forest Law Rev.* 2016;51:165, 172-180.
12. Attwell K, Navin M. How other countries get parents to vaccinate their kids (and what Australia can learn). *Medical Xpress*. September 18, 2019. <https://medicalxpress.com/news/2019-09-countries-parents-vaccinate-kids-australia.html>. Accessed October 4, 2019.
13. Mello MM, Studdert DM, Parmet WE. Shifting vaccination politics—the end of personal-belief exemptions in California. *N Engl J Med.* 2015;373(9):785-787.
14. France makes 11 child vaccines compulsory: no vaccines, no school. *EFE*. January 2018. <https://www.efe.com/efe/english/technology/france-makes-11-child-vaccines-compulsory-no-school/50000267-3480979>. Accessed October 4, 2019.
15. Meldrum M. “A calculated risk”: the Salk polio vaccine field trials of 1954. *BMJ.* 1998;317(167):1233-1236.
16. Brandon DT, Isaac LA, LaVeist TA. The legacy of Tuskegee and trust in medical care: is Tuskegee responsible for race differences in mistrust of medical care? *J Natl Med Assoc.* 2005;97(7):951-956.
17. Centers for Disease Control and Prevention. Tuskegee Study, 1932-1972. <https://www.cdc.gov/tuskegee/index.html>. Updated December 14, 2015. Accessed September 2, 2019.
18. Atwell K, Navin MC, Lopalco PL, Jestin C, Reiter S, Omer SB. Recent vaccine mandates in the United States, Europe, and Australia: a comparative study. *Vaccine.* 2018;36(48):7377-7384.
19. Wolfe RM, Sharp LK. Anti-vaccinationists past and present. *BMJ.* 2002;325(7361):430-432.
20. Strategic Advisory Group of Experts (SAGE) on Immunization. Interim recommendations on vaccination against Ebola virus disease (EVD). https://www.who.int/immunization/policy/position_papers/interim_ebola_recommendations_may_2019.pdf?ua=1. Updated May 7, 2019. Accessed September 2, 2019.
21. Leask J, Danchin M. Imposing penalties for vaccine rejection requires strong scrutiny. *J Pediatr Child Health.* 2017;53(5):439-444.

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