
COMMENTARY

Legal Epidemiology for Global Health Security and Universal Health Coverage

Alexandra L. Phelan and Rebecca Katz

Legal epidemiology is an increasingly useful tool for examining the implementation of international obligations or legal responses to common threats to public health. In their piece examining immunization laws across 20 Sub-Saharan African countries, Ghedamu and Mason Meier seek to demonstrate both objectives.¹

Under the International Health Regulations (IHR), countries are obliged to develop core capacities to prevent, detect, and respond to potential public health emergencies. The Joint External Evaluation (JEE), designed to assess national compliance with the IHR (and the Global Health Security Agenda framework used by Ghedamu and Mason Meier) includes specific targets around immunization for global health security.² (See Figure 1)

Immunization is also a fundamental component necessary for strengthening health systems and achieving universal health coverage. The right to health is a useful framework for achieving universal health coverage, requiring that health care goods and services are available, accessible, acceptable, and of good quality. Applying this framework, not only should laws and policies ensure that immunization is accessible, available, and of sufficient quality, achieving universal health coverage requires that immunization be acceptable to local communities. Recent events have demonstrated just how important community acceptability is for immunization.

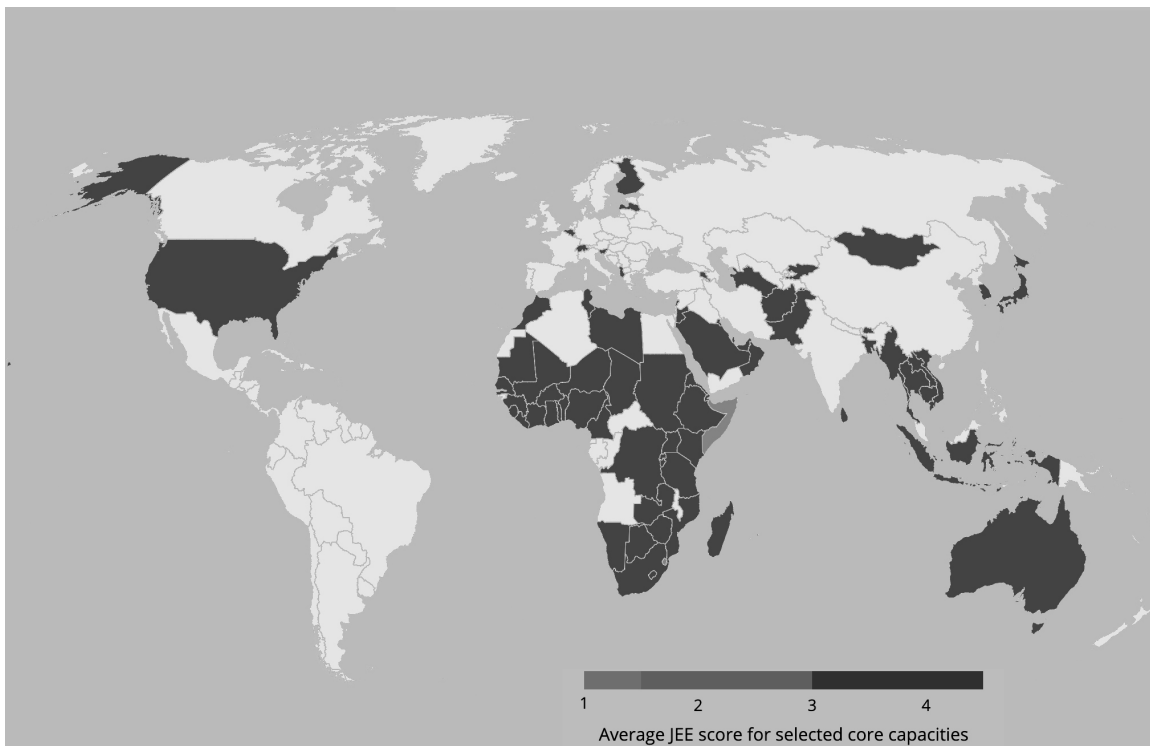
In New York City, a resurgence of measles cases resulting from low vaccination rates since Septem-

ber 2018 prompted the city's Board of Health to adopt a resolution requiring anyone living or working in affected ZIP codes to be immunized against measles, affirming the city Health Commissioner's earlier order.³ Failure to comply with the requirement is subject to a civil fine, unless prior immunization can be evidenced or there is a medical basis for refusal. A challenge to the resolution was dismissed by the Appellate Division, Second Department of the State of New York Supreme Court. As Ghedamu and Mason Meier note in their paper, there are a range of different ways in which vaccination requirements can be prescribed, including stipulating the age of immunization, what diseases must be immunized against (as a set list or with discretion to the Minister of Health), as well powers for additional mandatory vaccination requirements in cases of public health emergencies. While the nature of the laws may take many forms, the scientific underpinning of these laws is consistent: vaccination is successful "on the basis of high rates of immunization coverage among vulnerable populations."⁴ and that legal epidemiological studies have found that "strict, well-enforced vaccination mandates significantly reduce disease incidence rates."⁵ As a result, "laws will often allow the government to limit vaccination exemptions (other than health exemptions) in cases of public health emergencies."⁶ In general, vaccination is a substantially less restrictive alternative to other interventions to safeguard the public's health, such as quarantine or isolation, which public health laws may permit where necessary, depending on the nature of the disease and the vaccine, or for individuals objecting to vaccination or other medical countermeasures during emergencies.⁷ Ensuring that laws are appropriately tailored to be the least restrictive measure necessary is not only

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Figure 1

JEE Scores for Immunization, May 2019. Source: Georgetown Infectious Disease Atlas, available at <<http://tracking.ghscosting.org/>> (last visited August 21, 2019).



consistent with the International Health Regulations but also human rights.⁸

The Democratic Republic of Congo (DRC), one of the countries studied in Ghedamu and Mason Meier’s paper, provides slightly different insights into the role of law in immunization for global health security. Here, in the context of the rapidly contained outbreak

“has no codified immunization laws.”⁹ Consistent with the recommendation of the WHO’s Strategic Advisory Group of Experts on Immunization (SAGE), the protocol for expanded access/compassionate use of the Ebola vaccine in the current outbreak was approved by the DRC’s national regulatory authority. While these gaps in immunization legislation did not prevent the deployment of the experimental vaccine, the authors note that “continuing lack of legal authority will present a challenge to national capacity to realize vaccination requirements — especially in times of emergency.”¹⁰ In addition, it is important that decisions that affect communities are subject to the legislative process, ensuring population participation and oversight, as well as clarity and legitimacy for the exercise of public health powers.

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of Ebola in the northwest of the country in 2018, and again in the ongoing complex outbreak in the northeast, the government and international partners have administered over 100,000 doses of an experimental vaccine, despite the study finding that the country

Ghedamu and Mason Meier note that in addition to ensuring the availability and accessibility of vaccines “an effective national immunization program should include regulations to ensure that ... medicines meet proper quality standards.”¹¹ In corollary to this, and ensuring ongoing acceptability

of vaccines, national laws may incorporate liability waivers for manufacturers and schemes for compensating individuals who are harmed. Certain liability waivers and indemnification by governments can facilitate deployment of experimental vaccines under compassionate use programs. During the 2014-2016 Ebola outbreak in West Africa, the manufacturer of a deployed experimental Ebola vaccine only assumed a limited scope of liability, such as guaranteeing good manufacturing practice, requiring governments to indemnify the manufacturer, donors of the vaccine, and WHO.¹² During a public health emergency, governments must balance the ethical objective of reducing mortality and morbidity with the right to judicial or other relief when a person has been injured.¹³ Law plays a critical role in creating the environment that facilitates emergency responses, including adjusting legal standards such as indemnification, liability, and compensation schemes to ensure both access to justice and public health by avoiding lawsuits, or the risk of lawsuits, affecting the continuing supply of vaccines during an emergency.¹⁴

From New York to North Kivu, legal environments are relevant to the success in ensuring immunization is accessible, available, acceptable, and of sufficient quality. While case studies, model legislation, or comparisons between laws can be useful for broader policy surveillance activities, such as identifying trends, they are informative rather than instructive. Domestic laws that are developed, adopted, and implemented in one country may not be effective by simply transplanting them into another. However, as this study demonstrates, there is a diversity of legislative approaches to immunization, as well as a “complete absence of immunization law across a wide range of countries.” Ensuring a legal environment that empowers a government to protect public health, including realization of the right to health and other human rights, is cen-

tral to both global health security and universal health coverage. Immunization is a particularly powerful example of the synergy between these two approaches, which are often otherwise framed as competing, but, through appropriately tailored laws and budgetary prioritization, can propel advancements in both global health security and universal health coverage.

Note

The authors have no conflicts to disclose.

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