

# Assessing National Public Health Law to Prevent Infectious Disease Outbreaks: Immunization Law as a Basis for Global Health Security

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Immunization plays a critical role in preventing and mitigating infectious disease outbreaks, protecting the persons receiving the vaccination and, by interrupting the transmission of disease, the entire population. In today's interconnected world, where infectious diseases rarely stay contained within national borders, realizing global health security requires global immunization efforts to prevent infectious disease throughout the world. This global prevention effort will require attention to public health law. Public health law can expand immunization as essential to global health security, and global health security can serve as a catalyst for reforming public health law to expand immunization.

While robust research exists on the clinical and epidemiological efficacy of immunization, relatively few studies have analyzed how immunization laws affect public health outcomes, with little focus on these public health laws in low- and middle-income countries. Such legal epidemiology analysis can facilitate the comparative examination of national immunization laws necessary to understand the public health influence of varied legal approaches, identify the crucial attributes of national immunization laws, and facilitate the harmonization of effective legal practices. Policy surveillance is a necessary precursor for this research, providing comparative legal datasets that track the presence and attributes of immunization laws — across countries and over time. From these legal datasets, researchers can examine associations

between these legal data and epidemiological data (such as vaccination rates and other health outcomes) to determine the effect of vaccination law as a determinant of public health.

This article provides a foundation for policy surveillance research on national immunization law — examining national implementation of the Global Health Security Agenda (GHSA) by comparing the scope and content of immunization laws across 20 Sub-Saharan African countries. Part I reviews the evolving importance of immunization to public health and the legal frameworks necessary to support immunization coverage. As a basis for studying GHSA implementation through national law, Part II describes the methods by which this study (1) developed a legal framework that maps the attributes pertinent to immunization law; (2) created an assessment tool to determine the presence or absence of specific legal authorities; and (3) applied the assessment tool to code national immunization laws. Based upon this comparative coding research, Part III analyzes the scope and content of immunization laws across Sub-Saharan African countries, highlighting examples of national laws that meet identified attributes to prevent public health emergencies and protect public health. Part IV discusses the importance of legal epidemiology in linking these national immunization laws with public health outcomes, providing a public health justification for reforming national public health law. This article concludes by discussing the need for additional empirical research capable of assessing the role of national public health law as a determinant of global health security.

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## I. Background

Immunization refers to the process by which an individual intentionally develops resistance (or immunity) to one or more communicable diseases.<sup>1</sup> The most common form of immunization — vaccination — involves the introduction of a product, often an inactive form of an infectious agent, to prepare a person's immune system to fight a disease without subjecting that person to the disease symptoms.<sup>2</sup> While only those receiving a vaccination develop immunity to the disease, individual vaccination can provide population-level protection through "herd immunity."<sup>3</sup> Herd immunity occurs where even those without immunity to a disease are protected from exposure because a sufficient percentage of the population is immune, thereby interrupting the transmission of an infectious agent.<sup>4</sup>

Immunization has become one of the most successful public health interventions in human history, responsible for the greatest reductions in worldwide morbidity and mortality.<sup>5</sup> Once Edward Jenner developed the first vaccine against smallpox in 1796,<sup>6</sup> smallpox vaccination spread throughout the world alongside other public health measures; by 1979, smallpox — a disease that had been responsible for roughly 300 million deaths in the twentieth century — was eradicated.<sup>7</sup> Seeking to replicate this success, global eradication campaigns have been developed for a wide range of vaccine-preventable diseases, including measles, rubella, and polio. Widespread vaccination against polio has reduced the number of reported cases from an estimated 350,000 in 1988 to only 37 in 2016.<sup>8</sup>

Public health law is necessary to assure widespread vaccination,<sup>9</sup> and global governance institutions have sought to coordinate national immunization laws as a framework for global health security.<sup>10</sup> These law reforms have been supported by national governments, international organizations such as the World Health Organization (WHO), private organizations such as the Bill and Melinda Gates Foundation, and public-private partnerships such as Gavi, the Vaccine Alliance.<sup>11</sup> Yet, even as immunization is increasingly seen as a human right for all, millions continue to die each year from vaccine-preventable diseases,<sup>12</sup> creating an imperative under the GHSA to reform immunization law as a basis to facilitate vaccination and prevent disease.

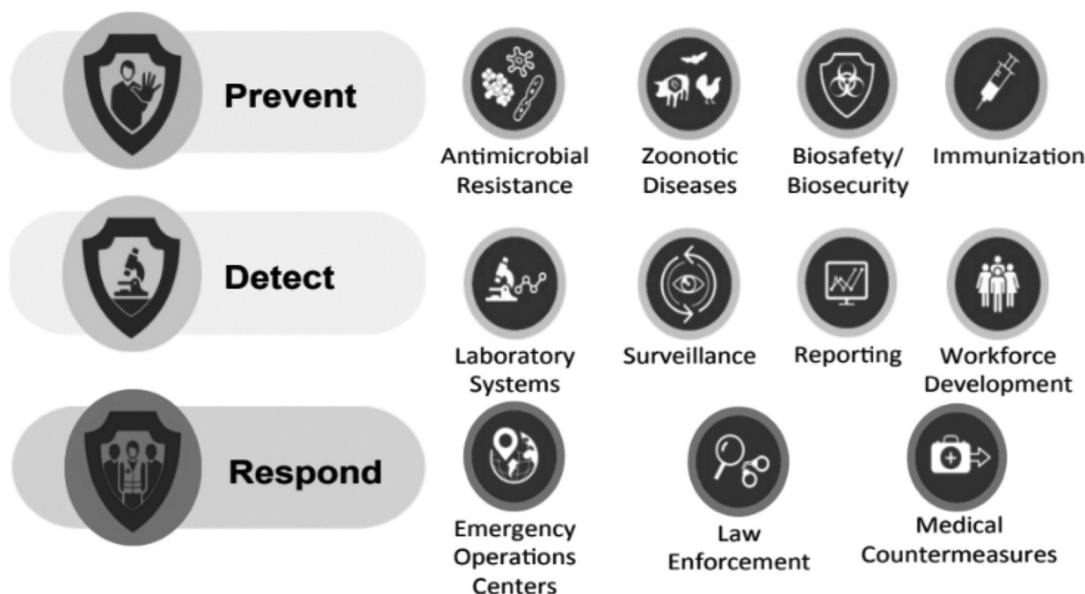
### A. Developing the GHSA

Given weaknesses in global efforts to control infectious disease, the GHSA was launched in February 2014 to "prevent, detect and effectively respond to infectious disease threats, whether naturally occurring or caused by accidental or intentional release of dangerous pathogens."<sup>13</sup> Seeking to fill gaps in national capacity to control infectious disease, representatives from 32 nations and 5 health organizations established key GHSA objectives to improve the global community's capability to prevent, detect, and respond to public health emergencies.<sup>14</sup> These objectives would be translated in May 2014 into 11 "action packages," which identify priority technical areas for global health security.<sup>15</sup>

The action package for immunization (prevent 4) was seen as essential to the prevention of global health

Figure 1

### GHSA Action Packages (Centers for Disease Control and Prevention)



security threats. In reducing infectious disease outbreaks, the five-year target for this action package is for nations to develop a “functioning national vaccine delivery system — with nationwide reach, effective distributions, access for marginalized populations, adequate cold chain, and ongoing quality control — that is able to respond to new disease threats.”<sup>16</sup> As a proxy indicator of immunization for vaccine-preventable diseases, GHSA implementation is assessed based upon at least 90% national coverage of measles-containing vaccine. While the GHSA does not address immunization for some of the most pressing public health concerns, the vaccination authority to address global health security threats can have broad application to a wide array of vaccine-preventable diseases.

Although nations took few initial steps to implement the GHSA, the GHSA Action Packages received a dramatic increase in political support following the 2014-2015 Ebola outbreak in West Africa.<sup>17</sup> This Ebola epidemic revealed weaknesses of existing global health governance institutions to respond effectively to public health emergencies.<sup>18</sup> When the Ebola outbreak occurred, WHO failed to act with sufficient urgency, leaving member countries without clear direction or sustained support.<sup>19</sup> The global response to the Ebola epidemic was reflective of the tendency toward fleeting investments in global health, with increased resources and capabilities declining in the immediate aftermath of the epidemic.<sup>20</sup> These shortcomings in the global response created an imperative to address national gaps in disease control authorities, with many governments thereafter demanding GHSA action plans as a “national security priority.”<sup>21</sup> Policymakers developed a five-year timeline for GHSA implementation (from 2015 to 2019) and requested that national governments create country-specific roadmaps to meet each action package as a basis to prevent, detect, and respond to infectious disease threats.<sup>22</sup>

### *B. The Need for National Public Health Law Reforms*

The GHSA is premised on a need for strong national health systems, which require robust national legal frameworks that implement the minimum standards set out under global health policy.<sup>23</sup> Although many nations have enacted laws to promote public health, existing laws may not be adequate to address the rate at which infectious disease epidemics can spread across borders.<sup>24</sup> Gaps in global health law have hampered responses to recent public health emergencies — including the SARS, Ebola, and Zika outbreaks — making it difficult, among other things, to quarantine infected or suspected cases, prescribe novel treatments, and coordinate responses across nations.<sup>25</sup> Many national laws lack clear authorities to control

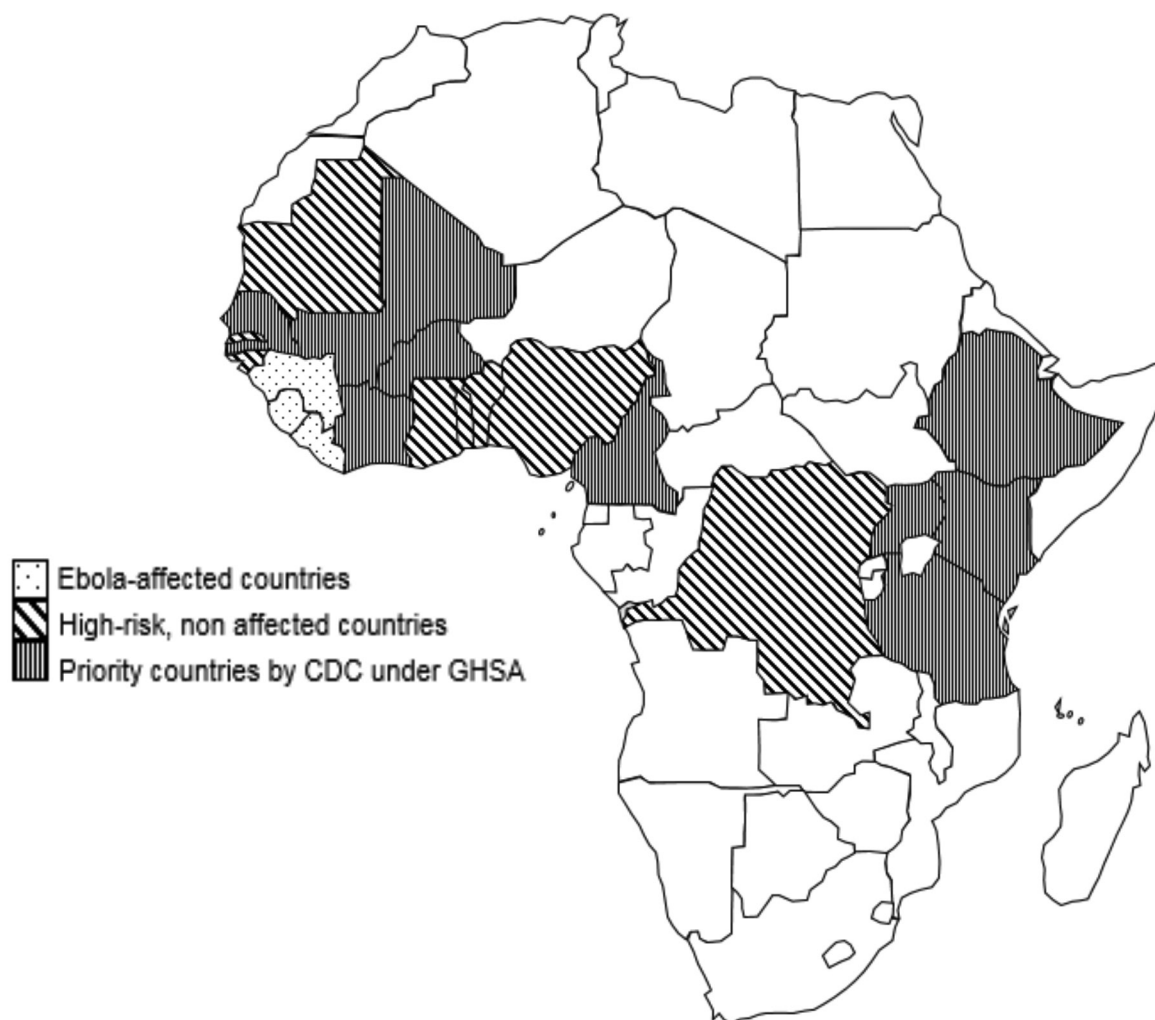
epidemics, yet it is at this national level where legal reforms can have the greatest impact on public health emergencies.<sup>26</sup>

Global health governance has only recently come to understand the importance of national public health law to infectious disease control.<sup>27</sup> While WHO, the World Organization for Animal Health (OIE), and the Food and Agriculture Organization of the United Nations (FAO) have recognized the importance of national law to reduce health risks at the “human-animal-ecosystems interfaces” under a “One Health” approach, existing international legal frameworks such as the WHO International Health Regulations (IHR) have yet to be fully implemented at the national level.<sup>28</sup> The need for immunization laws in strengthening health security at the national level is also essential in the implementation of the IHR.<sup>29</sup> Despite the promise that the IHR would harmonize national legislation for detecting and responding to public health emergencies of international concern, many nations have not yet undertaken the legal reforms to ensure necessary government authority.<sup>30</sup> As seen among countries at the center of the 2014-2015 Ebola epidemic (Guinea, Liberia, and Sierra Leone), while these countries have long been bound by the IHR as WHO Member States, they nevertheless lacked the health systems and public health laws necessary to address Ebola.<sup>31</sup>

Law has a foundational role in establishing the national authorities essential to assuring immunization in accordance with the GHSA.<sup>32</sup> Beyond mandatory vaccination requirements, national laws can prescribe immunization guidelines, including: the specific vaccines to mandate; which populations require a given vaccine (e.g., children, health workers); whether to prioritize specific groups (where resources are scarce); the most effective or efficient vaccine delivery methods; the immunization schedule to ensure effective public health protection; timeframes for reestablishing a vaccination schedule (especially after interruptions or delays in immunization); vaccine production, cost, safety, and liability; and even public education, communication, and incentives to increase immunization rates.<sup>33</sup> The public perception of the importance and safety of vaccinations will affect the ability of a country to efficiently vaccinate the population, but policymakers must have legal support, especially in low- and middle-income countries that lack comprehensive public health authorities.<sup>34</sup> By focusing on GHSA implementation through the multisectoral national laws necessary for immunization, it is possible to learn from weaknesses of legal frameworks in preventing public health emergencies, ensuring that such weaknesses do not undermine

Figure 2

**Map of 20 Sub-Saharan African countries included in sample**



national efforts to prevent future threats to global health security.

## II. Methods

In order to analyze the scope and content of immunization laws, this research:

1. Delineated the attributes of immunization laws, developing a policy surveillance framework.
2. Created an assessment tool to identify the relevant attributes of immunization laws.
3. Coded immunization laws across 20 Sub-Saharan countries, comparing the content of national immunization laws based upon identified attributes.

To determine the presence and characteristics of national laws supporting the GHSA Action Package on immunization, this study first developed a policy surveillance framework to identify specific attributes of national law relevant to immunization. This framework was developed through a comprehensive legal and public health literature review to characterize existing knowledge of successful legal approaches to implement GHSA immunization targets. Complemented by an examination of specific immunization laws from a variety of high-, middle-, and low-income countries, experts in immunization law reviewed these attributes to assure that they accurately and sufficiently captured the most salient features of national immunization laws.

Based on this legal framework, the study then created an assessment tool in LawAtlas (<http://lawatlas.org/>), a policy surveillance program, outlining questions to identify the content of pertinent attributes of national immunization laws. These coding questions allowed for either binary (yes or no) or categorical (multiple answers) responses. The questions were organized hierarchically, with multiple layers of questions allowing for greater detail about the attributes of a national law. For example, while a top-level question might ask whether the law requires individuals to receive a vaccination, lower-level questions might ask to whom the mandate applies and what diseases are covered.

Applying this assessment tool to national laws, this study mapped the national immunization legal landscape in 20 Sub-Saharan African countries, including Ebola-affected countries (in the 2014-2015 outbreak:

Guinea, Liberia, and Sierra Leone); countries classified by the U.S. Centers for Disease Control and Prevention (CDC) as high-risk countries (Benin, Democratic Republic of Congo, Gambia, Ghana, Guinea Bissau, Mauritania, Nigeria, and Togo); and countries independently prioritized by the CDC under GHSA commitments (Burkina Faso, Cameroon, Cote d'Ivoire, Ethiopia, Kenya, Mali, Senegal, Tanzania, and Uganda).

To facilitate this policy surveillance, researchers employed a multistep, redundant process to identify and collect relevant national laws, regulations, and other codified materials through online sources, the foreign law collection in the U.S. Library of Congress Law Library, and in-country sources in national ministries. This overlapping process sought to ensure that any failure to identify relevant laws indicated the absence of such laws.

Table 1

**Attributes of Law across 20 Sub-Saharan Countries**

	Vaccine Requirements		Supply Chains	Vaccine Administration Standards			Medicine Quality & Manufacturer Liability
	Mandating Vaccination	Objections and Exemptions		Administration Standards	Subsidized or Free Vaccination	Prioritization of Vaccine Access	
Benin	X			X			
Burkina Faso	X		X				
Cameroon							
Cote d'Ivoire							
Dem. Rep. of Congo							
Ethiopia	X						
Gambia							
Ghana	X	X			X		
Guinea	X						
Guinea-Bissau							
Kenya	X	X	X	X	X		
Liberia	X			X	X		X
Mali	X			X			
Mauritania							
Nigeria	X	X					
Senegal	X						
Sierra Leone			X				
Tanzania	X				X		
Togo	X				X		
Uganda	X				X		X

Once identified laws were collected, two trained policy researchers redundantly coded each national law using the coding questions in the assessment tool. This comparative analytic coding sought to classify specific legal attributes in national laws through an objective, rather than interpretive, examination of the law, thereby allowing future research to replicate this study and extend the dataset longitudinally. Disagreements among coders were discussed and resolved by consensus, making revisions to coding questions and answers where necessary to ensure consistent coding. This iterative coding process ensured a high-level of consistency among coders and increased intercoder reliability.

Notwithstanding the methodological rigor detailed above, this policy surveillance study has several limitations. Because many national laws are not publicly available or adequately disseminated, even in-country collection and verification cannot guarantee that a legal dataset includes all relevant laws in the examined countries. Moreover, this study sought to analyze only codified laws and regulations, and as a result, the content of this law may not fully reflect the “on-the-ground” reality of immunization. Yet despite these limitations, this comparative study — the first analytic coding study of national immunization laws — provides a baseline assessment of national immunization authority that can facilitate legal epidemiology research and public health law reforms.

### III. Results

Assessing the legal environment for immunization across 20 Sub-Saharan African countries, this coding analysis focused on the four attributes of immunization law categorized in Table 1: vaccine requirements, supply chains, vaccine administration, and medicines quality & manufacturer liability.

Of the 20 examined countries, this study found six countries without any immunization authority under national law — Cameroon, Cote d’Ivoire, Democratic Republic of Congo, Gambia, Guinea, and Mauritania — calling into question the importance of laws to the implementation of international immunization imperatives. For example, the Democratic Republic of Congo has no codified immunization laws, and yet in a recent Ebola outbreak, the government (together with local and international partners, including WHO), administered an experimental Ebola vaccine in regions where cases were reported.<sup>35</sup> Nevertheless, law and policy are distinctive tools for the protection of communities, and the promulgation of public health law is crucial to the enabling authorities of governmental public health systems.<sup>36</sup> The continuing lack of legal authority will present a challenge to national capacity to real-

ize vaccination requirements — especially in times of emergency. National law reform will thus be essential in assuring vaccination rates and underlying systems for vaccine implementation. Securing the promise of the GHSA, the following attributes and examples of immunization law can provide government authority to prevent disease.<sup>37</sup>

#### A. Vaccine Requirements

Enabling legal authority provides a government with the power to regulate vaccinations, integrating vaccine requirements into national public health systems. Such laws allow for evidence-based vaccine guidelines to be set by either a governmental or non-governmental agency. Immunizations are essential to reducing epidemic-prone diseases, and these legal authorities provide governments with the ability to ensure that proper vaccination policies are implemented. Within the examined countries, a number of national laws have enabled vaccination offices to coordinate, monitor, and implement national vaccination policies, establishing the authorized institutions to control all vaccination services.<sup>38</sup> Countries can give full authority to their designated health<sup>39</sup> ministers or ministries to ensure the creation and implementation of immunization policy, as seen where Nigeria<sup>40</sup> in 2014 provided the National Council on Health with the authority to ensure that all children under five and pregnant women must be vaccinated against infectious diseases.

#### National Health Bill, 2014 (Nigeria)

*(1) The National Council which shall be the highest policy making body in Nigeria on matters relating to health, shall:*

*(i) ensure that children between the ages of zero and five years and pregnant women are immunized with vaccines against infectious diseases.*

Rather than delegating to specific institutions, other national laws detail the specific guidelines around dosage and implementation of vaccination under law. In this latter category,<sup>41</sup> Mali’s 2008 *Arrête Interministériel Fixant La Liste Des Vaccinations Obligatoires, Leurs Calendriers et Les Conditions D’administration Des Vaccins* has established vaccine regulations around dosage and implementation of immunizations within public health institutions, with specific immunization requirements for students against Yellow Fever, Hepatitis B, and Tetanus:

#### Arrête Interministériel Fixant La Liste Des Vaccinations Obligatoires, Leurs Calendriers et Les Conditions D’administration Des Vaccins, 2008 (Mali)

## Chapitre 2: Des conditions d'administration des vaccins

*Article 5: L'administration des vaccins a lieu dans les établissements de santé publics centre de santé de collectivités territoriales, Centre de santé de Référence, Etablissements Publics Hospitaliers et Etablissements de Santé privés participant au service public dont les Centre de Santé Communautaire.*

*Toutefois, les agents de santé peuvent se déplacer dans les endroits précis, convenus avec les bénéficiaires potentiels, pour administrer les vaccins à des moments déterminés de commun accord.*

*Article 6: Les doses de vaccins nécessaires par type de vaccins sont:*

- *le BCG et le vaccin contre la rougeole sont administré en dose unique;*
- *le vaccin contre la poliomyélite est administré en 4 doses dont la toute première est désigné dose zéro;*
- *les vaccins contre la coqueluche, la diphtérie, hépatite B, le tétanos, la pneumonie à hémophiles influenzae B sont administrés en 3 doses*

**Article 7: Les intervalles entre les doses de vaccins sont:**

- *administration de la première dose des vaccins à doses multiples est séparée de la vaccination contre la tuberculose et de la 1ère dose de vaccin contre la poliomyélite de 4 semaines, au moins;*
- *un intervalle de 4 semaines, au moins sépare les administrations des vaccins à doses multiples;*
- *le 1er rappel des vaccins à doses multiples est fait à l'âge de 16 semaines;*
- *Le 2ème rappel est fait au plutôt à 6 ans et au plus tard, à 7 avant d'entrée à l'école;*
- *Lors de leur inscription à l'école, les enfants bénéficient de la vaccination contre la fièvre jaune, hépatite B et le tétanos.*

Ghana similarly enables authorization of immunizations through its *Vaccination Act of 1919*, which provides the Director of the Health Service with the ability to regulate the time and location at which individuals must be vaccinated and the method by which these vaccinations are to be distributed.

The Director also has the ability to regulate the inspection of vaccines and ensure treatment of individuals after vaccinations. Further, the law provides the Director with the authority to regulate public vaccinators and provide the conditions under which they are able to vaccinate.

## **Vaccination Act, 1919 (Ghana)**

### *4. Regulations by Deputy Director of Health Service*

*The Director-General of the Service may, subject to the approval in writing of the Minister by legislative instrument, make Regulations with respect to*

- (a) the times and places of attendance of persons on public vaccinators for the purposes of vaccination;*
- (b) the evidence to be accepted of successful vaccination, including inspection of the results of vaccination;*
- (c) the supply of lymph to public vaccinators;*
- (d) the method of vaccination by public vaccinators;*
- (e) the treatment of persons after vaccination; and*
- (f) the functions of assistant public vaccinators, and the limitations and condition under which those functions shall be performed.*

Through this authority, these vaccination requirements can provide for vaccination mandates and detail any permissible exemptions from mandatory vaccination.

### **I. MANDATORY VACCINATION**

The success of vaccination programs is only attainable on the basis of high rates of immunization coverage among vulnerable populations, and governments throughout the world have authorized mandatory vaccination policies to produce these high rates and ensure the herd immunity<sup>42</sup> necessary to protect populations.<sup>43</sup> Mandatory vaccination has a long history, dating back to 1806, when the Napoleonic Principalities of Piombino and Lucca enacted regulations requiring vaccination against smallpox.<sup>44</sup> Throughout the 19th century, numerous European nations enacted similar compulsory vaccination laws,<sup>45</sup> and at the start of the 20th century, Massachusetts became the first state in the United States requiring the general public to be vaccinated against smallpox.<sup>46</sup> While such mandates were and remain controversial, their legality has been largely upheld. For example, in the seminal 1905 case of *Jacobson v. Massachusetts*, the US Supreme Court upheld a Massachusetts state law allowing municipal boards of health to compel vaccination against smallpox, holding that a state's police powers "must embrace ... such reasonable regulations established directly by legislative enactment as will protect the public health and public safety."<sup>47</sup> The Court recognized that an individual's liberty interest against compulsory vaccination must yield to reason-

able restraints for the common good when such liberty would threaten the health and safety of others.<sup>48</sup> Subsequent cases have bolstered the justification for compulsory vaccination laws, finding that strict, well-enforced vaccination mandates significantly reduce disease incidence rates.<sup>49</sup>

The majority of the 20 sub-Saharan countries in this study have laws mandating vaccinations for all children. Nevertheless, these laws can differ on the appropriate age at which a child should be immunized. Countries such as Tanzania<sup>50</sup> and Togo<sup>51</sup> require infants to be immunized within the first twelve months while Ghana requires vaccination within the first three months.<sup>52</sup> The specific immunizations required also can differ by country. A country such as Liberia requires children to be immunized “*against poliomyelitis, smallpox and measles ...*”<sup>53</sup> while Mali requires vaccinations “*contre la coqueluche, la diphtérie, hépatite B, le tétanos, la pneumonie à hémophiles influenzae B sont administrés en 3 doses.*”<sup>54</sup> Rather than specifying diseases under law, several countries provide their Minister of Health with the authority to select the required vaccines.

#### **Code de la Santé, 2009 (Togo)**

*Art. 64 - L'administration des vaccins est obligatoire au cours de la première année de vie. Les différents rappels de ces vaccins sont également obligatoires dans les délais requis.*

*Un arrêté du ministre chargé de la Santé définit chaque fois que de besoin la liste de ces vaccins. Les parents ou les tuteurs sont personnellement tenus de faire vacciner leurs enfants.*

In cases of public health emergencies, many countries have codified an emergency mandate for supplemental mandatory vaccination requirements. Nations such as Liberia, Uganda, and Nigeria allow for their authorized minister to conduct compulsory immunization in either a specific area or the entire country in cases of emergency.

#### **Public Health Act, 1935 (Uganda)**

*39. Vaccination of persons in or entering Uganda.*

*(1) After the introduction of this Act:*

*(a) the Minister may by statutory order declare any area to be a compulsory vaccination area and shall in the order specify a period in which the vaccination of all unvaccinated persons dwelling in the area shall take place;*

*(b) every unvaccinated adult and the parent or guardian of every unvaccinated child in any area declared to be a compulsory vaccination*

*area shall cause himself or herself and the child to be vaccinated within the period specified;*  
*(c) every unvaccinated adult and the parent or guardian of every unvaccinated child entering Uganda shall cause himself or herself and the child to be vaccinated within two months.*

These emergency mandates are limited in some cases to a specific infectious disease.<sup>55</sup> To ensure that mandatory vaccinations are received, many of these laws require that documentation be presented to individuals after vaccinations. Countries such as Kenya, Ghana, and Uganda mandate that public vaccinators or medical providers who have performed a vaccination to provide a certificate of successful vaccination to the adult or child.

This documentation allows governments to take action for non-compliance with vaccination. To ensure enforcement, many of these laws also include penalties for non-compliance, including either a fine or imprisonment.<sup>56</sup>

#### **2. EXEMPTIONS FROM VACCINATION**

Over the past decade, researchers in many parts of the world have recognized an increase in individual objections to vaccination.<sup>57</sup> These increasing objections to vaccines, threatening herd immunity to diseases, has amplified the debate around exemptions to vaccination requirements. Throughout the world, exemptions to vaccinations are often permitted under law based on health reasons, religious beliefs, or philosophical objections.<sup>58</sup> Almost all countries explicitly allow exemptions necessary for health, usually given to individuals who have suppressed immune systems, are allergic to the vaccine, or might have medical contraindications with the vaccine.<sup>59</sup> Beyond medical exemptions, further exemptions may allow large populations to remain unimmunized, with higher exemption rates threatening higher disease risk.<sup>60</sup> Because of this, laws will often allow the government to limit vaccination exemptions (other than health exemptions) in cases of public health emergencies, with individuals who object to vaccination during emergencies either quarantined or isolated to stop any spread of the disease. Sub-Saharan countries that were assessed in this study do not have broad exemption laws, and any permissible objections to vaccinations were connected to health exemptions. Both Kenya<sup>61</sup> and Ghana<sup>62</sup> have laws that allow exemptions from vaccination mandates, but only based on a certificate given to them by a provider that states the adult or child is not fit to be vaccinated.



### **Public Health Law, 1986 (Kenya)**

#### *107. Person unfit for vaccination*

*(1) If any public vaccinator or medical practitioner is of opinion that any adult or child is not in a fit state to be vaccinated, he shall give to the adult or to the parent or guardian of the child a certificate under his hand according to Form No 1 in the Schedule, or to the like effect, that the adult or child is then in a state unfit for vaccination.*

While limiting individual freedom of choice, these limited exemptions to vaccination mandates serve to protect the public by supporting herd immunity against infectious disease.

#### *B. Supply Chain*

The production and distribution of vaccines requires a high level of quality control throughout the entire supply chain. Policies must address the need for transportation, storage, and the secure supervision of vaccines to safeguard vaccine administration.<sup>63</sup> Laws can provide requirements around licensure, supply, and

consistent vaccination supplies, stable stockpiles, and a steady number of providers. Periodically updated strategy and implementation plans must be created to ensure efficient and flexible measures during times of emergency.

Yet very few of the examined countries have laws addressing the supply chain. The countries with laws around vaccine supplies require direct government management of a national vaccine stockpile, with regulations that demand the safety and quality of vaccines at all stages of the supply chain. Kenya<sup>67</sup> and Sierra Leone<sup>68</sup> require a steady supply of drugs and medical supplies in their public health facilities and a requirement that essential medicines must also be maintained in reserves at all times.

### **National Pharmaceutical Procurement Unit Act, 2012 (Sierra Leone)**

*4. (1) The object for which the Unit is established is to provide an effective, efficient and transparent environment for the supply of essential medicines of requisite quality, efficacy, accessibility,*

**The production and distribution of vaccines requires a high level of quality control throughout the entire supply chain. Policies must address the need for transportation, storage, and the secure supervision of vaccines to safeguard vaccine administration. Laws can provide requirements around licensure, supply, and production of vaccines to ensure the safety of these vaccines.**

production of vaccines to ensure the safety of these vaccines.<sup>64</sup> Licensing regulations assure that each individual in the supply chain is trained on proper vaccine handling and storage. The supply and distribution of vaccines are in large part dependent on licensure within the market, and governments without robust licensure policies are dependent on license policies in the country of the manufacturer.<sup>65</sup> The law can also provide incentives for vaccine production and stockpiles for future emergencies. For example, in case of pandemic, there would arise a need to conduct mass vaccinations in a short period, and inventories of vaccines would enable a nation to distribute immunizations quickly. Thus, laws to manage vaccine stockpiles can also be extremely important — either in a public health emergency response or in filling gaps during vaccine storages.<sup>66</sup> This necessary infrastructure must be in place before an emergency occurs. Policy-makers need to create a system under national law in which the supply of vaccines will be able to meet the public's need in any situation, including the need for

*and affordability in public health institutions throughout Sierra Leone.*

*(2) Notwithstanding the generality of subsection (1), it shall be the function of the Unit to:*

*(a) procure essential medicines and medical consumables of requisite quality and efficacy for and on behalf of all public health facilities throughout Sierra Leone;*

*(b) receive as donation, store and distribute essential medicines and medical consumables of requisite quality and efficacy for and on behalf of all public health storage facilities throughout Sierra Leone;*

*(c) establish and maintain inventory control procedures of essential medicines and medical consumables at all levels of the public healthcare system;*

*(d) undertake accurate and systematic recording, monitoring and regular reporting of essential medicines and medical consumables stock levels*

*in all public health facilities throughout Sierra Leone;*

*(e) engage, train and maintain the requisite number and quality of staff that will ensure the effective and efficient operation of the Unit;*

*(f) provide suitable storage and packing for drugs procured by the Unit that will ensure that drugs in storage and transit are secure and that their quality, safety and efficacy are maintained until delivery to the end-user;*

*(g) monitor, inspect and ensure that storage and packing meet such standard as is required for the storage and transit of medicines and medical consumables intended for public use;*

*(h) maintain vehicles and other means of transport for the distribution of drugs; and*

*(i) do all such things as are necessary, expedient or conducive to the attainment of the general object of the Unit and in accordance with the Public Procurement Act, 2004 (Act No. 14 2004)*

Sierra Leone has thus established the National Pharmaceutical Procurement Units to ensure the appropriate environment for the supply of essential medicines, and in Kenya, the law also requires an “effective monitoring and evaluation mechanism” to ensure proper protocols and necessitates transparency of information relating to the storage and supply of drugs.

### *C. Vaccine Administration*

National laws can also include standards around the administration of vaccines. Policymakers can prescribe immunization guidelines, including the most effective or efficient delivery methods, the immunization schedule to ensure ideal coverage, the timeframes for getting back on-schedule after interruptions or delays in immunization, and even the publicity to increase immunization rates. To avoid adverse health effects, which can lead to public backlash against immunization and lower vaccination rates, laws can institute safe injection practices<sup>69</sup> such as providers using clean needles and maintaining proper protective wear to avoid bodily fluids. Regulations can also ensure the safe disposal of biomaterials and the creation of workplace safety procedures. Where laws in the examined countries address vaccine administration, Liberia’s *Public Health Law of 1976* created a “public immunizer” position, in which an immunizer is appointed by the Minister of Health and Social Welfare to administer vaccines against communicable diseases.<sup>70</sup> In managing vaccine administration, Mali’s *Inter-ministerial Orders setting the List of Compulsory Vaccinations, Their Calendars and Conditions of Vaccine Administration of 2008* describes the neces-

sary steps in the administration of several vaccines.<sup>71</sup> These laws not only lessen the risk for potential harms to patients and providers, but they can also increase vaccination rates and herd immunity through regulatory efforts to facilitate both affordability through subsidized or free vaccination and accessibility through prioritization of specific individuals.

#### 1. SUBSIDIZED OR FREE VACCINATION

Where vaccine administration can be limited by the individual costs of vaccination, many countries have established legal guarantees of subsidized or free vaccinations to protect individual and public health. In many cases, the burden of disease is often higher in impoverished communities, and the ability to improve the health of these communities can have potentially larger impacts on the entire population.<sup>72</sup>

Numerous countries require that all vaccinations provided by the public vaccinator must be free of charge.<sup>73</sup>

#### **Public Health Act, 1935 (Uganda)**

*43. No fee to be charged for a certificate or for vaccination by public vaccinator. (1) No fee or remuneration shall be charged to the person vaccinated by any public vaccinator for any certificate granted under this Act, nor for any vaccination done by him or her under this Act.*

#### **Vaccination Act, 1919 (Ghana)**

##### *2. Free vaccination*

*(1) A public vaccinator shall vaccinate, free of charge, the persons who present themselves or are presented for the purpose, or persons who under this Act are, or become, liable to be vaccinated.*

#### **Public Health Act, 1986 (Kenya) 110**

*(1) No fee or remuneration shall be charged to the person vaccinated by any public vaccinator for any certificate granted under this Act, nor for any vaccination done by him in pursuance of this Act.*

In some cases, these vaccinations are free only to specific sub-populations, including children and pregnant women. Uniquely, the country of Togo has a provision that mandates an employer to cover costs for vaccinations of any employee that has come into contact with any infection.

#### 2. PRIORITIZATION OF ACCESS TO VACCINATION

Laws often prioritize access to vaccines for specific individuals, especially in emergency situations and during supply shortages. To assure a prioritization

scheme for immunization in advance of outbreaks, national regulators can consider vaccine availability and the relative vulnerability of different populations, providing guidelines to prioritize access to vaccination for vulnerable groups and those who come in close contact with vulnerable groups. In addition to vulnerable individuals, specific professions — including health care workers, firefighters, police, military, transportation, education, and sanitation workers — are often provided priority access to vaccination. While this assessment did not identify any national laws that establish a prioritization scheme for access to vaccinations, such laws are widespread in other countries, prioritizing vaccination access either at all times or in the context of a public health emergency.

#### *D. Medicine Quality and Manufacturer Liability*

Beyond the availability and accessibility of vaccinations, an effective national immunization program should include regulations to ensure that these medicines meet proper quality standards.<sup>74</sup> The creation of a national medicine regulatory authority (NMRA) is seen as an appropriate institution to assess the safety, efficacy, and quality of vaccines. This institutional authority can monitor drug manufacturing through consistent inspections and post-marketing surveillance — identifying poor quality and counterfeit vaccines. Through vaccine registration, the Uganda *National Drug Policy and Authority Act of 1993*<sup>75</sup> provides its national drug authority with the power to approve and examine any new or imported drug.

#### **National Drug Policy and Authority Act, 1993**

*(Uganda)*

##### *35. Drug regulation and registration of specialties.*

*(1) The drug authority:*

*(a) may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug;*

*(b) shall institute a system for the approval of drugs or drug combinations not included in the national list of essential drugs.*

##### *36. Drug quality.*

*(1) The drug authority shall advise the Minister on measures to be taken to ensure the quality of drugs imported into or held in stock in the country.*

*(2) The execution of the measures prescribed shall be entrusted to bodies charged with the importation and distribution of drugs.*

*(3) The inspection of drugs and measures prescribed may be delegated to the chief of pharmaceuticals and health supplies or any other person*

*properly qualified in pharmaceuticals and health supplies.*

Liberia similarly created the Liberia Medicines and Health Products Regulatory Authority in 2010 to ensure proper approval and registration of medicines, issuing registration licenses for all drugs and permits for all drug manufactures.<sup>76</sup>

To assure the continuing supply of vaccines from the private sector, where vaccine production has fallen in part because of legal liability for those who are harmed,<sup>77</sup> national laws can support either liability waivers for manufacturers or compensation programs for those who are harmed. While no examined country has pursued such liability protections, and experimental vaccines were deployed during the 2018 Ebola epidemic without interruption,<sup>78</sup> such liability laws have been developed in the United States and Europe to assure that lawsuits do not limit the supply of vaccines.<sup>79</sup>

#### **IV. Discussion**

The results of this study highlight both the diversity of approaches to immunization under national law and the complete absence of immunization law across a wide range of countries. Law reforms will be necessary to provide a foundation for expanding immunization as a basis to prevent infectious disease.<sup>80</sup> Immunization law is not a panacea, but such laws can be part of a larger set of national reforms that are necessary to realize global health security and promote public health.<sup>81</sup> Where law is seen as an essential tool for protecting the public's health, legal epidemiology can allow researchers to understand the impacts of these policies on public health outcomes, providing justification for public health law reforms.

In the United States, scholars, practitioners, and advocates have begun to conduct policy surveillance to inform policymakers and understand trends in state and federal policies to advance global health security.<sup>82</sup> Following the 2014-2015 Ebola outbreak, the US Center for Disease Control and Prevention (CDC) conducted a policy surveillance study across US states — looking at policies concerning Ebola screening and monitoring of asymptomatic individuals.<sup>83</sup> This systematic policy surveillance compared state policies with CDC guidance and determined states to be either less or more restrictive than recommended. Based upon these results, the CDC advised state governments to harmonize policies with neighboring states to ensure legal clarity during times of infectious disease outbreaks. Comparative policy surveillance studies like these can be replicated internationally and policy recommendations can be tailored to the needs of each country.

In developing these national laws as a foundation to meet the GHSA, there is a need for rigorous empirical analysis of the impacts of such immunization law reforms on disease prevention outcomes. Legal epidemiology has rapidly become a path to empirical analysis of public health law, and immunization law provides a straightforward approach to legal epidemiology across nations. Many nations collect public health data on immunization rates, alongside outcome data on outbreak incidence and prevalence for a range of infectious diseases. These data provide legal epidemiologists — in collaboration with public health practitioners, researchers, lawyers, and governments — with the ability to examine both national laws (as an independent variable) and public health outcomes (as a dependent variable) to analyze the public health impact of vaccination laws within each country.<sup>84</sup> Policy surveillance on immunization laws, paired with public health data on disease outbreaks, can allow policymakers to understand the positive and negative effects of legal attributes on public health and reform laws based upon empirical comparisons with other countries. Where regional health governance has been effective in promoting national health law reform,<sup>85</sup> the recent creation of the Africa CDC has established a regional governance framework to support countries in identifying best legal practices within Sub-Saharan Africa and providing an empirical basis to harmonize laws across countries.

These reformed laws can assure that immunization policies provide the greatest benefit to public health while proving the least restrictive of individual rights. Although invaluable to the public's health, immunization law poses a risk of infringing of personal rights and freedoms.<sup>86</sup> Echoing rights infringements during the 2014 Ebola outbreak in Liberia, where entire communities were quarantined forcefully,<sup>87</sup> the Democratic Republic of Congo recently acted through the police to bring an individual back to the hospital after he had left.<sup>88</sup> These cases exemplify the tendency of infectious disease control policies to infringe on individual rights, with these rights infringements undercutting public health efforts. Especially where the law provides for mandatory vaccination, there is a potential for derogations from individual rights, and it will be necessary to assure that human rights are protected under immunization law. Where the state is obligated under international law to ensure a balance between the goals of public health and the rights of the individual,<sup>89</sup> comparisons across national legal practices can provide understanding of the appropriate balance between public health and human rights, making vaccinations the norm and exemptions a rare occurrence.

While there is no need to standardize immunization law globally — with each country having distinct disease control concerns that can be addressed within contextualized national policies — policymakers can look to models in other countries to share lessons and support reforms. This research has identified gaps in national immunization laws, and each country can look to other national approaches in filling these gaps, developing the public health law reforms necessary to strengthen public health systems. As a foundation for legal epidemiology research, policymakers can continuously work with public health practitioners, researchers, and lawyers to assure that any law adopted is continuously improving public health.

## Conclusion

With the world at increasing risk of infectious disease, policymakers must create robust national health systems that can support efforts to prevent disease. Where a lack of immunization can create an opening for an infectious disease outbreak, which can quickly spread throughout a rapidly globalizing world, vaccines are an important tool for global health security and public health promotion. The GHSA has provided a model for key aspects of infectious disease control, but for the GHSA to function appropriately, national governments must develop legal frameworks to implement GHSA imperatives. Through policy surveillance of immunization laws across various countries, researchers can play a central role in assisting policymakers to understand the range of policy approaches to expand immunization. Supported by legal epidemiology, it is possible for researchers to combine policy surveillance with epidemiological data, clarifying the impact of these laws on public health and providing empirical justification for public health law reform. By assessing the role of law as a determinant of public health, such research can catalyze necessary law reforms, allowing national policymakers to create the legal structures needed for global health security.

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