

EXAMINING NATIONAL PUBLIC HEALTH LAW TO REALIZE THE GLOBAL HEALTH SECURITY AGENDA

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ABSTRACT

Where the Global Health Security Agenda (GHSA) seeks to accelerate progress toward a world safe and secure from public health emergencies, the realization of GHSA 'Action Packages' will require national governments to establish necessary legal frameworks to prevent, detect, and respond to infectious disease. By analyzing the scope and content of existing national legislation in each of the GHSA Action Packages, this comparative cross-national research has developed a framework that disaggregates the legal domains necessary to meet each Action Package target. Based upon these legal domains, this study developed an assessment tool that can identify specific attributes of national legislation. This article applies this tool to assess the legal environment in twenty Sub-Saharan African countries, examining the content of laws across the GHSA Action Packages, analyzing the legal domains necessary to implement each Action Package, and highlighting specific national laws that reflect attributes of each legal domain.

KEYWORDS: Global health security, Public health emergencies, Public health law

I. INTRODUCTION

Recognizing global health security as an international security priority, national governments came together with international organizations and public and private stakeholders in early 2014 to develop the Global Health Security Agenda (GHSA). With

the launch of the GHSA followed almost immediately by the outbreak of the 2014–2015 Ebola pandemic, states have faced an immediate imperative to meet eleven GHSA ‘Action Packages’ for preventing, detecting, and responding to public health emergencies. However, to realize the GHSA, national governments must establish appropriate legal authorities. This article examines national legal structures conducive to implementing GHSA Action Packages. Part II describes the evolution of the GHSA as a catalyst for national efforts to prevent, detect, and respond to public health emergencies across the Action Packages. Identifying the legal foundations of these Action Packages, Part III describes the methods by which this study (i) developed a legal framework that maps the legal domains pertinent to each Action Package; (ii) created an assessment tool to determine the presence or absence of specific legal authorities; and (iii) applied the assessment tool to code the legal landscape in twenty Sub-Saharan African countries. Based upon this cross-national empirical research, Part IV analyzes the scope and content of national legislation across the legal domains of each Action Package, highlighting examples of national laws that meet attributes of each legal domain. This article concludes by examining the promise of empirical research as the basis for understanding national legislation—beyond global health security and beyond Sub-Saharan Africa—with legislative coding serving as a foundation for comparative legal epidemiology to examine the role of law as a determinant of public health.

II. BACKGROUND: THE GHSA

The existential threat of infectious diseases—to public health, economic growth, and political stability—has long driven the global community to action, developing an evolving set of international public health agreements and structuring national public health practices to prevent, detect, and respond to public health threats. Drawing on early national measures for quarantine, sanitation, and immunization, formal cooperation among the western world’s economic powers developed through a series of sanitary conferences, which culminated in the first International Sanitary Convention of 1892.¹ With the 1948 birth of the World Health Organization (WHO) and the subsequent adoption of the 1969 International Health Regulations (IHR), notions of health security expanded geographically to encompass the world and expanded substantively to address an increasing range of infectious disease threats.² Today, this imperative to meet public health threats is conceptualized through a focus on ‘global health security,’ defined by WHO to require action ‘to reduce the vulnerability of people around the world to new, acute, or rapidly spreading risks to health, particularly those that threaten to cross borders.’³ While many have challenged the ‘securitization’ of public health,⁴ merging infectious disease efforts with the bioterrorism response and

1 LO Gostin and R Katz, ‘The International Health Regulations: The Governing Framework for Global Health Security’ (2016) 94(2) *Milbank Q* 264.

2 L Weir, ‘Inventing Global Health Security’ in S Rushton and J Youde (eds), *Routledge Handbook on Global Health Security* (Routledge 2015).

3 WHO, *The World Health Report 2007—A Safer Future: Global Public Health Security in the 21st Century* (WHO 2007).

4 SE Davies, ‘Securitizing Infectious Disease’ (2008) 84(2) *Int’l Aff* 295; T Murphy and N Whitty, ‘Is Human Rights Prepared? Risk, Rights And Public Health Emergencies’ (2009) 17 *Med L Rev* 219; LO Gostin and A Phelan, ‘The Global Health Security Agenda in an Age of Biosecurity’ (2014) 312(1) *JAMA* 27.

infringing individual rights to protect the public, evolving approaches to global health security have become a central focus of global health in foreign policy.⁵

Yet the policies developed by international institutions of global health governance have not been commensurate to the rising threat of infectious disease in an increasingly interconnected world.⁶ With the 2002–2004 outbreak of severe acute respiratory syndrome (SARS) precipitating the revision of the IHR, the IHR (2005)⁷ reflected the evolved conception of emerging and reemerging diseases and embraced an ‘all hazards’ strategy that addressed ‘biological, chemical, and radio-nuclear events, as well as zoonotic diseases and threats to food safety’.⁸ The new IHR represented an acknowledgment that global health preparedness necessitated a broader range of actions beyond border measures, introducing minimum core national capacity requirements for national legislation, policy, and financing; coordination and national focal point communications; surveillance; response; preparedness; risk communication; and laboratories.⁹ While a number of countries strengthened their capacities under the IHR, it soon became clear that many were struggling to meet these minimum core capacities, with only 20% reporting IHR compliance.¹⁰ Political collaboration through global health governance can facilitate compliance,¹¹ but IHR implementation will only be possible if true national capacity and ownership is achieved.¹² National reforms are necessary to realize national capacities, meet international legal obligations, and promote global health security.

Given these shortcomings in IHR implementation at the national level, national governments came together with international organizations and public and private stakeholders in early 2014 to develop the GHSA.¹³ Through multi-stakeholder collaboration, the GHSA seeks to advance efforts to address infectious disease threats, including the implementation of IHR core capacities, recognizing substantial overlap between GHSA objectives and IHR minimum core capacities.¹⁴

The eleven GHSA ‘Action Packages’ focus on three major capacity areas: to prevent (preemptively guard against threats), detect (determine when a threat has

5 J Michaud ‘Health Security and Foreign Policy’ in S Rushton and J Youde (eds), *Routledge Handbook on Global Health Security* (Routledge 2015); DL Heymann and others, ‘Global Health Security: the Wider Lessons from the West African Ebola Virus Disease Epidemic’ (2015) 385(9980) *Lancet* 1884.

6 LO Gostin, *Global Health Law* (Harvard UP 2014).

7 WHO, *International Health Regulations* (WHO 2005).

8 SF Halabi, LO Gostin and JS Crowley, *Global Management of Infectious Diseases after Ebola* (OUP 2016) 104.

9 WHO, *Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties* (WHO 2013).

10 R Katz and others, ‘Global Health Security Agenda and the International Health Regulations: Moving Forward’ (2014) 12(5) *Biosecur Bioterror* 231.

11 Davies (n 4).

12 Gostin and Katz (n 1).

13 GHSA, ‘Global Health Security Agenda’ (2014) <<https://www.ghsagenda.org/>> accessed 20 September 2016; T Inglesby and JE Fischer, ‘Moving Ahead on the Global Health Security Agenda’ (2014) 12(2) *Biosecur Bioterror* 63.

14 See Katz and others (n 10).

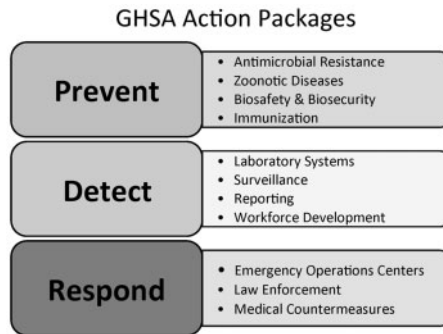


Figure 1 GHSA Action Packages

arisen), and respond (address threats as they are occurring) to global health security, as diagrammed in [Figure 1](#) above¹⁵:

Under the GHSA, national governments are urged to build capacity over 5 years to support these GHSA Action Packages.¹⁶

A. Developing the GHSA

In light of increasing concern about prevailing weaknesses in global health policy on infectious diseases and epidemics, the GHSA was developed on February 13, 2014 as ‘a plan to . . . prevent, detect and effectively respond to infectious disease threats, whether naturally occurring or caused by accidental or intentional release of dangerous pathogens.’¹⁷ Once public health policymakers identified urgent gaps in existing prevention and containment capacities, they subsequently established nine critical objectives to improve the international community’s capacity to mitigate and address public health emergencies.¹⁸ These nine objectives were grouped under three capacity areas (prevent, detect, and respond) based on the type of action each would require.¹⁹ These nine objectives were further discussed and developed during the GHSA development meeting in Helsinki, Finland in May 2014.²⁰ Representatives from thirty-two states and five health organizations—in addition to professionals from various sectors, including medicine, foreign affairs, agriculture, development, defense, and national security—participated in the decision-making process, expanding the nine critical objectives into the eleven key Action Packages.²¹

15 GHSA Commitment Development Meeting, Helsinki, Finland, 5–6 May 2014, <<http://www.globalhealth.gov/global-health-topics/global-health-security/ghsagenda-finland.html>> accessed 8 November 2015.

16 CDC, ‘Meeting in Seoul, Korea’ (2015) <http://www.cdc.gov/globalhealth/security/events/korea_2015.html> accessed 8 November 2015.

17 US Department of Health and Human Services, GlobalHealth.gov, *Global Health Security Agenda; Concepts and Objectives* (2014) <<http://www.globalhealth.gov/global-health-topics/global-health-security/ghsconceptsandobj.html>> accessed 20 September 2016.

18 Ibid.

19 Ibid.

20 GHSA Commitment Development Meeting (n 15).

21 Ibid. The initial objective of preventing the emergence and spread of antimicrobial drug-resistant organisms and emerging zoonotic diseases was split into two Action Packages, ‘Antimicrobial resistance’ and ‘Zoonotic diseases’, and one Action Package, ‘Linking law enforcement with public health professionals’ was added.

The GHSA enjoyed a moderate reception at its introduction but experienced a swift increase in political support as the Ebola outbreak swept West Africa during the summer of 2014.²² As the epidemic spread, drawing attention to weaknesses in global health governance for public health emergencies, national governments turned to the GHSA with monetary contributions and called for action plans to meet this ‘national security priority’.²³ A 5-year timeline for implementation was established from 2015 to 2019, and roadmaps for GHSA member countries were created to organize the activities necessary to realize each Action Package.²⁴ Each roadmap is articulated based upon how a national government can best meet its needs for GHSA implementation, and, as each roadmap reflects the priorities and resources of an individual country, no roadmap is the same for any two countries. As a result, distinct national legal infrastructures are now seen as critical to GHSA efforts to ensure that national systems can detect, prevent, and respond to infectious disease threats in accordance with global health security frameworks.

B. The Need for National Public Health Law Reforms

Recent public health emergencies have demonstrated a need for strong national health systems, which require robust national legal frameworks that reflect the minimum standards set out at the international level. The 2014–2015 Ebola epidemic revealed weaknesses of existing global health governance institutions to respond effectively to public health emergencies.²⁵ When the Ebola outbreak occurred, WHO failed to act with sufficient urgency, leaving member countries without clear direction.²⁶ Even as the epidemic spread, the global response to Ebola highlighted the tendency toward fleeting investments in global health, with resources and capabilities declining quickly in the immediate aftermath of the epidemic.²⁷ Based upon this inadequate WHO response, scholars have questioned global governance, concluding that ‘it is problematic to simply rely on international norms, regulations and treaties to alleviate global health crises resulting from epidemics’ where ‘the efficacy of treaties like the International Health Regulations are compromised’ by cyclical political attention and investment toward global health security.²⁸ Although global health governance institutions have sought to address these failings in preparing for future outbreaks,²⁹ with some arguing that WHO moved too quickly to respond to the Zika epidemic in

22 HW Cho and C Chu ‘Out of Africa, into the Global Health Security Agenda’ (2014) 5(6) *Osong Public Health Res Perspect* 313.

23 GHSA Commitment Development Meeting (n 15).

24 CDC, ‘Country Roadmaps’ (2016) <<https://www.ghsagenda.org/where-ghsa.html>> accessed 1 December 2016.

25 J Busby, KA Grépin and J Youde, ‘Introduction’ (2016) 10(3) *Glob Health Gov* 3.

26 WHO, *Report of the Ebola Interim Assessment Panel* (WHO 2015).

27 C Clinton and D Sridhar, *Governing Global Health: Who Runs the World and Why?* (OUP 2017).

28 A Price-Smith and J Porreca, ‘Fear Apathy and the Ebola Crisis (2014-15): Psychology and Problems of Global Health Governance’ (2016) 10(1) *Glob Health Gov* 17.

29 S Moon, ‘Will Ebola Change the Game? Ten Essential Reforms Before the Next Pandemic. The Report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola’ (2015) 386(2204) *The Lancet* 2204; UN High Level Panel on the Global Response to Health Crises, *Protecting Humanity from Future Health Crises* (UN 2016).

South America,³⁰ institutional reforms have proven particularly difficult where WHO continues to be underfunded and national governments lack global support to prevent, detect, and respond to infectious diseases and other public health emergencies.³¹

These shortcomings in the global response to recent epidemics have created an imperative to address national gaps in legal authority to ensure essential public health services. Although many nations have enacted laws to support public health, existing laws may not be adequate to address the speed at which infectious disease epidemics can cross borders.³² Gaps in national legal infrastructure have hampered national 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.³³ 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 global frameworks such as the IHR and Performance of Veterinary Services Pathway (OIE PVS) have yet to be fully realized at the national level.³⁴ In particular, 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 taken the legal steps to ensure necessary government authority.³⁵ As seen among countries at the center of the Ebola epidemic (Guinea, Liberia, and Sierra Leone), these states were signatories to the IHR, but they nevertheless lacked the institutions to address Ebola where ‘WHO failed to assist low and middle income countries in developing the capabilities needed for effective health systems and pandemic preparedness.’³⁶ Many countries lack legal infrastructures to control epidemics, yet it is at this national level where legal reforms can have the greatest impact on public health emergencies.³⁷ By focusing on GHSA implementation through multisectoral national laws, it is possible to learn from past obstacles to preventing, detecting, and responding to public health emergencies, ensuring that such missteps do not undermine national responses to future global health security threats.

30 DP Fidler, ‘Global Health Diplomacy and the Ebola Outbreak’ in SF Halabi, LO Gostin, and JS Crowley (eds), *Global Management of Infectious Disease After Ebola* (OUP 2016).

31 See eg T Mackey, ‘Lessons from Liberia: Global Health Governance in the Post-Ebola Paradigm’ (2016) 10(1) *Glob Health Gov* 60.

32 Gostin (n 6).

33 See LO Gostin, ‘Good Science + Good Ethics = Good Law: Five Rules for Epidemic Preparedness’ (2015) 93(1) *Milbank Q* 19; JG Hodge and others, ‘Global Emergency Legal Responses to the 2014 Ebola Outbreak’ (2014) 42(4) *JL Med Ethics* 595.

34 Katz and others (n 10).

35 FM Burkle, ‘Global Health Security Demands a Strong International Health Regulations Treaty and Leadership from a Highly Resourced World Health Organization’ (2015) 9(5) *Disaster Med Public Health Prep* 568.

36 S Harman, ‘Norms Won’t Save You: Ebola and the Norm of Global Health Security’ (2016) 10(1) *Glob Health Gov* 11.

37 R Morhard and R Katz, ‘Legal Regulatory Capacity to Support the Global Health Security Agenda’ (2014) 12(5) *Biosecur Bioterror* 254.

III. METHODS

To identify the scope and content of national laws supporting the GHSA Action Packages, this research examined national laws by:

- (A) developing a legal framework that maps the legal domains pertinent to each Action Package;
- (B) creating an assessment tool to determine the presence or absence of specific legal authorities under national law; and
- (C) mapping the legal landscape in twenty countries, coding and analyzing these national laws using *LawAtlas*, and identifying the presence or absence of legal authorities to prevent, detect, and respond to infectious disease threats.

A. Developing Legal Framework

To analyze the scope and content of national legislation that can support GHSA Action Packages, the researchers developed a legal framework that identifies the legal domains pertinent to each Action Package. These 'legal domains' encompass specific areas of law necessary to meet Action Package targets. The researchers undertook legal and public health research (specific to each GHSA Action Package) to characterize what is known about successful legal approaches to implement targets established under the GHSA. Legal domains were then linked to each GHSA Action Package target based upon: (i) examples of specific laws from a variety of high-, middle-, and low-income countries; (ii) legal approaches that were not employed in any country but proposed in the literature; and (iii) policy factors that could influence implementation and enforcement of these legal approaches. These legal domains were reviewed by public health subject-matter experts in each Action Package to assure that legal domains were appropriately defined and delineated.

B. Creating Assessment Tool

Based upon the legal domains contained in the Legal Framework, the researchers then developed a Legal Domain Assessment Tool (LDAT) to describe the scope and content of each legal domain, identify specific attributes of national legislation, and categorize national legal authorities. The LDAT consists of coding questions to identify pertinent attributes of national law within a single legal domain that can vary across countries. Such questions can document: (i) whether there are specific national laws responsive to a legal domain; and (ii) what legal authorities and mandates are covered by those laws. Coding questions were developed as either binary (yes or no) or categorical (with multiple choices) and were structured in a hierarchy of three layers (parent, child, and grandchild), with each layer elucidating more detail from the law. For example, while a parent question could be broad, asking whether a law exists (eg 'Is there a law providing for vaccination authority?'), child and grandchild questions would probe for additional details and features of the law (eg, 'What diseases are covered by the vaccination authority?'). The authors assessed the coding questions for their objectivity in assessing codes and on their substance in meeting the GHSA.

C. Mapping Legal Landscapes

Employing the LDAT to map national legal landscapes, the researchers analyzed twenty Sub-Saharan African countries for their national codification of legal authorities

necessary to meet GHSA Action Packages. With cross-comparability of results across Sub-Saharan Africa due to the influence of regional political unions and regional health governance, the countries in the analysis include: (i) Ebola-Affected Countries (Guinea, Liberia, and Sierra Leone); (ii) countries classified by the US Centers for Disease Control and Prevention (CDC) as High Risk Non-Affected Countries (Benin, Democratic Republic of Congo, Gambia, Ghana, Guinea Bissau, Mauritania, Nigeria, and Togo); and (iii) countries prioritized by the CDC under the GHSA (Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Mali, Senegal, Tanzania, and Uganda). The analysis of legal landscapes sought to collect, compile, and code national laws.

1. Collection and compilation of laws

Searching for relevant national public health laws that meet the objectives of each GHSA Action Package, the researchers identified relevant national statutes, regulations, and other governmental orders through:

- online materials—exploring open access databases, including GlobaLex, IDRL, FAOLEX, the World Legal Information Institute, and the websites of national ministries of justice and health;
- foreign law collections in the US Library of Congress Law Library—examining collections of national legal publications, including official gazettes, codes, and administrative rules and regulations; and
- in-country sources in national ministries—seeking specific laws that were not available online, including from within the ministry of justice or ministry of health.

This multistep, overlapping process of collecting national laws sought to validate any possible ‘null finding’ of laws (where the absence of any collected laws indicates the absence of any such laws), ensuring that the aggregated results were accurate, complete, and current.

Once specific laws were identified, the research team compiled the collected information in ‘master sheets’, with each master sheet corresponding to a single legal domain. The researchers developed the master sheets by citing relevant national laws and specific legal provisions that address a given legal domain. Once completed, the master sheets were used to guide data entry into *MonQcle*, a content management platform for *LawAtlas*, an interactive web-based policy surveillance portal.³⁸ This online content management allowed for the coding, comparison, and publication of public health laws that implement legal domains of the GHSA Action Packages.

2. Coding of laws

Once uploaded online in *MonQcle*, research teams at three universities coded the compiled laws based on the coding questions established in the LDAT. The goal of

38 *LawAtlas* is a legal mapping tool and web-based platform created by the Policy Surveillance Program of the Center for Public Health Law Research, funded by the Robert Wood Johnson Foundation and administered by Temple University's Beasley School of Law. *LawAtlas* is the central, authoritative resource for systematic collection, measurement, and display of laws and high-quality empirical legal data pertinent to the public's health.

such coding was to read, observe, and record the law (in its original language), with objective questions that asked for the coder's observation of key legal attributes (rather than an interpretation of those attributes) and thereby created an objective basis for consistent coding (from which comparative analysis could later be developed). As these coding decisions provide the results for this analysis of national law, the researchers sought to assure consistency in coding designations across the research teams. Every member of each research team underwent technical training on the use of *MonQcle* and substantive training on the GHSA Action Packages. With each Action Package coded independently by two coders,³⁹ the research teams met with supervisors on a weekly basis to review the redundant coding of national laws and consider misapplied codes.⁴⁰ Facilitating a shared understanding of code definitions, any disagreements among coders were discussed and resolved to ensure that similar laws would be coded consistently, adjusting the coding questions to reflect new interpretations and definitions.⁴¹ This iterative coding process has ensured a high level of consistency across the coders and enhanced intercoder reliability in the results.⁴²

D. Limitations

Although this qualitative coding study presents novel findings on national laws that meet GHSA imperatives, facilitating comparative research across an encompassing set of national contexts, there are limitations to legal mapping in both (i) analyzing the content of national laws and (ii) assessing the national authorities to meet GHSA Action Packages.

In limiting efforts to analyze the content of national laws, biases in the dataset (in the collection of national laws) may constrain the potential of this research to draw conclusions on national laws that meet GHSA imperatives. It has been well documented that many national laws are not publicly available, raising an inherent inability to 'disprove the null' where no laws are found and creating a selection bias toward available laws.⁴³ Although the researchers have sought to alleviate this bias through

39 With two members of the research team independently examining each law, this redundancy serves as a confirmation that all appropriate coding responses have been applied. See eg J Heymann and others, 'Assessing Compliance with the CRC: Indicators of Law and Policy in 191 Countries' (2014) 22(3) *Int'l J Children's Rts* 425.

40 See L Burla and others, 'From Text to Codings: Intercoder Reliability Assessment in Qualitative Content Analysis' (2008) 57(2) *Nursing Res* 113.

41 KM MacQueen and others, 'Codebook Development for Team-Based Qualitative Analysis' (1998) 10(2) *CAM* 31.

42 Consistency refers to how steadily each coder identifies and applies the same code to a given text, 'examin[ing] the extent to which different interviewers, observers, or coders using the same instrument or measure get equivalent results.' RA Singleton and BC Straits, *Approaches to Social Research* (OUP 2010) 136. Applying 'consistency' to the coding process, '[i]ntercoder reliability assesses the degree to which codings of text by multiple coders are similar.' DJ Hruschka and others, 'Reliability in Coding Open-Ended Data: Lessons Learned from HIV Behavioral Research' (2004) 16(3) *Field Methods* 307, 310.

For each set of redundant coders in this project, the rate of divergence between coders was less than 5% throughout the project. The teams discussed all divergences throughout the process—recoding as necessary—and the project team reanalyzed all of the questions, responses, and citations prior to publishing the project online in *LawAtlas*.

43 JC Reitz, 'How to Do Comparative Law' (1998) 46(4) *Am J Comp Law* 617.

in-country verification and collection where necessary, it is clear that there are limitations among governments in their processes for disseminating laws. The countries with the least progress in implementing GHSA Action Packages are also likely to be those with the least transparent legal authorities.⁴⁴ Because of this limitation in collecting laws, it is not clear whether the national laws coded in this study represent the complete dataset of national laws in a given legal domain.

In limiting conclusions on the implementation of the GHSA, there are additional methodological concerns that national laws do not reflect the actual implementation of GHSA Action Packages. Where this coding only measures the ways in which governments have codified Action Packages in national law, it is unclear whether the law ‘on the books’ represents the law ‘on the ground’, i.e. whether governments have implemented Action Packages in government practice.⁴⁵ Compounded by the prevalence of nonlegal responses to address health security, this study has not examined policy agendas, ministry guidance documents, inter-ministerial memoranda, national budgets, and other approaches that may meet government imperatives to prevent, detect, and respond to health security threats. Finally, it is unclear from this comparative legal analysis whether such national laws and policies are effective in preventing, detecting, and responding to disease, and additional ‘legal epidemiology’ research, based upon these results, will be necessary to study the effect of these laws on national health systems and public health outcomes.⁴⁶

Notwithstanding these limitations, this study provides comprehensive and systematic results of national legal efforts in accordance with GHSA Action Packages.

IV. RESULTS: NATIONAL LAW IN ACCORDANCE WITH THE GHSA

Based upon coding results, the researchers analyzed the attributes of laws in each legal domain across twenty Sub-Saharan African countries, creating the following analysis of national laws to prevent, detect, and respond to public health emergencies (Table 1).

This part presents an overview of these findings by GHSA Action Package, highlighting examples of national laws for each legal domain that are responsive to LDAT coding questions and indicating where no country in the twenty-country sample has a law that is responsive to a particular LDAT coding question. While this study does not seek to develop ‘model legislation’ or to prioritize ‘template laws’ (as such prescriptive analysis would not be advisable given the diverse legal environments in this study), this analysis maps legal authorities across countries that reflect the legal domains of GHSA Action Packages. The national decision to reform laws into greater conformity with GHSA Action Packages is a political issue that is beyond the scope of this comparative legal analysis.

44 WHO, *Advancing the Right to Health: The Vital Role of Law* (WHO 2017).

45 Where is it unclear whether national laws are developed simply to comply with international imperatives (without any subsequent actions by the national government), additional ‘on the ground’ research—employing interview methodologies and anthropologic observation with key national informants—will be necessary to examine the links between national law and government practice. Reitz (n 43).

46 S Burris and others, ‘A Transdisciplinary Approach to Public Health Law: The Emerging Practice of Legal Epidemiology’ (2016) 37 *Annu Rev Public Health* 135; G Marks-Sultan and others, ‘National Public Health Law: a Role for WHO in Capacity-Building and Promoting Transparency’ (2016) 94(7) *Bull World Health Organ* 534.

A. Antimicrobial Resistance—Prevent 1

Antimicrobial resistance (AMR) raises global concerns, affecting all countries and populations, and poses the risk that medicines may prove ineffective in treating disease. Arising from harmful agricultural, veterinary, and medical practices, WHO has found that antimicrobials are ‘among the most misused of all medicines’.⁴⁸ An effective response to AMR requires new norms and behaviors across sectors, yet global governance institutions are only beginning to address the implementation of such measures.⁴⁹ Any truly meaningful action to combat AMR will require coordination and cooperation across governments, with countries establishing clear legal guidelines that, *inter alia*, address the use of animal feed supplemented with antibiotics; alter the use of substandard, counterfeit drugs in place of high-quality antibiotics; and change medical and veterinary treatment practices.⁵⁰ This will require addressing legal domains for: (i) enabling authority; (ii) medicines regulation; (iii) animal health; (iv) AMR surveillance; and (v) professional guidelines.

1. Enabling authority

The law can establish specific government authority to combat antimicrobial resistance. While the health sector is often the lead sector responsible for antimicrobial authority, antimicrobial resistance authority often implicates other sectors, including medicines, public health, veterinary medicine, science, and agriculture.⁵¹ Despite the existence of such laws in other regions, none of the examined countries has developed enabling legislation for addressing AMR.

2. Medicines regulation

The law to address AMR can govern the use of antimicrobials through general medicines regulation.⁵² In doing so, the law can regulate the use of antimicrobials (for both human and veterinary medications) by:

- authorizing the government to classify medicines to be dispensed by prescription only;
- providing labeling requirements for antimicrobials;
- preventing the creation and use of substandard/counterfeit medicines; and
- including advertising/promotion restrictions for antimicrobials.

47 The full coding results, with legal provisions in their original language, can be found at <http://lawatlas.org/page/global-health-security-agenda> (accessed 20 March 2017).

48 WHO, *Antimicrobial Resistance: Global Report on Surveillance* (WHO 2014).

49 WHO, *Antimicrobial Resistance Draft Global Action Plan on Antimicrobial Resistance* (WHO 2015).

50 SJ Hoffman and others, ‘An International Legal Framework to Address Antimicrobial Resistance’ (2015) 93(2) *Bull World Health Organ* 66.

51 K Schneider and L Garrett, ‘Non-Therapeutic Use of Antibiotics in Animal Agriculture, Corresponding Resistance Rates, and What Can Be Done About It’ (19 June 2009), Center for Global Development <<https://www.cgdev.org/article/non-therapeutic-use-antibiotics-animal-agriculture-corresponding-resistance-rates-and-what>> accessed 20 March 2017.

52 See eg National Drug Policy and Authority Act 2014, art 5 (Uganda).

In addition, the law can specify a medicine regulatory authority to provide premarket approval of medicines, treatment guidelines, postmarket surveillance for medicines, and the power to recall medicines.⁵³

3. Animal health

The law can independently regulate the use of antimicrobials in animals—whether through the medicines, agriculture, fisheries, food, or drugs sectors.⁵⁴ Covering both farm and aquatic animals, this law can create measures to limit the use of antibiotics for animals through bans, veterinary supervision, limitations in feed, and prescription requirements. Facilitating implementation, the law can authorize the inspection of farms/fisheries, including by requiring livestock/fisheries and domestic animal owners to notify officials about both the appearance of disease and the use of antimicrobial treatments and by establishing procedures for managing infected animals. Where these standards are violated, the law can authorize enforcement to mandate facility closure, animal recalls, or financial remediation.

4. AMR surveillance

The law can authorize epidemiological surveillance and early detection specific to antimicrobial resistance.⁵⁵ Such a law can:

- require surveillance of antimicrobial prescribing/use patterns;
- integrate surveillance and laboratory systems capable of testing samples from human, animal, and plant populations;
- require testing of strains of disease to assess antimicrobial resistance, specifying laboratory authority to identify WHO priority AMR pathogens; and
- require international reporting of resistant pathogens as a public health emergency of international concern under the IHR (2005).

5. Professional guidelines

The law can authorize treatment guidelines specific to antimicrobials and applicable to physicians, nurses, veterinarians, and pharmacists. In doing so, such a law can require health professionals to obtain training on antimicrobial resistance, require laboratory confirmation prior to treating with antibiotics, create dispensing limitations or prescription requirements for antimicrobials, require health professionals to report antimicrobial resistance (both suspected and confirmed) to the national surveillance system, and authorize sanctions against non-compliant professionals. However, none of the examined countries has developed professional treatment guidelines for AMR or required the establishment of AMR and Healthcare Acquired Infection (HAI) guidelines for health facilities.

53 See eg Decree No 2006-396 of 31 July 2006 on the responsibilities, structure and functioning of the Ministry of Health, art 61 (Benin).

54 See eg Ethiopian Veterinary Drug and Feed Control Proclamation of 2011, arts 3, 6, 7 (Ethiopia).

55 See eg Interministerial Order No 275 MSPM-CAB-BL of 3 February 2005 establishing a National Laboratory Network, art 2 (Senegal).

B. Zoonotic Disease—Prevent 2

Zoonotic infectious diseases account for more than 70% of human diseases and have been linked to over 60% of all new diseases.⁵⁶ With agriculture central to many developing economies, many nations in Sub-Saharan African have developed legal and regulatory frameworks to enable the intersectoral collaboration required to manage public health risks at the human–animal interface.⁵⁷ These legal frameworks can provide authority to, *inter alia*, license veterinarians, restrict animal movement, license animal husbandry, take action during outbreaks, conduct epidemiological surveillance, and develop integrated surveillance and laboratory systems that can test human, animal, and plant population samples. This will require addressing legal domains for: (i) enabling authority; (ii) surveillance and laboratories; (iii) animal production; (iv) zoonotic medicines; and (v) trade.

1. Enabling authority

The law can establish a government authority for veterinary medicine.⁵⁸ This law can authorize the appointment of a chief veterinary officer and authorize the government to:

- control animal diseases;
- take action in an outbreak;
- conduct epidemiological surveillance;
- share data;
- regulate zoning;
- recall animals/animal products; and
- compensate for loss.⁵⁹

2. Surveillance and Laboratories

The law can provide epidemiological surveillance of zoonotic disease, often specific to prioritized diseases.⁶⁰ Such a law can integrate surveillance authority for human, animal, and plant populations under the ‘One Health’ approach,⁶¹ requiring the notification of a zoonotic disease outbreak across government sectors and authorizing reports about animal diseases to an international organization (eg, OIE, WHO). To do so, the law can certify laboratories for zoonotic disease, including the integration of laboratory systems capable of testing samples from human, animal, and plant populations and the establishment of distinct certification requirements for laboratory technicians who work with zoonotic disease, as seen under West African Union Law.⁶²

56 KE Jones and others, ‘Global Trends in Emerging Infectious Diseases’ (2008) 451 Nature 990.

57 WHO, Managing Zoonotic Public Health Risks at the Human-Animal-Ecosystem Interface <http://www.who.int/foodsafety/about/flyer_zoonoses.pdf> accessed 18 September 2016.

58 See eg Public Health Law of 1976, s 64.4. National Board for veterinary medicine: Liberian Medical Board (Liberia).

59 See eg Law No AN VII-0016/FP/AGRI-EL of 22 November 1987 on the Animal Health Code, 1989, art 7 (Burkina Faso).

60 See eg Law No 99-002 of 12 February 1999 on animal health in the territory of the Togolese Republic authorizes epidemiological monitoring of zoonotic disease, arts 10–13 (Togo).

61 See eg Order No R-001056 of 24 September 2002 creating the Mauritanian Network for the Epidemic Monitoring of Animal Diseases (Mauritania).

62 See eg Regulation No 04/2006/Cm/UEMOA establishing a Laboratory Network Responsible for the Control of the Quality of Veterinary Medicines in the UEMOA Zone, art 4 (UEMOA).

3. *Animal production*

The law can require the registration of all animal husbandry and processing establishments.⁶³ Covering farm and/or aquaculture facilities, the law can regulate the housing of animals (including equipment and facilities) and require safety and hygiene procedures in rearing, staff behaviors, and washing facilities.⁶⁴ The law can require regular health checks of animals and the notification of a die-off to the government.⁶⁵ In food production, the law can separately authorize the regulation of slaughterhouses,⁶⁶ requiring their certification and outlining specific rules on the construction of slaughterhouses, hygienic conditions, animal tracing, and meat handling. Finally, the law can provide authority to inspect all animal production and aquaculture establishments,⁶⁷ outlining the required qualifications of inspectors and the powers of inspectors to enter property, seize, quarantine, take samples, cull, and destroy.

4. *Zoonotic Medicines*

The law can provide an independent regulatory authority for zoonotic medicines.⁶⁸ Either through the medicines or agriculture sector, such laws can provide regulatory functions for marketing, production, import, storage, transport, packaging, recalls, labeling, traceability, inspection, and surveillance of zoonotic medicines. Requiring the specific use of zoonotic vaccines, in accordance with the immunization requirements in Prevent 4 below, such a law can mandate routine or emergency animal vaccination for specific vaccine-preventable diseases.⁶⁹

5. *Trade*

The law can regulate the trade of animals and movements across national boundaries, including both imports and exports,⁷⁰ requiring government certification for the international movement of live animals and specifying the processes regarding entry/exit points.

C. Biosafety and Biosecurity—Prevent 3

Biosafety and biosecurity protect populations by securing dangerous pathogens and preventing intentional misuse. While grouped together, ‘biosafety’ refers to the laboratory ‘containment principles, technologies and practices that are implemented to prevent *unintentional* exposure to pathogens and toxins, or their accidental release,’ whereas ‘biosecurity’ refers to ‘institutional and personal security measures designed to prevent the loss, theft, misuse, diversion, or *intentional* release of pathogens and toxins’.⁷¹ Legislation plays an essential role in strengthening national and regional

63 See eg Decree No 98-70 of 13 February 1998 defining the General Rules for the Installation of Livestock Operations, art 5 (Côte d’Ivoire).

64 See eg Decree-Law 9/2011 Approves the Regulation of Fish Inspection, art 7 (Guinea-Bissau).

65 See eg Animal Diseases Act of 2003, art 14 (Tanzania).

66 See eg Meat Control Act of 1972 (Kenya).

67 See eg Fisheries Act of 2007, art 71 (The Gambia).

68 See eg Kenya Veterinary Vaccines Production Institute Order of 1990, art 5 (Kenya).

69 See eg Animal Diseases Act of 2003, art 12 (Tanzania).

70 See eg Code of Livestock and Animal Products, 1995, arts 41-46 (Guinea).

71 WHO, *Laboratory Biosafety Manual* (WHO 2004) 47 (emphasis added).

capacities to manage biological material and promote safe and responsible conduct, including, *inter alia*, biological agent and toxin classification, prevention measures, response protocols, and reporting mechanisms.⁷² Where national laws must create or assign an entity as the primary authority to regulate biosafety and biosecurity, the law must provide this entity with sufficient power to carry out such regulation on all aspects related to biosafety and biosecurity, including the authority to identify biological agents and toxins of concern, identify and criminalize undesirable behavior, license those authorized for legitimate use, and mandate specific protocols to address problems of unintentional exposure to or misuse of such agents.⁷³ This will require addressing legal domains for: (i) enabling authority; (ii) identifying biological agents and toxins; (iii) prohibiting proliferation; and (iv) transfers and waste disposal.

1. Enabling authority

The law can authorize a lead government entity to regulate laboratory biosafety and biosecurity. This law can provide authority to regulate import and export, mandate specific protocols, prohibit undesirable behavior, and establish biosafety and biosecurity practices. Pursuant to these authorities, the law can require the development of a national biosecurity emergency response plan. However, no country in this sample has developed such an agency or developed such laws for addressing biosafety and biosecurity.⁷⁴

2. Identifying biological agents and toxins

The law can provide authority for biological risk evaluations of dangerous pathogens,⁷⁵ with provisions to:

- list prohibited toxins;
- list agents of concern—those regulated but not prohibited;
- categorize agents and toxins—by ability to be weaponized, potential for infection, means of transmission, communicability within a population, severity of harm, availability and effectiveness of preventive measures or medical treatments; and
- provide for testing to identify pathogens.

3. Prohibiting proliferation

The law can authorize the government to regulate the persons, laboratories, and/or facilities that can produce, use, and store biological agents and toxins. Such a law can require registration of those licensed to handle biological agents and toxins, provide

72 V Sutton, *Biosecurity Law and Policy: Biosecurity, Biosafety, and Biodefense Law* (Vagas Publishing 2014) 454–570.

73 DP Fidler and LO Gostin, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (Stanford UP 2007) 187–218.

74 While many laws in this sample were found to have the word ‘biosafety’ or ‘biosecurity’ in the title of the law, these laws often address genetically modified organisms (GMO), defining biosafety or biosecurity inapposite to their meaning under the GHSA. While GMOs can be considered as an unknown species in the environment, a threat to naive organisms, or a risk for unknown side effects due to the insertion of new genes—which could pose a risk of harm to human health—these prospective harms are not traditionally considered a laboratory biosafety or biosecurity issue and are outside the scope of this Action Package.

75 See eg Order No 409/PJL/AN of 27 November 1989 on toxic and dangerous waste, art 5 (Cameroon).

biological risk management training, and explicitly prohibit all activities in the development, possession, and transfer of biological agents for the purpose of producing biological weapons. However, no country in this sample has developed such laws, established biosafety and biosecurity practices for laboratories and facilities, or authorized inspection (and de-accreditation) of laboratories and facilities.

4. *Transfers and waste disposal*

The law can address the transfer (handling, storage, and transport) of biological agents and toxins.⁷⁶ Such a law can require reporting of transfers of biological agents and toxins (including purchases, sales, and disposals), regulate the transport and storage of agents, and create trade restrictions over both import and export of biological agents and toxins. Given the enduring risks posed by agents and toxins, the law can additionally regulate the disposal of hazardous waste,⁷⁷ including biohazardous waste, hazardous waste, and chemical waste in the context of hospitals, labs, and private medical facilities.

D. Immunization—Prevent 4

Immunization is an integral part of any country's public health measures, with many countries relying upon longstanding laws related to vaccination against epidemic-prone diseases. When implementing national immunization programs, legislation can prescribe specific guidelines, including, *inter alia*, which vaccines to mandate for specific populations, whether to subsidize vaccine coverage, the immunization schedule to ensure herd immunity, incentives to increase vaccine supply and immunization rates, and vaccine prioritization in emergency situations.⁷⁸ In developing these regulations, WHO recommends that national authorities collaborate with either a national immunization technical advisory group or extra-national experts.⁷⁹ The laws that derive from this expert consultation can mandate vaccination coverage within certain populations (for either routine or emergency prevention); however, because such mandates often limit individual rights, policymakers must balance the public health benefits of mandatory vaccination against the cost to individual freedoms.⁸⁰ This will require addressing legal domains for: (i) enabling authority; (ii) supply chain; (iii) vaccine administration; (iv) vaccination registration and liability.

1. *Enabling authority*

The law can authorize the government to regulate and set the timing of routine and/or emergency vaccination.⁸¹ Such vaccine guidelines can be set by either a government ministry or an independent agency. These guidelines can have provisions for

76 See eg Public Health Act of 2012, art 46 (Ghana).

77 See eg Order No 409/PJL/AN of 27 November 1989 on toxic and dangerous waste, arts 1–2 (Cameroon).

78 LO Gostin, 'Medical Countermeasures for Pandemic Influenza: Ethics and the Law' (2006) 295(5) JAMA, 554.

79 P Duclos, 'National Immunization Technical Advisory Groups (NITAGs): Guidance for Their Establishment and Strengthening' (2010) 28S Vaccine, A18.

80 DA Salmon and others, 'Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, and Future' (2006) 367(9508) Lancet 436.

81 See eg Health Code 2009, art 6 (Togo).

mandatory vaccinations,⁸² which can address specific vaccine-preventable diseases and specific vulnerable populations while allowing limited individual exceptions from vaccination mandates for health, religious, or philosophical reasons. In cases of a public health emergency, the law can allow for supplemental mandatory vaccination requirements.⁸³ To enforce vaccination guidelines and requirements, such laws can require documentation (eg certificate of successful vaccination) to provide proof of vaccination⁸⁴ and allow the government to take action for non-compliance with vaccine mandates, including a fine, imprisonment, or compulsory vaccination.⁸⁵

2. Supply chain

The law can have provisions to manage a national vaccine stockpile.⁸⁶ Such a law can have provisions to distribute vaccines throughout the country, license manufacturers in the vaccine supply chain, provide for the storage of vaccines, and increase the production of vaccines in a public health emergency.

3. Vaccine administration

The law can have provisions to provide for the administration of vaccines,⁸⁷ including provisions to license and train actors who are authorized to administer vaccines. Assuring widespread vaccination levels to facilitate herd immunity, the law can establish eligibility requirements for subsidized or free vaccination.⁸⁸ In the context of a public health emergency, the law can prioritize access to vaccinations to specific necessary professions or specific vulnerable populations. However, no country in this sample has developed such a prioritization scheme.

4. Vaccination registration and liability

The law can have provisions to provide for the registration of vaccines.⁸⁹ Such laws can assure the quality of vaccines through postmarketing surveillance. Where necessary to support the development of vaccinations, especially in the context of a public health emergency, the law can provide limited liability protections for vaccine manufacturers and administrators and/or a compensation fund for those who are harmed by vaccination.

E. National Laboratory Systems—Detect 1

A national laboratory system is necessary for the detection of infectious diseases, yet ‘laboratory medicine is the most neglected pillar in the developing countries.’⁹⁰

82 See eg Interministerial Order No 08 3160 of 13 November 2008 defining the List of Compulsory Vaccinations, Calendars and Conditions of Administration of Vaccines, arts 2, 3, 4, 7 (Mali).

83 See eg Nigerian Public Health Act of 2014, s 24 (Nigeria).

84 See eg Public Health Act of 1986, art 109 (Kenya).

85 See eg Vaccination Act of 1919, art 15 (Ghana).

86 See eg Organizing and Functioning of the National Directorate of the Expanded Program on Immunization and Primary Health Care, art 7 (2007) (Benin).

87 See eg Interministerial Order No 08 3160/MS/MESSRS-SG of 13 November 2008 defining the List of Compulsory Vaccinations, Calendars and Conditions of Administration of Vaccines, art 5 (Mali).

88 See eg Public Health Act of 1935, art 43 (Uganda).

89 See eg Medicines and Health Products Regulatory Authority Act of 2010, s 1 (Liberia).

90 JN Nkengasong, ‘A Shifting Paradigm in Strengthening Laboratory Health Systems for Global Health. Acting Now, Acting Collectively, but Acting Differently’ (2010) 134(3) *Am J Clin Pathol* 359.

Where new pandemics and the threat of bioterrorism have stimulated the development of more robust national laboratory systems, laboratories (and laboratory networks) are seen as essential, *inter alia*, in identifying pathogens, detecting drug resistance, managing data, and surveilling the spread of disease.⁹¹ In facilitating these functions, legislation is necessary to authorize laboratories and laboratory staff, prescribe core laboratory standards, provide basic conditions for laboratory operations, and mandate the inspection of laboratories for compliance with law. This will require addressing legal domains for: (i) enabling authority; (ii) laboratory standards and inspection; and (iii) data protection.

1. Enabling authority

The law can provide government authority for a national laboratory system for infectious disease reporting.⁹² Such a law can specify a national reference laboratory and can establish sentinel or regional laboratories. Organizing this system, the law can create a certification system for laboratories.⁹³ Applicable to public and/or private laboratories, the government (operating through either the science, health, public health, or trade sector) can set these certification standards or delegate this authority to nongovernmental professional organizations, with different certifications (depending on the degree of risk) and processes to maintain/revoke certification.

2. Laboratory standards and inspection

Meeting certification requirements, the law can provide standards for the operation of an infectious disease laboratory.⁹⁴ Laboratory standards can be based upon the type of disease/pathogen testing and can cover human health surveillance, animal health surveillance, and environmental health surveillance. To monitor and assess these standards, the law can authorize public health authorities to inspect laboratories.⁹⁵

3. Confidentiality and data protection

The law can address the protection of individual health data in the testing of laboratory specimens.⁹⁶

F. Real-Time Surveillance—Detect 2/3

Surveillance includes the systematic collection and analysis of data for public health purposes, and states must have capacity to rapidly detect epidemic events and to disseminate public health information for assessment and response.⁹⁷ Public health

91 M Best and J Sakde, 'Practical Recommendations for Strengthening National and Regional Laboratory Networks in Africa in the Global Health Security Era' (2016) 5(3) *African J Lab Med* 2225.

92 See eg Interministerial Order No 13.128 of 2 July 2015 establishing and regulating the organization and operation of the National Public Health Laboratory, art 3 (Senegal).

93 See eg Science Technology and Innovation Act, No 28 of 2013, art 17 (Kenya).

94 See eg Health Code 2009, arts 219–220 (Togo).

95 See eg Order No AN-VIII-31 FP.SAN.AS.SG of 4 January 1991 organizing the Ministry of Health and Social Action, art 215 (Burkina Faso).

96 See eg Health Code 2009, art 575 (Togo).

97 WHO (n 7).

surveillance includes six core activities to inform public health actions: detection, registration, confirmation (both epidemiologic and laboratory), reporting, analyses, and feedback.⁹⁸ Integrating human and animal surveillance, legislation can empower the responsible agencies to conduct all surveillance and control functions, to impose reporting requirements on both public and private actors, and to coordinate the sharing of information through reporting.⁹⁹ This will require addressing legal domains for: (i) enabling authority; (ii) surveillance scope; (iii) communication across sectors; (iv) communication between sub-national and national authorities; and (v) data privacy and information sharing.

1. Enabling authority

The law can provide government authority for surveillance of public health events,¹⁰⁰ assigning a public health agency for surveillance.¹⁰¹ In identifying the responsible agency, the law can provide different government agencies with surveillance authority for different events of significance for human health and animal health, giving surveillance authority to the Health, Public Health, Animal, Water, Food, Medicines, and Terrorism sectors. Through this authority, the law can provide both (i) diagnostic capacity for detection and identification and (ii) analysis capacity for epidemiologic investigation.¹⁰²

2. Surveillance scope

Surveillance authority can be based on either all public health events or specific notifiable infectious diseases or symptoms.¹⁰³ Where the laws specify notifiable infectious diseases, these laws can (i) cover a specific range of diseases or any communicable disease or condition that the ministry declares and (ii) apply to either suspected or confirmed cases.

3. Communication across sectors

The law can establish a single sector to coordinate national surveillance and aggregate information collected across sectors (human, animal, and food), communicating that information across sectors.¹⁰⁴ The law can either authorize ongoing coordination or limit coordination to specified events of public health significance. The coordinating sector can change based upon the nature of the public health event, with the law assigning specific points of contact within each sector to facilitate cross-sectoral communication under the One Health approach.

98 SJN McNabb and others, 'Conceptual Framework of Public Health Surveillance and Action and Its Application in Health Sector Reform' (2002) 2(2) BMC Public Health.

99 J Halliday and others 'Bringing Together Emerging and Endemic Zoonoses Surveillance: Shared Challenges and a Common Solution' (2012) 367(1604) Philos Trans R Soc Britain 2872; DL Hyneman and others, 'SARS Legacy: Outbreak Reporting is Expected and Respected' (2013) 381(9869) Lancet 779.

100 See eg Public Health Act of 1989, art 4 (The Gambia).

101 See eg Order No AN-VIII-31 FP.SAN.AS.SG of 4 January 1991, art 109 (Burkina Faso).

102 See eg Public Health Act of 2012, Annex I (Ghana).

103 See eg Decree No 07-165 of 23 May 2007 establishing the List of Compulsory Diseases and Conditions of this Declaration, art 1 (Mali).

104 See eg Law No 012-2014 of 22 April 2014 on the Law of Prevention and Risk Management, Humanitarian and Disaster Crisis, art 61 (Burkina Faso).

4. *Communication with national authorities*

The law can additionally establish a national actor to coordinate surveillance across governance levels (national, subnational, and local).¹⁰⁵ This coordination can be either (i) general or limited to specific diseases and (ii) ongoing or limited to specified events of public health significance.

5. *Data privacy and information sharing*

To conduct surveillance, the law can provide for the sharing of identifiable health information without consent,¹⁰⁶ with laws at times mirroring language on data privacy directly from the IHR.¹⁰⁷ Such a law can provide processes to limit the disclosure of private health data and provide processes for notification of at-risk individuals.

G. Reporting—Detect 4

Integral to public health surveillance, reporting involves the movement of public health surveillance data collected from lower levels of the health system (eg health facilities) to higher ones (eg district or national office, or international organizations).¹⁰⁸ Prompt notification of the appropriate authorities concerning public health events is key to a rapid response, requiring reporting by ‘mandatory reporters’, including: public health actors and public officials and institutions (police, educational institutions, correctional facilities); private stakeholders, including health-care providers and facilities, pharmacists, drug manufacturers, food manufacturers and food serving industries; and educational facilities and other licensed facilities such as nursing homes.¹⁰⁹ Where the law requires a necessary link between the detection of a threat to public health and analysis of that threat by policymakers, the law may create incentives to report, sanctions for failure to report rapidly, and authorities for health officials to proactively collect data. This will require addressing legal domains for: (i) enabling authority; (ii) reporting timeframe; (iii) international reporting; and (iv) data privacy.

1. *Enabling authority*

The law can provide mandatory requirements for national disease reporting,¹¹⁰ specifying who has a duty to report (whether government officials, public health actors, private health-care providers, and/or veterinarians/health-care facilities) and who is authorized to receive reports (whether at the regional or national level and which ministry).¹¹¹ The reported diseases and conditions can be specified under law to include:

- the IHR reportable diseases or any uncommon illness of potential public health concern;
- specified diseases or other conditions (medicine adverse effects, animal control; environmental health); and

105 See eg Public Health Act Bill of 2004, s 9 (Nigeria).

106 See eg Right to Access Information Act of 2013, art 21 (Sierra Leone).

107 See eg Public Health Act of 2012, art 45 (Ghana).

108 Scott and others (n 98).

109 S Roush and others, ‘Mandatory Reporting of Diseases and Conditions by Health Care Professionals and Laboratories’ (1999) 282(2) JAMA 164.

110 See eg Public Health Act of 2009, art 10 (Tanzania).

111 See eg Code of Public Health, 1997, art 158 (Guinea).

- suspected or confirmed harms.

Further, there can be specific legal incentives to report specified diseases or sanctions for failure to report, with the government having authority to conduct inspections to collect reports.

2. Reporting timeframe

The law can require reporting to occur within a certain amount of time (often 24 or 48 hours), with sanctions for failure to report in a timely manner.¹¹² With nations moving toward ‘real-time’ communication through electronic reporting systems, these reporting timeframes can change in the context of an emergency.

3. International reporting

In accordance with international law, the law can mandate international disease reporting of public health emergencies.¹¹³ The law can specify a particular government agency for international disease reporting, identifying the reporting agency that serves as the National IHR Focal Point, the OIE Delegate, and the INFOSAN reporting institution.¹¹⁴ Such a law can mandate a separate timeframe for international reporting.

4. Data privacy

Similar to the privacy protections in national surveillance systems, reporting processes can have processes to protect the privacy of identifiable health information.¹¹⁵ Such protections against the unauthorized disclosure of identifiable health information can occur by de-identifying data or creating sanctions for breach of privacy.

H. Workforce Development—Detect 5

Workforce development is necessary to ensure that health professionals and non-traditional health professionals receive sufficient education and maintain the skills, training, and licenses or certifications necessary to conduct activities within their defined scope of practice.¹¹⁶ Legislation concerning the health security workforce often focuses on (i) enabling legislation for setting professional standards, including education, training, and skill requirements, (ii) licensure or certification requirements, and (iii) scope of practice and related standards.¹¹⁷ To the extent the law does not explicitly prescribe such standards, it can establish and authorize bodies, councils, or associations—whether public, quasi-public, or private—with the responsibility to

112 See eg Public Health Law of 1976, s 12.3 (Liberia).

113 See eg Public Health Act of 2012, art 168 (Ghana).

114 See eg Order No 3460 on the Creation, Attribution, Organization and Functioning of the Pastes of Sanitary Monitoring of the Frontiers of the Republic of Benin 2010, art 4 (Benin).

115 See eg Food, Medicine, and Healthcare Administration and Control Proclamation of 2009, arts 3–4 (Ethiopia).

116 R Beaglehole and MR Dal Poz, ‘Public Health Workforce: Challenges and Policy Issues’ (2003) 1(4) Hum Res Health.

117 WHO, *Good Practice in Occupational Health Services: A Contribution to Workplace Health* (WHO Regional Office for Europe 2002).

accredit educational institutions, license professionals, determine scope of practice standards, and discipline professionals for malpractice. This will require addressing legal domains for: (i) enabling legislation; (ii) licensing and certification; and (iii) scope and standards of practice.

1. Enabling legislation

Enabling legislation can set educational mandates for workforce development of health professionals. Through either the education, health, public health, or agriculture sector, the law can provide educational standards for health professionals.¹¹⁸ Such laws can accredit educational institutions for health professionals, including medical professionals (doctors, nurses, and pharmacists),¹¹⁹ public health professionals (epidemiologists and lab technicians),¹²⁰ and veterinary professionals (veterinarians, para-veterinarians, and agricultural practitioners).¹²¹

2. Licensing and certification

The law can set licensing standards for health professionals, either through the government or delegated to nongovernmental professional organizations, providing powers for licensure of medical professionals, public health officers, pharmacists, nurses, epidemiologists, laboratory scientists, and biostatisticians.¹²² With a license often required for practice, licensing can be granted based upon an examination, practice, training, and/or a degree. Establishing standards/processes for revocation of licensure, the law can provide processes for maintaining licensure through good standing, continuing education, and/or a fee.¹²³

3. Scope and standards of practice

The law can establish the scope of practice for health practitioners, whether set by the government or delegated to nongovernmental professional organizations, including for medical and public health professionals (doctors, nurses, pharmacists, epidemiologists, and lab technicians)¹²⁴ and veterinary professionals (veterinarians, para-veterinarians, and agricultural practitioners).¹²⁵ This scope of practice can change in the event of a public health emergency.

I. Emergency Operations Centers—Respond 1

Emergency operations centers (EOCs) serve as central command and control centers for facilitating, leading, and coordinating government responses to public health emergencies.¹²⁶ As governments respond to all types of hazards (including infectious

118 See eg Ethiopian Health Professionals Council Establishment Council of Ministers Regulations of 2002, art 4, 14 (Ethiopia).

119 See eg Medical and Dental Practitioners Act of 2004, art 9 (Nigeria).

120 See eg Public Health Officers (Training, Registration and Licensing) Act 2013, art 22 (Kenya).

121 See eg Veterinary Act 2003, art 2 (Tanzania).

122 See eg Public Health Law 1976, s 62.5 (Liberia).

123 *ibid* s 61.21.

124 See eg Health Code 2009, art 161 (Togo).

125 See eg Veterinary Surgeons and Veterinary Para-Professionals Act of 2011, art 14 (Kenya).

126 IFRC, Introduction to the Guidelines for the domestic facilitation and regulation of international disaster relief and initial recovery assistance (IFRC: Geneva, 2011).

disease outbreaks; natural, accidental, or deliberate release of chemical, biological, or radiological materials; and natural disasters), an emergency operations center is critical to: coordinating a multisectoral response, communicating with emergency responders, managing public health information, and serving as the national focal point with international organizations.¹²⁷ While some countries and regions have some form of an EOC in place, many still lack a legal framework on either a national or local level to effectively coordinate an emergency response.¹²⁸ Authorizing these functions, legislation can outline the framework for organizing EOC operations, define leadership hierarchies for decision-making, and delineate the roles and responsibilities for EOC staff.¹²⁹ This will require addressing legal domains for: (i) enabling authority; (ii) sub-national EOCs; (iii) EOC functions; and (iv) staff authority.

1. Enabling authority

The law can authorize a national EOC to coordinate disaster risk reduction and management.¹³⁰ The national EOC can be situated under the ministry of health or another ministry.

2. Sub-national EOCs

In addition to a national EOC, the law can also authorize EOCs at the sub-national level (state, regional, and municipal).¹³¹ Such sub-national facilities can be permanently installed or authorized on an ‘as needed basis’. These subnational EOCs can either apply their own processes during an emergency or follow the processes set by the national EOC.

3. EOC functions

The law can specify when the EOC is activated (under conditions of public health emergency, bioterrorism, natural disaster, and/or all- (or multi-) hazards).¹³² Such laws can specify the timing of a coordinated emergency response following the declaration of an emergency, delineate a command authority, and establish who directs the coordination. In the context of an emergency, the law can specify the range of EOC response functions, including authorities for: declaration of a public health emergency, surveillance and monitoring, coordination and direction, international reporting, communication with foreign EOCs, information sharing across sectors, and communication with the public.¹³³

127 WHO, *Public Health Emergency Operations Center Network (EOC-NET): Consultation Meeting* (WHO 2012) <http://apps.who.int/iris/bitstream/10665/85378/1/WHO_HSE_GCR_2013.4_eng.pdf> accessed 8 June 2016.

128 CC Tsai and others, ‘A Research on the Three-Year Performance of the Regional Emergency Operation Centers in Taiwan’ (2013) 68(2) *Nat Hazards* 1109.

129 LY Landesman, *Public Health Management of Disasters: The Practice Guide* (APHA 2012).

130 See eg Disaster Management Act of 2015, art 5 (Tanzania).

131 See eg Decree No 87-408 of 7 December 1987 Organizing the National Disaster Relief and Disaster Relief Organization, art 9 (Benin).

132 See eg Decree No 2012-988 of 10 October 2012 Creating, Assigning, Organizing and Operating the National Platform for Risk Reduction and Disaster Management, art 4 (Côte d’Ivoire).

133 Ibid art 5.

4. Staff authority

The law can also specify the roles and responsibilities of core EOC staff.¹³⁴ Such authority can require the establishment of a specialist response force for disasters, require a response team from multiple sectors, establish training for EOC staff, and permit volunteers. In carrying out their authority, the law can provide staff with requisition/seizure authority over property, materials, and people.¹³⁵

J. Linking Public Health with Law and Multisectoral Rapid Response—Respond 2

A multisector rapid response, building collaborations among public health and law enforcement authorities, can improve government abilities to respond to biological threats and can close operational gaps between agencies.¹³⁶ When one sector alone cannot mitigate the multifaceted impact of a public health emergency, multisector collaboration allows a concerted effort (i) by government, business and civil society and (ii) between international, national, and local actors. Creating multisectoral response laws can assist in establishing collaborations between public health, law enforcement, and biosurveillance networks and in developing and formulating protocols for, *inter alia*, coordination, integrated planning, and management of relationships across sectors.¹³⁷ Legislation can provide guidelines for building collaborations across and within national agencies to respond to public health emergencies, addressing issues of: disaster risk management, quarantine and isolation, and links between public health law and law enforcement authorities.¹³⁸ This will require addressing legal domains for: (i) enabling authority; (ii) disaster risk management; (iii) quarantine and isolation; and (iv) international assistance.

1. Enabling authority

The law can provide legal authority for a response across multiple sectors in the event of a biological event of suspected or confirmed deliberate origin.¹³⁹ The law can specify whether such a multisectoral response requires the declaration of a state of emergency, whether for a biological event, a natural disaster, or an event of deliberate origin. Indicating what sectors have authority in a multisectoral response—including the health, public health, law enforcement, justice, emergency management, interior, military, agriculture, energy, and environment sectors—the law can give different sectors authority to conduct a criminal or epidemiological investigation. In coordinating the response by all sectors, a coordinating agency can be set under law (changing based upon the nature of the event), with focal points in each ministry.¹⁴⁰

134 See eg Disaster Management Act of 2015, art 24 (Tanzania).

135 See eg National Emergency Management Agency (Establishment, etc) Decree of 1999, art 20 (Nigeria).

136 C Streck, 'Global Public Policy Networks as Coalitions for Change' in DC Esty and MH Ivanova (eds), *Global Environmental Governance: Options and Opportunities* (Yale School of Forestry and Environmental Studies 2002) 121–140.

137 Fidler and Gostin (n 73).

138 IFRC and UNDP, *Effective Law and Regulation for Disaster Risk Reduction: A Multi Country Report* (IFRC and UNDP 2014).

139 See eg Public Health Act of 2012, art 173 (Ghana).

140 See eg Order No 5025 on the Creation, Attributions, Composition and Functioning of Rapid Response Teams for Epidemics 2007, art 9 (Benin).

2. Disaster risk management

The law can specify legal procedures for responding in the event of a biological event of suspected or confirmed deliberate origin.¹⁴¹ Such a law can codify these legal procedures in an emergency operations plan, with specified roles/responsibilities for each sector.¹⁴²

3. Quarantine and isolation

The law can provide explicit authority for quarantine and isolation.¹⁴³ This quarantine and isolation authority can specify whether such authority requires the declaration of a state of emergency, and if so, what types of declarations trigger a quarantine or isolation response. Specifying which sectors have authority to quarantine and isolate, the law can specify the criteria for assessing quarantine and isolation decisions—whether based upon suspected infection, exposure to infected persons, or lack of vaccination—and can clarify whether quarantine/isolation decisions require an independent health/risk assessment.¹⁴⁴ Assuring that such decisions do not infringe rights, the law can clarify the grounds and processes by which quarantine/isolation decisions can be challenged.¹⁴⁵

4. International assistance

In the event of a public health emergency, the law can indicate how the state can provide and/or request effective and timely international assistance.¹⁴⁶ Such laws can require reporting to an international organization, permit agreements with other nations for mutual aid, and provide processes to request (and respond to requests for) assistance.

K. Medical Countermeasures and Personnel Deployment—Respond 3

Effectively responding to public health emergencies requires national frameworks for transferring (i.e. sending and receiving) both medical countermeasures and personnel among international partners.¹⁴⁷ Medical countermeasures (both pharmaceutical and nonpharmaceutical) require health professionals for their effective deployment; however, local health professionals often cannot sufficiently meet demand during public health emergencies, requiring a rapid influx of international actors.¹⁴⁸ Where no international legal framework addresses the transfer of these medical countermeasures and personnel, the lack of national legislation can hamper effective international responses

141 See eg Law No 012-2014 of 22 April 2014 on the Law of Prevention and Risk Management, Humanitarian and Disaster Crisis, art 34 (Burkina Faso).

142 See eg Nigerian Public Health Act Bill of 2004, s 6 (Nigeria).

143 See eg Public Health Act of 1989, art 13 (The Gambia).

144 See eg Nigerian Public Health Act Bill of 2004, s 26 (Nigeria).

145 See eg Public Health Law of 1976, s 4.14 (Liberia).

146 See eg Law No 012-2014 of 22 April 2014 on the Law of Prevention and Risk Management, Humanitarian and Disaster Crisis, art 69 (Burkina Faso).

147 MJ Marinissen and others, 'Strengthening Global Health Security by Developing Capacities to Deploy Medical Countermeasures Internationally' (2014) 12(5) *Biosecurity & Bioterrorism* 284.

148 B Davidson and others, 'Legal Challenges to the International Deployment of Government Public Health and Medical Personnel during Public Health Emergencies: Impact on National and Global Health Security' (2015) 43(1) *J LM Ethics* 103.

to public health emergencies, limiting the ability to send or receive medical countermeasures with foreign governments or accept personnel into a country's health system.¹⁴⁹ Some patient protections must be waived during times of public health emergency, and national laws are necessary to allow for, *inter alia*, visa waivers, recognition of foreign licenses, liability protections, and product authorizations.¹⁵⁰ This will require addressing legal domains for: (i) enabling legislation; (ii) product authorization; (iii) license to practice; and (iv) individual liability.

1. Enabling legislation

The law can enable medical personnel deployment by authorizing visas, as seen in the West African Union (UEMOA), which has developed regional visas for physicians, pharmacists, and veterinarians.¹⁵¹ Such laws can apply at all times or only in the context of a declared emergency. In enabling personnel deployment, such international visa agreements can provide for visa waivers, expedited visas, or special disaster visas. However, no countries in this sample have developed any such bilateral or multilateral agreements.

2. Product authorization

The law can additionally authorize product authorization for medical countermeasures (material aid), whether at all times or only in the context of a declared emergency; however, no countries in this sample have developed such product authorizations. In facilitating medical countermeasures, the law can provide for priority authorization, expanded scope of use (eg unapproved, use beyond labeling, use beyond expiration date, and use without a prescription), or waive applicable laws for stockpiling and storing medical countermeasures. Further, the law can manage duties, customs, taxes, or tariffs for medical countermeasures if necessary to respond to a disaster or emergency. International agreements can provide such customs waivers in times of public health emergency.

3. License to Practice

The law can manage licenses to practice for foreign assistance workers.¹⁵² Such laws can apply at all times or only in the context of a declared emergency and operate either by providing a domestic license or by recognizing a corresponding license from another country. In addition, the law can support international agreements to provide mutually recognized licenses to practice across nations in the context of a disaster or emergency, as seen in the enabling legislation above under West African Union (UEMOA) law.

149 Morhard and Katz (n 37).

150 D Fisher, *Law and Legal Issues in International Disaster Response: A Desk Study* (IFRC 2007) 40–41.

151 Relative A La Libre Circulation Et A L'établissement Des Médecins Ressortissants De L'union Au Sein De L'espace UEMOA (2005); Relative A La Libre Circulation Et A L'établissement Des Pharmaciens Ressortissants De L'union Au Sein De L'espace UEMOA (2008); Relative A La Libre Circulation Et A L'établissements Docteurs Vétérinaires Ressortissants des Etats Membres De L'UEMOA Au Sein De L'union (2012).

152 See eg Nigerian Public Health Act Bill of 2014, s 29 (Nigeria).

4. *Individual liability*

When authorized to act in another country as part of a medical deployment, the law can further provide personal liability protections.¹⁵³ Such laws can apply at all times or only in the context of a declared emergency and operate either under certain conditions (eg when invited, when carrying out duties under scope of practice, or when acting in good faith), under certain areas of immunity from liability (criminal and/or civil), or under certain standards of responsibility (eg criminal misconduct, willful misconduct, gross negligence, reckless misconduct, or negligence).

V. CONCLUSION

International efforts to address global health security have long focused on public health science rather than on the enabling legislation and authorizing regulations that empower, mandate, and authorize governments to prevent, detect, and respond to public health emergencies. This study has found that national legislation for health security can be either absent, antiquated, or incommensurate to contemporary public health threats and the speed of infectious disease transmission across national borders. To achieve GHSA objectives and targets, new or supplemental legal authorities and powers are needed to strengthen existing legal frameworks and implement the IHR and OIE frameworks.

For the GHSA to function optimally, national governments must establish a minimum package of elements that comprise the necessary legal framework to support the GHSA Action Packages. This research has identified such a necessary framework for national health security law and specific gaps in national laws across Sub-Saharan Africa, presenting opportunities for improved GHSA implementation through public health law reform. With the birth of an Africa CDC, this new regional health governance initiative holds the promise of reforming national public health laws and harmonizing those laws to reflect global health security imperatives. Such national law reform efforts will become crucial as the global health governance landscape shifts in the years to come.

There is little dispute that law plays a central role in structuring, enabling, and implementing public health systems. In establishing good legal practices for preventing, detecting, and responding to infectious disease threats, these findings can be used to frame more specific datasets and hypotheses for future policy surveillance studies—both on the political environments conducive to law reforms and on the impact of law reforms on health outcomes. As the public health legal community engages in empirical research on national public health law, this ‘legal epidemiology’ agenda will be able to analyze the politics of public health law reform and the role of law as a determinant of public health. Translated into international and comparative legal research for global health, such a global health law research agenda can provide evidence-based best practices to support national laws that realize global health security.

ACKNOWLEDGEMENTS

The authors are grateful for the research assistance of scholars, practitioners, and students throughout the world: in the development of legal framework (Michele Forzley, Megan Averill, Jessica Vapnek, Nathan Chan, Ivana Mrazova, Mar Martínez, Shayla Birath, Eeshan Khandekar, and Natasha Vengrinovich); the collection of national laws (Britton Tripp, Meredith Parker, Anna Tordjmann, Sousena Kebede, Elsie Dotse, Maximillian Seunik, and Alessandra Bassalobre Garcia); the coding of national laws at the University of North Carolina at Chapel Hill (Nataniel Leental, Britton Tripp, Savannah Wooten, Hannah Olaniyan, Chismindi Onwuteaka, Zakaria Merdi, and Amma Boake), Temple University Beasley School of Law (Deven A. Amin, Dana J. Bonfiglio, Danielle Froschhauser, Christopher S. Gagne, Elizabeth M. Hines, Seth Litwack, Joseph P. Mathew, Megan A. Moore, Adam R. Nester, Kent A. Quidachay, Victoria E. Ruby & Carly A. Shanaha), and the O'Neill Institute for National and Global Health Law at Georgetown University (Faith Boateng, Elizabeth Makumbi, Elsie Dotse, Juliette Herault, and Maha Munir); and the drafting of this article (Eeshan Khandekar, Savannah Wooten, and Florian Kastler).

This research uses data collected under Cooperative Agreement/Contract No. 200-2010-35770, Task Order 13 funded by Centers for Disease Control and Prevention (CDC). The content of this publication does not necessarily reflect the views, analysis or policies of FHI 360 or Centers for Disease Control and Prevention (CDC), nor does any mention of trade names, commercial products, or organizations imply endorsement by FHI 360 or Centers for Disease Control and Prevention (CDC).

Conflict of interest statement. None declared.