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Health Law

THE IMPORTANCE OF MONITORING DOMESTIC PUBLIC HEALTH LAW AND LEGAL SYSTEMS SUPPORTING GLOBAL HEALTH GOVERNANCE: DEVELOPMENT OF AN ANALYTICAL FRAMEWORK TO ASSESS THE DOMESTIC PUBLIC HEALTH LAW SITUATION IN THE WESTERN PACIFIC REGION COUNTRIES

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Abstract: The aims of this study are to present an argument that emphasizes the usefulness of an analysis framework for analyzing public health law and legal systems; identifying methods for improving the application of this framework, including its academic value for public health law; and enhancing the future use of the framework for supporting global health governance. To help formulate the initial analysis framework and tool, we have, along with expert consultations, conducted a literature review on global health governance and public health law. Meetings were also held with World Health Organization (WHO) Western Pacific Regional Office (WPRO) technical staff members on the applicability and benefits of the framework and tool. Monitoring public health laws and legal systems of countries can be used to understand governance and improve people's health.

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I. BACKGROUND

Public health develops through the contributions of people in a variety of professions, including doctors, healthcare workers, scientists, and epidemiologists. However, since the recognition in the field of public health, economists have also had an integral role, as have management specialists, statisticians, and sociologists. Now, lawyers and experts in various legal disciplines are taking on an increasingly important role. The law is now recognized as an essential tool for public health.

In 1948, the International Digest of Health Legislation (IDHL) was established by the World Health Organization (WHO); the IDHL contained a selection of national and international health legislations that had been gathered in Geneva. It envisioned protecting people from disease through legal approaches. Despite the long tradition, this vision has not been implemented and is not being updated. However, this vision is still respected today, and we now are trying to bring it back to life.

Since 2010, the WHO Regional Office has been developing a framework for public health law for member states to use in analyzing their own health regulatory and/or legal status. An expert consultation was convened in May 2011 in Manila, the Philippines, in order to support external technical assistance in public health law and discuss the current public health law situation in the Western Pacific Regional Office (WPRO) countries and to agree on, and offer advice on, objectives and methods for the development of a legal assessment framework¹.

The first draft of the tool for assessing country-level public health law was developed to assess whether member states were embracing, adopting, and adapting the global health policies promulgated by the WHO. In developing the tool, the first step was to look at key WHO policies and initiatives including the WHO Constitution, the health-related Millennium Development Goals

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(MDGs), the International Health Regulations 2005 (IHR 2005), the Alma-Ata Declaration on Primary Health Care (PHC), the Framework Convention on Tobacco Control (FCTC), and various WHO recommendations, World Health Reports, and WPRO publications. The IDHL was also consulted.

Given the broad definition of public health and the variety of laws that, directly or indirectly, affect health, the participants further agreed to narrow the field to four areas, based on significant WHO work². This “Analysis Tool to Assess Public Health Law” is comprised of four independent modules covering: (1) the IDHL; (2) strategies for health systems based on the values of PHC; (3) International Health Regulations (IHR) 2005; and (4) the FCTC.

The analysis framework is distinct from the assessment tool. Indeed, the tool is only a small part of the analysis framework. The current paper describes the analysis of domestic public health law. Primary data have been collected using the tool, and secondary data have been obtained from other sources, such as descriptions of countries’ legal frameworks and of the human resources available for implementing health law in particular countries. The last two are not explicitly collected using the tool but are reflected in the final country reports written up by experts, and so become part of the larger analysis framework.

This new analytical framework is expected to provide the means for countries and individuals to evaluate the status of country-level public health law and legislation. The draft framework contains an introduction, objectives, a proposed work timetable, terms of reference, a list of issues, references to the six building blocks of the WHO health systems framework, the subject headings of the IDHL, recommendations regarding methodology, and lists of indicators and information sources. After the analysis tool was drafted, it was circulated to consultation participants and feedback was collected³. It was revised according to the feedback before its first implementation.

Thus, the current study aims to find the answers to the above questions by describing the development and processes of the analysis framework for conducting in-country analyses of public health law and legal systems. The specific purposes are as follows: to present the fundamental basis and demonstrate the usefulness of the framework as a global health governance tool for analyzing public health law and legal systems in different countries; and to suggest future directions and models for assessing domestic public health law and legal systems and supporting global health governance.

II. METHODS

Different research methodologies were used to achieve each of the above objectives. To establish the fundamental basis and demonstrate the usefulness of the framework, expert consultation meetings were held, academic workshops attended, and literature reviews on global health governance and public health law were undertaken. Historical health legislation trends and other trends were reviewed to identify the strengths and weaknesses of the proposed analysis framework, develop suggested future directions and models for assessing domestic public health law and legal systems, and support global health governance.

III. RESULTS AND DISCUSSION

A. The Usefulness of the Framework as a Global Health Governance Tool

1) Public Health Law

Public health law is the study of the legal powers and duties of the state, and of the limitations on the power of the state to ensure the common good and autonomy, privacy, liberty, proprietary, and other legally protected interests of individuals⁴. Collaboration with its public health advocacy partners assures the conditions for people to be healthy. Despite the significance of public health laws and legislation, many developing countries still lack adequate public health legislation, or have legislation that is outdated and fails to address the contemporary public health issues of their people. The results of recent researches on public health legal preparedness—a subject which encompasses evaluating current public health laws, amending and supplementing those laws, and training the persons who implement, interpret, and study public health law—indicate that there is a need to carry out concerted public health legal actions in developing and developed countries alike.

Working from the strong belief that law can be a tool for promoting public health, the WHO created the Health Law team in 1948, which in turn initiated the IDHL; the IDHL was intended for all those who were interested in the administrative and legislative aspects of public health. Currently the international landscape is changing dramatically, and appreciation of the IDHL should be rising.

2) Global Health Governance and Legal Approach

Global health governance is defined as “the management of the structural and normative aspects of the determinants and outcomes of global health”⁵. Our world becomes more interconnected every day. However, due to more globalization, economic interdependence, and movement of people and products across the world,⁶ greater interconnection means increased threats to global public health. In terms of the notions of upstream, midstream, and downstream factors, global health studies have been focusing on downstream and midstream factors. Downstream factors are micro-level factors that include the effects of upstream and midstream factors on physiological and biological functioning. Midstream factors are intermediate level factors that include psychosocial factors, including social support and health-related behaviors. Recently, there is a consensus that upstream investments should be directed at the fundamental causes of poor health and inequities. Upstream factors are macro-level factors that include the social structural influences on health and health systems, government policies, and the other social, physical, economic, and environmental factors that determine health. Law is one of the major upstream factors. This means that law can be a strong tool for public health from now on.

In the area of public health law, rights pertaining to infectious diseases are usually categorized as negative rights. For example, isolation and quarantine measures may affect human rights such as the rights to liberty and security of person, autonomy, and privacy. Tensions between individual rights and the interests of the community, such as in the area of public health, should be resolved with reference to pre-established principles and guiding tools. On the other hand, non-communicable diseases (NCDs) such as heart disease, stroke, cancer, chronic respiratory disease, and diabetes are a prominent leading cause of death and disability in the industrialized world. With respect to positive right, public health laws aimed at addressing basic needs and strengthening health systems, accountability, transparency, and enforcement are increasingly needed for achieving the goals of global health governance.

3) International Health Law

Issues of health are increasingly transnational in scope and involve complex legal issues. Protecting the public’s health and improving individual health outcomes requires international innovation and collaboration among legal systems⁷. At the international level, the contemporary global health challenges reveal our inter-dependence and demand collective consensus and action.

National and international health laws should be mutually supportive, and are vital for protecting and promoting health. Furthermore, the importance of health legislation is reflected in many national Constitutions and in the WHO's Constitution. Under Article 63 of the WHO Constitution, each member state is required to promptly communicate to the Organization important health related new laws and regulations that have been published in their state.

The preference for binding instruments reflects the widely held view that non-binding instruments are weak, inferior, and ineffective in stimulating national compliance. Binding instruments are perceived as more credible because hard law is seen as raising the moral, political, and legal stakes of compliance. Furthermore, the fact that treaties need to go through a process of domestic ratification further bolsters the credibility of these binding commitments. Non-binding instruments such as resolutions, declarations, codes of conduct, and guiding principles may be adopted under the auspices of international organizations. Some commentators refer to non-binding instruments as soft law; such instruments are thought of as halfway houses in the legislative process.

4) Domestication of International Health Law

International lawmaking is a strong tool for global governance. Governments, in response to the challenges of interdependence, are increasingly working together through transnational networks external to formal international organizations. However, the sovereignty and equality of states represent the basic constitutional doctrine of the law of nations⁸. With regard to sovereignty and the nature of International Law, compliance with International law is largely voluntary. To a great extent, the responsibility for developing and applying legal rules lies with the individual states themselves. In the international system, there is no supranational authority that can police and enforce the law. In the real world, enforcement is rare in the international system, and in contemporary global health treaties, lawyers emphasize promoting implementation or compliance, although questions remain about enforcement mechanisms.

Due to the need for consent from states, international laws are usually the universal lowest common denominator. There is no international legislature and no standard approach to the creation of international laws, no international executive authority, nor an effective international judiciary. Severe problems in international legislative processes and treaty compliance are exacerbated

by the expense and slowness of the lawmaking process⁹. In addition, there is a capacity shortage for monitoring the public health law situations and legal systems of countries with regard to their conformity with international health law or global consensus regarding health law¹⁰. Thus, an analysis of the public health laws and legal system of various countries can help support the goals of global health governance.

5) Usefulness of Domestic Analysis on Public Health Law

In the expert consultations on public health law, the participants noted that, while the public health laws of different countries are at different levels of development, constraints exist at all levels and several aspects need to be addressed as priority issues. An analysis framework was formulated to help improve countries' utilization of public health law. It addressed the need for routine monitoring of public health law, for feedback to improve the quality of public health law, and for appropriate and coordinated technical support, to be managed by the individual countries themselves, with support from international agencies. While public health laws can be improved through reviewing their impact on health, international society should support the development, use, and prioritization of standard indicators.

Developing a tool for assessing country-level public health law and legislation is a vital step in promoting public health legal preparedness, and ultimately in improving the health and welfare of each country's population. It would assist health officials in understanding both their international commitments and the range of domestic laws, identifying possible gaps in public health and other legislation, and in assessing the comprehensiveness of a country's health law through a series of questions. Through this process, one can expect that recommendations will be developed as to what each country needs to do with regard to public health law.

B) Directions for Monitoring Domestic Public Health Law and Legal System so as to Support Global Health Governance

1) Basic Principles and Timeline of the Regulatory Framework

To establish a possible basis for the development of needed legislation, an inventory of health laws, legislation, and regulation issues as reflected in the resolutions of the World Health Assembly (WHA) and the WPRO Regional Committee Meetings (RCM) was undertaken. A review of the resolutions of the WHA from the 57th to the 65th, and of the resolutions of the RCMs from

the 1st to the 62nd revealed that several health-law-related issues were being discussed on a regular basis, but that very little follow-up had been done in terms of acceptance and application within countries.

Using the subject categories and scope notes, the current status of IDHL adoption by Western Pacific Region country was checked. Among the 37 countries and areas, 15 countries were up-to-date. However, information on nine countries - Brunei Darussalam, Cambodia, French Polynesia, Lao PDR, Malaysia, Mongolia, Nauru, Palau, and Philippines - was not available. The information concerning six other countries, including China, Hong Kong China, Republic of Korea, Marshall Islands, New Zealand, and Vietnam, had not been updated. For seven other countries, including American Samoa, Guam, Macao, New Caledonia, the Pitcairn Islands, and Wallis and Futuna, information was limited due to fact that the local persons in charge of updating it were absent, so that IDHL management was poor.

Based on many publications from Headquarters and from regional offices from 2001 to 2012, the results of the review of the WHO's public health law activities showed that communicable disease preparedness was the issue most frequently discussed by the IHR, and tobacco control was the issue most frequently discussed by the FCTC. In addition, mental health, human rights, the fight against obesity, and food safety were also topics regularly covered in the publications. Only the South-East Asia Regional Office (SEARO) had undertaken a cross-country comparison focusing on specific themes such as tobacco control, and, among some countries in the region, patent legislation. The WPRO, on the other hand, was the only regional office that had focused on general law issues. However, it must be concluded that, in the final analysis, no broad cross-country comparison on domestic public health law and legal systems was included in the publications.

Through the analysis of the history of the WHO's legal activities, basic lessons emerged for the further development of countries' regulatory frameworks. First, there is a need to establish appropriate monitoring mechanisms. Many of the WHA and RCM's resolutions mention health law issues, but due to either unclear phrasing or lack of monitoring, their recommendations have not been implemented. Second, regulation is a function of governance which, according to the WHO, is one of the six building blocks for health systems strengthening. So, when regulatory frameworks are being developed, governance issues need to be addressed concurrently. Leaving it broad and vague as in the IDHL, should be avoided, and hence this project is developing a comparative law

web site that will assist the development of the domestic public health law framework.

In Stage I, a consensus, regarding the goals and the various steps of the assessment/analysis process, was reached. The basic draft of the tool was created, as well as guidelines on the building of teams and selection of responsible officers and/or professionals in the selected countries. In Stage II, the tool was further tested in an additional country, and team building and selection of responsible officers and/or professionals in the selected countries was again reviewed. In the future, the tool will be further developed to reflect specific in-country situations or existing legal assessments. Stage III will focus on developing additional agendas or models containing specific analysis tools for specific legal areas, creating a comparative international law website, and disseminating the approach to other regions of the world.

2) Suggestions Regarding Further Development of the Assessment Tool

During the initial review of the assessment tool and its use in the field, it was found that there was considerable overlap between the different modules; thus, further development of the tool along the lines of so-called “Levels” is required. Level 1 is based on the IDHL. However, the categorization of the themes does not reflect current global health trends, and the monitoring and updating system is poorly developed. However, the IDHL is now the only tool available that covers most health issues from a public health law perspective. Thus, embracing the width and breadth of the headings of the IDHL, which could be made more complete, but would then perhaps be less accessible to those without legal backgrounds, is perhaps inevitable. Because the current Modules 2 to 4 are fairly specific, and differ from the IDHL in their categorization of the issues, detailed health system issues, IHR issues, and FCTC issues can be categorized as Level 2 issues. The criteria for designating them as Level 2 issues include: (1) they fall into larger categories in the IDHL; (2) to provide more detailed assessments, there is a need for the development of legal instruments or legal improvements by experts or specialists in these specific areas; and (3) they are elements of an emerging and/or important immediate agenda as assessed by local legal experts or local researchers. Level 3 issues, according to the assessment tool, are those arising from emerging agendas, but which, as yet, have no real legal implications, or those limited to specific agendas within the IDHL framework, such as that of antimicrobial resistance, the marketing of food for children, or abortion. In summary, it is recommended that the assessment tool be changed to incorporate the concept

of levels (1–3).

3) Suggestions on Making the Results of the Assessment Visible

Once the data collected using the assessment tool have been compiled and analyzed, there is a need to make the results more comprehensible and visible. Several possible methods for accomplishing this goal are proposed below. First, the development of a comparison table that highlights the scores by using different colors; for example, the health MDG scorecard for low- and middle-income countries (LMICs) highlights some of the key MDG indicators. For the eleven LMIC countries, the health-related MDG indicators can be illustrated using specific numerical values and color codes, such as green for “on track,” orange for “insufficient progress,” and red for “off track.” Alternatively, a chart could be developed that lists/ranks all the countries with regard to a specific subject, as in “The World Abortion Policies 2011” wall chart developed by the United Nations. The wall chart also includes estimates of the countries’ abortion rates, fertility rates, maternal mortality ratios, levels of contraceptive use, and estimates of regional rates of unsafe abortions. Using a wall chart, one can clearly illustrate the public health law situations of all countries. A third possible method is to develop a “Snapshot” chart giving a quick overview of selected laws in each country. An example is provided below: “Making the Law Work for the HIV Response.”

4) Suggestion Regarding Establishing a Public Health Law Network

A third possible method for expanding the analysis framework is to establish a Regional Health Law Forum (HLF) consisting of health law experts and specialists, local researchers, policymakers, lawmakers and government officials. As the Technical Advisory Group (TAG) mechanism currently operates, the objectives of the HLF meetings are to review progress, identify obstacles, and recommend key actions needed for (1) establishing leadership and governance standards for public health law; (2) identifying priority areas for strengthening regulatory capacity in the region; (3) reviewing progress, discussing plans, specifying critical issues, and proposing ways to accelerate the introduction of essential public health law components within domestic law frameworks; and (4) providing partners with the opportunity to be updated on progress, challenges, priority activities, and funding requirements and gaps.

Another method for developing networks is to establish a parliamentary committee of health lawmakers led by the WHO Regional Office. In SEARO,

the Regional Conference of Parliamentarians holds annual meetings since 1996. The third possibility is to make use of the annual Regional Committee Meeting (RCM), to allow high-level government officers of the region's Ministries of Health to present their situations and share their experiences. By holding a public health law session or side meeting in the RCM, sharing information on national legislation and reports on progress in regulation development can be enabled. In order to support their efforts to upgrade their health law capacity, countries with similar legal systems could also be grouped together in side meetings, or seminars, organized to focus on their legal development status, health law capacity, or specific health agendas.

5) Suggestions Creating Websites and Databases on Public Health Law

The fourth model, or product, that can be developed based on the results of the use of the assessment tool and analysis framework is the establishment of a common website. First, websites are useful in developing links to related issues and organizations. Many developed countries have their own English-language law websites. For example, Australia, Japan, and the Republic of Korea have their own databases and public websites. However, when documents are published on the Internet, or can be downloaded from databases, their legal status needs to be clarified. In the Western Pacific Region, there are some existing sub-regional databases and information sites, such as the "PacLII Databases," which cover 22 pacific island countries and areas. "Wash Law" has also been established for legal research on the web. It consists of different sections, including: (1) the Pacific Islands Legal Information Institute, (2) the Pacific Islands Law Collection, (3) the World Legal Information Institute, and (4) updates to various laws.

Second, websites and databases can be created containing actual statutes, the results of analyses, information on seminars and meetings, and discussion groups debating the latest information. For example, the European Public Health Law Network was established in 2007 as part of the European Union's co-funded Public Health Law Flu project. Along similar lines, a Western Pacific Public Health Law Network (WPPHLN) website could be developed. The aim of the WPPHLN would be to develop and coordinate a sustainable network of Western Pacific professionals and stakeholders for whose work public health law has relevance. The target audience would be public health professionals, researchers, lawyers, policymakers, and service delivery professionals. It would offer information on: (1) the goals and vision of the WPPHLN, (2) law database(s), (3) the results of comparison analyses, (4) research and articles

accessible to members, and (5) workshops and events, as well as providing (6) a forum and discussion room.

V. KEY FINDINGS AND CONCLUSIONS

The objective of this study was to demonstrate the importance of monitoring domestic public health laws and legal systems in supporting global health governance, through the development of an analysis framework and tool for assessing public health law in the Western Pacific Regional countries. The results demonstrated the usefulness of an assessment framework for analyzing the public health law and legal systems of different countries in support of global health governance.

To prepare for presenting the fundamental basis and demonstrating the usefulness of the analysis framework as a global health governance tool for analyzing public health law and legal systems in different countries, we attended expert consultation meetings and academic workshops and conducted a literature review on global health governance and public health law. Through the support of the regional office of the WHO, it was possible to hold expert consultation meetings on public health law in this region that helped us develop the analysis framework. The WPRO has conducted many health-law-related activities over the last few decades, so profiles of regional health law experts were available. Having highly experienced health law experts involved proved useful in the development and subsequent discussions of the analysis framework. However, there may have been a selection bias. In addition, the expert group was composed of health law experts, and may have excluded experts on global health governance. Due to time and financial constraints, the 1st and 2nd expert consultations were limited in length to one day each. This was found to be an insufficient amount of time for discussing all of the relevant issues. In terms of the literature review, the researcher tried to collect as many materials as possible, but some important materials may have been missed. Only a few WPRO technical staff members were interviewed. Were the interviews conducted before the first expert meeting, more information could have been collected to help in the development of the assessment tool and its content.

In order to be able to suggest future directions and models for assessing domestic public health law and legal systems supporting global health governance, earlier health legislation activities and similar analyses aimed to identify the strengths and weaknesses of the proposed analysis framework, were reviewed. In the two expert meetings, there was not enough discussion of

future directions and model development. The results of this study demonstrated that public health law allows for legal and administrative systems that can support social conditions that enable people to live healthy lives. However, questions can be raised about the effectiveness of public health law, such as whether legal approaches or non-legal approaches are more effective. Under the current global architecture, in order to understand strategies for supporting governance that supports the improvement of people's health, the WHO/WPRO may require a more interdisciplinary approach to addressing health law issues within countries and monitoring public health law and legal systems in these countries.

The question was raised as to whether such health law assessments can be helpful for changing or improving public health in the real world, and whether such assessments are needed when a country is implementing its health sector program or policies well. Where possible, countries should still be encouraged to enact the kind of legislation required for providing a better legal basis for public health programs. Given that other global surveys have been conducted, this analytical framework could be redundant. However, the current existing global surveys are fragmented by issue. There is no overall monitoring system for the whole spectrum of public health law and legal systems in different countries.

Finally, the vision for future monitoring of domestic public health law and legal systems for supporting global health governance proposed in this study includes: (1) further development of the tool for assessing health law, (2) the creation of websites and databases of public health laws to enable sharing of experiences, and (3) the establishment of networks to further enhance analyses and establishment of domestic public health law based on international health laws. If an inventory of all relevant laws, orders, and regulations relating to health (including this with health-related implications) is compiled, it could serve as a useful resource for many countries to consult. Similarly, compiling and reviewing lists of domestic health laws in line with the international health laws is useful both for domestic monitoring as well as for contributing to global health governance.

There is a need for follow-up research. First, building the capacities of local researchers and/or other people that deal with domestic public health law should be covered in future studies. Second, the current modules need to be improved. Finally, considering current realities, studies should investigate how health can be improved through direct monitoring of public health law and how legal systems can be used to improve health law capacity or coverage.

In conclusion, the usefulness of the analysis framework as a global health governance tool for analyzing public health law and legal systems in different countries was demonstrated in this study. In the crowded landscape of global health governance today, the role of the WHO as an intergovernmental organization is to help protect the public's health and improve individual health outcomes through the promotion of appropriate legal systems. Several models were proposed to embed the development of regulatory frameworks in domestic and international health agendas, through refinement of the tool's questionnaires, color-coding of its results, applying different presentation methods, developing model legislation lists, and creating commonly accessible websites and public health law support/discussion groups. Through the development of an analytical framework for assessing the domestic public health law situation in the Western Pacific Regional countries, the importance of monitoring domestic public health law and legal systems for supporting global health governance was demonstrated.

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