Importance of Monitoring Domestic Public Health Law and Legal System Supporting Global Health Governance:

Development of an Analytical Framework to Assess the Domestic Public Health Law Situation in Western Pacific Region Countries

Yuri Lee

The Graduate School
Yonsei University
Department of Public Health

Importance of Monitoring Domestic Public Health Law and Legal System Supporting Global Health Governance:

Development of an Analytical Framework to Assess the Domestic Public Health Law Situation in Western Pacific Region Countries

A Dissertation
Submitted to the Department of Public Health and the Graduate School of Yonsei University in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Public Health

Yuri Lee

December 2012

This certifies that the dissertation of Yuri Lee is approved.

	[signature]
	Thesis Supervisor: [Myongsei Sohn]
	[signature]
•	Thesis Committee Member #1
	[signature]
	Thesis Committee Member #2
	[signature]
	Thesis Committee Member #3
	[signature]
	Thesis Committee Member #4
	[signature]
	Thesis Committee Member #5

The Graduate School

Yonsei University

December 2012

Contents

	1
1. Background	3
2. Objectives	7
3. Methods	8
3.1. Holding Experts Meetings	10
3.1.1. The 1 st Expert Consultation on Public Health Law	10
3.1.2. The 2 nd Expert Consultation on Public Health Law	11
3.2. Using the Tool to Undertake In-Country Assessment	12
3.2.1. Conducting Pilot Test for Four countries	12
3.2.2. Conducting the Implementation Test for One country .	13
3.3. Collecting Extensive Opinions from Experts	14
3.3.1. Attending International Academic Conferences	14
3.3.2. Gathering Opinions from Academic Public Health Exp	erts15
3.3.3. Interviewing WHO Technical Staff	16
3.4. Desk Review	17
3.4.1. Conducting Literature Review	17
3.4.2. Reviewing the History of WHO's Health Legis	slation related
Activities	17
	19

4.1. Reasoning the usefulness of the framework as a tool of Global l	Health
Governance	20
4.1.1. Public Health Law	20
4.1.2. Importance of Global Health Governance	24
4.1.3. Global Health Architecture and Role of WHO	26
4.1.4. International Health Law	28
4.1.5. Domestication of International Health Law	30
4.1.6. Global Regulatory Frameworks including WHO	31
4.1.7. Usefulness of In-country Analysis on Legal System	32
4.2. Ways for Improving Application of the Framework	35
4.2.1. Country Assessment Results	35
4.2.1.1. Public Health Law in the Republic of Korea	35
4.2.1.2. Public Health Law in Philippines	38
4.2.1.3. Public Health Law in Samoa	40
4.2.1.4. Public Health Law in Vanuatu	43
4.2.1.5. Public Health Law in the Kingdom of Cambodia	44
4.2.2. Pilot Test Results: Appropriateness of the Tool and Potential for U	Jse 49
4.2.2.1. Appropriateness of the Tool	49
4.2.2.2. Suggestions for Improving the Tool	50
4.2.2.3. Possible Use of the Tool	51
4.2.2.4. Suggestions for Establishing the Assessment Process	51
4.2.3. Implementing Test Results: Developing the Assessment Process mode	el53
4.2.4. Identified Challenges through Analysis process and suggesting	ng for
future assessment	55
4.2.4.1. Importance of Getting Concurrence from Government	55
4.2.4.2. Quality Control of Local Researcher	56
4.2.4.3. Role of the Academic Institution and Local Researcher	58
4.2.4.4. Standardizing the Reporting Form and Result Template	58
4.2.4.5. Importance of Gathering Human Resources Information	59

4.2.4.6. Importance of Gathering Country Background60
4.2.4.7. Receiving Feedback for Tool Itself and Assessment Process61
4.2.5. Comparative Analysis Results: Focusing on Existence of Law61
4.2.5.1. Health Law Coverage in the Republic of Korea67
4.2.5.2. Health Law Coverage in Philippines69
4.2.5.3. Health Law Coverage in Samoa71
4.2.5.4. Health Law Coverage in Vanuatu76
4.2.5.5. Health Law Coverage in the Kingdom of Cambodia79
4.2.6. Comparative Analysis Results: Focusing on Type of Law83
4.2.7. Assessing the Results, Providing the Final Analysis: Points for
Attention91
4.3. Model for Monitoring Domestic Public Health Law and Legal System
Supporting Global Health Governance
4.3.1. Analytical Results on WHO Historical Legal Activities93
4.3.2. Basic Principal and Timeline of the WHO Regulatory Framework 96
4.3.3. Model 1 – Analysis Tool development97
4.3.4. Model 2 – Making the results of the assessment visible100
4.3.5. Model 3 – Establishment of public health law networking104
4.3.6. Model 4 – Creation of website and data base106
4.3.7. Model 5 – Enactment of model law and domestication of international
health law
5. Discussion
6. Conclusion
References

Tables

Table 1. Profiling the Health Laws in the Republic of Korea37			
Table 2. Nomenclature Designation used for Laws in the Philippines38			
Table 3. Profiling the Health Laws in Philippines			
Table 4. Profiling the Health Laws in Samoa41			
Table 5. Profiling the Health Laws in Vanuatu			
Table 6. Legal Hierarchy in the Kingdom of Cambodia44			
Table 7. Profiling the Health Laws in the Kingdom of Cambodia46			
Table 8. Comparative Analysis Result – Yes/No Box			
Table 9. Law Typology84			
Table 10. Comparative Law Analysis Result of Module 1			
Table 11. Comparative Law Analysis Result of Module 2			
Table 12. Comparative Law Analysis Result of Module 3			
Table 13. Comparative Law Analysis Result of Module 490			
Table 14. Timeline of the Development for Public Health Law Framework97			
Figures			
Figure 1. Flow Chart of the Study Design9			
Figure 2: Flow Chart for the Team Process in Cambodia Implementing Test $.53$			
Figure 3. Timeline of the Development for Public Health Law Framework 96 $$			
Figure 4. Developing the 'Level' Concept for the Assessment Tool98			
Figure 5. Health MDGs scorecard for LMICs in the Western Pacific Region 101			
Figure 6. World Abortion Policies 2011			
Figure 7. Making the Law Work for the HIV Response			
Figure 8. Website Structure of the European Public Health Law Network 108			

Annexes

Annex 1. Tool to Assess Health Law	127
Annex 2. Result Report Form: Excel Version	141
Annex 3. Final Report Template	142

Abstract

The World Health Organization (WHO) Western Pacific Regional Office (WPRO) initiated a Public Health Law project in 2010, trying to develop a tool for monitoring the public health law situation in the WPRO countries. The project conducted pilot tests in four WPRO countries to check the appropriateness of a Public Health Analysis tool. Now, they are preparing to extend the assessment to new countries based on previous experience and learning. However issues have been raised about this 'Analysis Tool to Assess Public Health Law' which is comprised of four modules with a total of 90 questions, including its usefulness and future use, which still need to be answered. So, the aims of this study are 1) to present for an argument and demonstrate the usefulness of analyzing public health law and legal systems in countries as a tool of global health governance, 2) to identify the methods for the improvement of the application of an analysis framework including the academic value for public health law, and 3) to further enhance the future use of the framework for measuring domestic public health law and legal systems supporting global health governance.

Literature review was undertaken on global health governance and public health law. At the same time international forums and conferences were attended to update academic perspectives on the same topic. Expert consultations were held on public health law in the Western Pacific Region to formulate the initial analysis framework and tool, which was subsequently pilot tested in four countries: Republic of Korea, Philippines, Vanuatu and Samoa. After a further revision, Kingdom of Cambodia was included too as a country implementing pilot test to establish the whole assessment process and its implications. In addition further meetings were held with technical staff in WHO/WPRO to review the applicability of the framework and analysis tool. To form the foundation of this thesis and the further design of a model for incounty monitoring for public health law supporting global governance, historical

health legislation related activities were analyzed, as well as similar cases reviewed to understand the model's strengths and weaknesses.

As infrastructure and intervention, Public health law provides a legal and administrative means that assures social conditions in which people can live healthy life. Monitoring public health law and legal systems in countries as one tool to understand governance that supports the improvement of people's health is a major strategy for WHO/WPRO. The appropriateness and usefulness of the analysis framework and its assessment tool for public health law were confirmed through applying it in selected countries in the Western Pacific Region. The pilot tests confirmed that special consideration should be given to its implementation process, such as getting concurrence from government and qualification of the local researchers as well as to the analysis of the assessment, such as quality control, analysis methods and implication of such to describe the local public health law and regulatory situation in a country. Lastly, the future vision for monitoring domestic public health law and legal systems supporting global health governance was proposed that includes 1) further development of the tool to assess health law, 2) creation of website and database of public health laws, 3) the establishment of networking to further enhance the analysis and establishment of domestic public health law on the basis of international health laws.

Developing an assessment framework to analyze public health law and legal systems in countries as a tool for global health governance was demonstrated and proved useful. Secondly the tool added academic value by its applicability in different countries resulting in significant data collection and the ability to provide an overview of the public health law situation in selected WPRO countries.

Key words: Global Health Governance, Public Health Law, Legal System, Western Pacific Region, World Health Organization (WHO)

1. Background

Public health law is a vital social legal mechanism that ensures the condition for people to be healthy. Amending and supplementing public health laws to better fulfill such role starts from evaluation of the current status of public health law and legislation.

From 2010, the WHO Regional Office has been developing a framework on public health law that Member States could use to analyze their own health regulatory and/or legal status. An expert consultation was convened from 5 to 6 May 2011 in Manila, Philippines in order to solicit external technical assistance in public health law and discuss the current situation of public health law in WPRO countries and to advise and agree on the objectives and methods of the development of a legal assessment framework. (WHO/WPRO 1st Expert Consultation Meeting Report, 2011) After the 1st expert consultation, a group of experts developed an analyzing tool to be used for country assessment of public health law of the member states.

The 1st draft of the tool for assessing country-level public health law in the Western Pacific Region was developed to assess whether member states embrace, adopt, or adapt global health policies as promulgated by WHO. For 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 (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 International Digest on Health Legislation (IDHL) was also consulted.

Given the broad definition of public health and the law that affect the health, directly or indirectly, the participants further agreed to narrow the field to four areas based on significant WHO work (Kim SY et al., 2012). This "Analysis Tool to Assess Public Health Law" comprises of 4 independent

modules: (1) International Digest on Health Legislation (IDHL); (2) Health systems based on the value of Primary Health Care (PHC) Values; (3) International Health Regulations (IHL) 2005; and (4) Framework Convention on Tobacco Control (FCTC).

Module 1 covers the IDHL for gaining a comprehensive look at the country's public health legislation. Each question addresses a specific subject heading or sub-category in the IDHL and follows the order of the IDHL. Module 2 covers PHC for determining the extent of a country's legislative framework toward achieving the principles of PHC, specifically the questions related to the 6 building blocks as identified by the WHO as being essential toward strengthening health systems. Module 3 covers the IHR for determining the extent of a country's compliance toward its international responsibilities in public health. The questions address the provisions of the IHR, particularly those provisions relating to law. Finally, Module 4 covers the FCTC for determining the extent of a country's compliance toward its international responsibilities in tobacco control. The questions address the provisions of the FCTC, particularly those provisions relating to law. (Kim SY et al., 2012)

The tool follows a questionnaire format that asks country respondents, be it government officials and/or academics with legal competency, to determine whether primary and/or subsidiary legislation exists in the country on a specific topic and, if so, to cite the relevant law, describe the pertinent points, and attach and/or link to the full text where available. (see Annex 1)

Meanwhile, there is distinction between the analysis framework and the assessment tool. The tool is only a small part of the analysis framework. What this thesis is covering is to describe the analysis of domestic public health law. Primary data with the tool as well a secondary data from other sources, for example, a description of the legal framework in the country or the human resources for health law in a country have been collected. The last two are not explicitly collected in the tool but are reflected in the final country report as written up by the experts, i.e. so become part of the bigger analysis framework.

This new analytical framework 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, proposed timetable of work, terms of reference, issues, references to the six building blocks of the WHO health systems framework and the subject headings of the IDHL, methodology, indicators and information sources. After the analysis tool was drafted, it was circulated to consultation participants and feedback collected. It was revised accordingly, before its first implementation

The pilot surveys were conducted in selected countries including the Republic of Korea, Philippines, Samoa and Vanuatu by respective experts interviewing either formally government officials or informally through WHO country office consultations. Pilot survey responses were collected from the country teams and compared to baseline reviews gathered by parallel literature reviews. (WHO/WPRO 2nd Expert Consultation Meeting Report, 2011) The pilot responses were checked for availability, verification of accuracy, timeliness and amendments, and pilot survey country teams also submitted feedback about their experiences using the tool.

Another in-country analysis was conducted in the Kingdom of Cambodia called the implementation test for checking the whole process of assessment and finding possible tool implications that could possibly hamper or support the implementation of the tool. At this moment, another five counties including Mongolia, Papua New Guinea, Malaysia, the Solomon Islands, and Lao PDR have expressed interest to undertake such a public health law; this will be initiated in 2013.

However, throughout the pilot phase the necessity and usefulness of the tool have been tested, including what has to happen as a result of the public health law status review in a country. Main questions this project has been facing were 1) the question of effectiveness of law on public health, for example which methods are more effective between legal approaches versus non-legal approaches, 2) the status of International Health Law in global health

governance differentiating and respecting national sovereign versus implementing international law, 3) ability for external organizations to undertake such legal monitoring, 4) whether such health law assessments can be helpful for changing or improving the real world in public health areas? 5) whether using an unified tool can be used under varied historical and cultural background in countries, 6) whether this is a need for an assessment especially when a country is well implementing its health sector program or policies, and 7) whether there is a future for such an assessment tool.

So, this dissertation aims to find the answers to the above questions by describing the development and process of the analysis framework to conduct in-country analysis of public health law and legal systems.

2. Objectives

The aims of this study are

- to present the fundamental basis and demonstrate the usefulness of an analysis framework for public health law and legal system in countries as a tool of global health governance,
- 2) to identify challenges faced during the demonstration tests and finding methods to improve the application of the analysis framework including the academic value for public health law (in the short term), and
- 3) to suggest future direction and model for measuring domestic public health law and legal systems supporting global health governance (in the long term).

3. Methods

For each of the objectives above different study methodologies were applied.

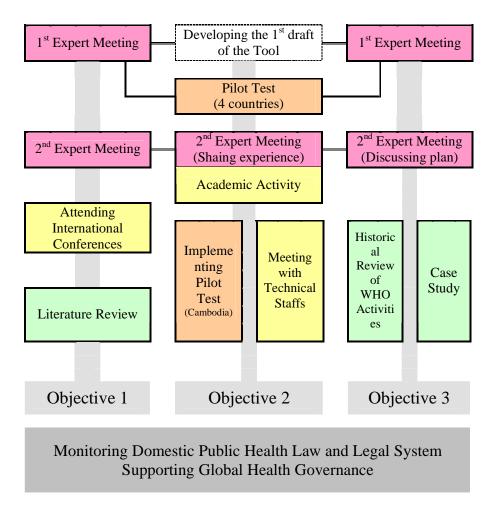
To present the fundamental basis and demonstrate the usefulness of an analysis framework for public health law and legal system in countries as a tool of global health governance, experts consultation meetings were held, academic workshops attended and literature review on global health governance and public health law undertaken.

To identify challenges faced during the demonstration tests and finding methods to improve the application of the analysis framework including academic value for public health law, pilot tests were conducted in four countries, a second expert meeting was held to discuss pilot results, a further implementation pilot test was done in Cambodia, and meetings were held with technical and academic staff.

To suggest future direction and model for measuring domestic public health law and legal systems supporting global health governance, historical health legislation activities and similar analyses were reviewed, to identify strengths and weakness of the proposed analysis framework.

Figure 1 shows the study design with different methodologies for undertaking this study. Contents of the chapter 3.1. holding experts meetings are colored in pink, 3.2. applying tool to in-country assessment are colored in orange, 3.3. collecting extensive opinions from exerts are colored in yellow, and 3.4. desk review are colored in green. Developing the 1st version of the tool which is in box dotted line is the basis for this study. (see Figure 1)

Figure 1: Flow Chart of the Study Design



3.1. Holding Expert Meetings

3.1.1. The 1st Expert Consultation on Public Health Law

An Expert Consultation on Public Health Law was held at the World Health Organization Regional Office for the Western Pacific in Manila, Philippines from 5 to 6 May 2011. The meeting was attended by seven temporary advisers and six WHO staffs. The expert panel was invited to the meeting to advise and agree on the objectives and methods of the development of the framework. The objectives of the meeting were to develop a framework for the legal analysis tool, and to identify the next steps to interact with partners and countries that would like to use the tool.

The expert panel were expected to agree on the goal and objectives of the framework and its development. Once the goal and objective were clearly identified, discussions of whether it is feasible to meet the agreed goal and objectives were made. Specifically, the panel discussed 1) what is the framework for analyzing public health laws and regulations in country, 2) what are the visions, goals and objectives of the framework, for example is it to assist countries in assessing the quality of existing public health law and legislation, and to allow cross country comparisons and contrast, and 3) what are the core values and the key policies of WHO that need to be incorporated into the preparations of the framework.

The experts also discussed and deliberated on best possible method for developing the analysis framework. The discussion points were 1) what are the methods of developing the framework, qualitative or quantitative methods, key informant interview or questionnaires, 2) what are the steps in implementing the framework, and 3) what is the basic format of the framework especially how a key instrument such as the International Digest of Health Legislation (IDHL) need to WHO key policies to be adopted by countries.

In another session, the experts discussed the specific details of framework development, implementation and management. Specifically 1) determining and assigning of country focal points or advisors, 2) who will be the respondents of the survey: should they be public health experts, public officials, WHO country office staff, or from the academia, 3) how would the survey team be build and what are the inclusion criteria and how should the team be trained and managed, 4) how should the questions be formulated: should they be open or closed or categorized into common and specific questions, 5) how should the data be collected: for example, will they be required to answer the questions only, or also attach references, 6) will the data be confidential or open to public, and 7) who will be in charge of managing the data. (WHO/WPRO 1st Expert Consultation Meeting Report, 2011)

The outcome of the first expert consultation was a legal analysis tool to assess the situation of public health law in countries. After that, a pilot test of the tool was conducted in four countries including the Republic of Korea, Philippines, Samoa, and Vanuatu. It was further proposed that four experts present at the meeting undertake the pilot test of the 1st draft tool. The consultants were chosen on criteria of knowledge about the public health law sector in the Western Pacific Region.

3.1.2. The 2nd Expert Consultation on Public Health Law

A Second Expert Consultation on Public Health Law was held in Seoul, Republic of Korea in October 2011. The meeting was organized as a follow-up to the first expert consultation. The meeting brought together eight legal advisers from five countries to interact with WHO staff.

The second expert consultation was designed to share the preliminary results and experiences in conducting the pilot test and to encourage feedback and suggestions for further development of the tool and methodology before it be launched in other countries. The specific objectives of the meeting were 1) to

present the results of the pilot test of the analysis tool and evaluate the findings, 2) to gather comments on the difficulties experienced in using the tool so that it can be further enhanced for use throughout the region, 3) to prepare for the symposium session on public health law in the 43rd Asia-Pacific Academic Consortium for Public Health Conference and 4) to agree on the way forward. The discussions covered the goal and purpose of the analysis tool, results of the pilot test and difficulties in carrying out the test, defining responsible personnel for future use, structure and contents of the tool and other operational issues. (WHO/WPRO 2nd Expert Consultation Meeting Report, 2011)

3.2. Using the Tool to Undertake In-Country Assessment

3.2.1. Conducting Pilot Test for Four Countries

The analysis tool was tested in four countries namely, the Republic of Korea, Philippines, Samoa and in Vanuatu. An Agreement of Performance Work contract was given to four experts to conduct the field test. They lead the pilot test in their country by conducting key informant interviews, meeting people with superior knowledge of public health law in their country such as senior government officials, professional associations, and academia or training institutions. The intent was to gather in-depth information about the public health law situation in countries and improve the analysis tool in preparation for its launching to other countries.

It was agreed by the experts during the first expert consultation that people will experience in public health law in their country and their participation during the first consultation will conduct the pilot tests. Each expert was gathering the information about public health law of each country such as list the law name, year, and sections and attaching the pertinent section of the law either electronically or in hard copy and both in the original language and the official English translation if available. Through some meetings with interested persons in each country, the accuracy of the information collected,

was checked assess effectiveness and utility of the tool, and assessed difficulties identified in applying the tool. After that, the experts prepared the summary of the findings.

The final reports of the pilot test included the lists and contents of the different public health laws including 1) introduction, 2) process of the pilot test (time required, participants, response of questions, assessment of contents, evaluation of tool, discussion), 3) result of the pilot test (list the law by name, year and section, final evaluation of the each countries situation on Public Health Law, suitability or appropriateness of the tool), 4) suggestions (difficulties using the tool and how it can be improved, how the analysis tool can be used) and 5) appendix (interview list with contact details, current law).

3.2.2. Conducting the Implementation Test for One Country

The purpose of the implementation test was to apply the tool in Cambodia to develop the model for conducting the whole process of the assessment using a local researcher/expert. Activities were 1) conducting desk review to find laws regulation and initial analysis of the contents, 2) organizing and undertaking country visit to country and collecting data and document on public health law using the analysis tool, and 3) making a synthesis of public health information on the country and reviewing the overall process and lessons learned on the implementation of the tool, to improve it further in the future

The process required the participation of a local researcher. This local researcher should have strong background in public health legislation. Although legal training was not essential the local researcher should be familiar with the country's laws in general such as constitutional or civil or criminal codes that related to public health. Activities of the local researcher were 1) to complete the tool in draft and identify parts requiring further discussion with other legal experts, 2) to conduct a desk review to compile list of relevant legislation and obtaining legislation in all forms available, 3) to interview other legal experts with superior knowledge of local public health law, and 4) to meet with experts

to review issues discussed during interviews with other legal experts and about the application and completion of the tool in-country.

3.3. Collecting Extensive Opinions from Experts

3.3.1. Attending International Academic Conferences

Three conferences relating to global health governance and public health law were attended to understand international trends.

First, the 'Globalizing Asia: Health Law, Governance, and Policy, Issues, Approaches and Gaps' conference was held from 16 to 18 April 2012, in Bangkok, Thailand. It was hosted by Thammasat University and co-sponsors were International Development Law Organization (IDLO), World Health Organization (WHO), Rockefeller Foundation, and others. This conference was 1) focusing on the impact of globalization on the health, laws, governance, and policies on the nations of Asia, 2) trying to discuss moving toward a unified system of global health laws and governance, 3) seeking an urgent need for capacity building in international health law, governance, and policy. Speakers and participants came from the private and public sectors in law, governance, and policy across Asia and were experts in global health, international law and public health law, health governance, and health policy. Representatives from Australia, Bangladesh, Bhutan, China, India, Indonesia, Italy, Myanmar, Nepal, Sri Lanka, Timon-Leste, Thailand, and Vietnam were participated.

Second, the '2012 National Health Law Conference: Global Health Challenges and the Role of Law' conference was held 4 to 5 May 2012 in Toronto, Canada. It was hosted by the faculty of Law in the University of Toronto. The conference was 1) bringing together leading scholars, policy-makers, practicing lawyers and health care professionals, 2) exploring how law can address global health challenges and making real progressive change, 3) exploring to meet challenges through law and litigation such as human rights

litigation, 4) reviewing the context and circumstances where law and litigation can really make a positive difference, 5) observing where is law simply used by vested interests to further inequities, and 6) exploring access to care and essential medicines on the part of the most vulnerable including poor, mentally ill, and aboriginal populations, the rise and inequitable impact of medical tourism, the spread of chronic diseases around the world, exponential increases in smoking in countries, the obesity epidemic and so forth.

Third, a summer program on 'Global Health Law and Governance at Georgetown Law' was held from 18 to 22 June 2012 in Washington DC, United States. It was hosted by Georgetown University, O'Neill Institute for National and Global Health Law. This program focused on 1) providing students with a solid foundation in global health law and governance, 2) considering issues and themes central to this emerging filed in order to equip tomorrow's leaders in global health, 3) bringing together practitioners, policymakers, advocates and leading academics in global health to learn the foundation of global health law and governance over five days period, 4) exploring why global health and global health law are emerging as central issues of multilateral concern, why existing global governance systems are frequently ineffective, and the strengths and limitations of international law as a tool for improving the health of the world's population, especially the poorest and most vulnerable, and 5) providing an excellent opportunity for professional development and networking in an interdisciplinary setting.

3.3.2. Gathering Opinions from Academic Public Health Experts

The 43rd Asia Pacific Academic Consortium for Public Health (APACPH) was held from 19–22 October 2011, Seoul, Korea. APACPH is an international non-profit organization, consisting of the largest and most influential schools of Public Health in the Asia-Pacific region and dedicated in improving professional education for public health. Through its activities, APACPH has contributed greatly in promoting public health law policies and

enhancing both the capacity and sustainability of public health systems around the world. The discussion on the 43rd APACPH Conference was mainly focus on "Public Health Law" in the areas of establishment of public health law system in underdeveloped Asian countries and international cooperative system to improve public health standards in the Asia-Pacific region.

A pre-meeting was held on 18 October 2011 as one the of the APACPH meeting symposia. to conduct the 2nd Public Health Law Meeting, taking advantage of the presence of other public health law experts attending the APACPH; see description in 3.1.2

The next APACPH meeting was held 15 to 17 October 2012 in Colombo Sri Lanka hosted by the faculty of medicine, University of Colombo, Sri Lanka. The organizing committee of the conference invited to make a presentation on 'Results of the Pilot test in Republic of Korea, Philippines, Vanuatu, Samoa, and Kingdom of Cambodia' at the symposium on "Law, Ethics and Human Right". In this session, related issues including the 'Overall the Analysis Tool of International Public Health Law and Its Current Development Status', 'Current Results of Certain Countries in the Analysis Tool of International Public Health Law Project focusing Cambodia case' were presented followed by an open discussion from the floor.

3.3.3. Interviewing WHO Technical Staff

Interviewing appropriate field experts including WHO technical staff was undertaken to introduce the tool, and getting ideas for the assessment tool's application. The purposes of the interviews were 1) to gather data of existing international instruments and current legal activities and existing laws relating to specific agendas for health from the expert, 2) to get information on the need to establish public health policies and legal systems in countries in Western Pacific Region, and 3) to obtain experts' suggestion to revise the modules and to integrate its results into WHO/WPRO activities.

Interview points were 1) important public health law areas in specific technical areas, 2) existing international instruments or global surveys which include legal questionnaires, 3) current legal system or legislative statutes in the regional countries, 4) gaps among WHA and RCM resolutions, existing international instrument, and current legislative status in countries, 5) gaps of relevant questions of the modules and suggestions to upgrade or change the module, 6) current needs of legal support in WHO/WPRO, and 7) advocating for integrating assessment results into specific technical areas.

3.4. Desk Review

3.4.1. Conducting Literature Review

To present the fundamental basis and demonstrate the usefulness of an analysis framework for public health law and legal system in countries as a tool of global health governance literature review on global health governance and public health law was undertaken. A comprehensive reference review was undertaken of textbooks, articles, WHO publications, and meeting materials from intern-governmental organizations was done by searching the internet (e.g. pub-med), the library in WHO/WPRO, databases in WHO, the library in Yonsei University, and National Assembly Library.

3.4.2. Reviewing the History of WHO's Health Legislation related Activities

WHO's historical activities with regards to public health law were reviewed using World Health Assembly Resolutions, Regional Committee Meeting Resolutions, and International Digest of Health Legislation and other publications published by WHO. This included detailed reviewing of public health law activities in WHO, and many publications from Headquarters, and regional offices from 2001 to 2012.

Four publications from Headquarters were reviewed: 1) International Health Regulation (2005): A brief Introduction to Implementation in National Legislation, 2009, 2) International Health Regulation (2005): Toolkit for implementation in National Legislation, The National IHR Focal Point, 2009, 3) International Digest of Health Legislation (IDHL), and 4) WHO Resource Book on Mental Health, Human Rights and Legislation, 2005, as well as four publications from the Western Pacific Regional Office including 1) Using Domestic Law in the Fight Against Obesity: An Introductory Guide for the Pacific, 2003, 2) Enhancing Health Policy Development: A Practical Guide to Understand the Legislative Process, 2004, 3) Enforcement of Public Health Legislation, 2006, and 4) Public Health Law in the Pacific: A Reviewers Companion (Genevieve Howse, 2012)

In addition, six publications from the South-East Asia Region (SEARO) were reviewed, including 1) Regional Health Forum WHO South-East Asia Regional Volume 7 Number 2, 2003, 2) Food and Chemical Safety, 10-point Regional Strategy for Food Safety in the South-East Asia Region, 3) Tobacco Control Legislation: Report of an Inter-country Workshop, 2008, 4) Review of Patent Legislation of India, Indonesia, Sri Lanka and Thailand: Measures to Safeguard Public Health, 2004, 5) A Systematic Approach to Developing and Implementing Mental Health Legislation, 2004, and 6) Meeting the Needs of Persons in Mental Disorders through Legislation, Proceedings of Regional Workshop on Mental Health Legislation 2001. Three publications from the WHO European Region (EURO) were reviewed including 1) Legislating for Smoke-free Workplaces, European Tobacco Control Policy Series, 2006, 2) Fact Sheet on Smoke Free Legislation, and 3) Housing and Health Regulations in Europe: Summary Document, 2007. Two publication from the WHO Africa Region (AFRO) including 1) African Parties to the WHO Framework Convention on Tobacco Control Prepare to Implement Treaty, 2007, and 2) International Health Regulation (2005): Areas of Work for Implementation, 2007, and lastly one publication from Eastern Mediterranean Region (EMRO) namely WHO's Framework Convention on Tobacco Control: A Response to the Global Epidemic, 2010.

3.4.3. Case Studies

Furthermore, case studies on health legislation issues were reviewed to identify implications for the analysis framework, including different strengths and weaknesses.

These case studies included: the color code of Millennium Development Goals (MDGs), wall-chart of World Abortion Policies 2011 by United Nations (UN), country reports and comparative tables from Framework Convention on Tobacco Control by WHO, and Making the Law Work for the HIV Response July 2010 by UNAIDS. For establishing network, the examples of parliamentary committees were reviewed such as 'Regional Conference Parliamentarian' by SEARO, and 'Regional Consultation on Constituting a Regional Parliamentarian Forum' by EMRO. For creating the website and database sample, the European Public Health Law Network (EPHLN) was reviewed. For enacting model law and domestication of international health law, Essential Medicine List by WHO and Uniform Law and Model Act by United States case were reviewed.

4. Results

4.1. Reasoning the Usefulness of the Framework as a Tool of Global Health Governance

4.1.1. Public Health Law

The International Covenant on Economic, Social and Cultural Rights (ICESCR) Article 12 recognizes 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.' Governments are to take the necessary steps to reduce stillbirth and infant mortality rates and "for the healthy development of the child", improve environmental and industrial hygiene; prevent, treat, and control epidemic, occupational and other disease, and create conditions to ensure 'all medical service and medical attention in the event of sickness'. Explaining the broad notion of the right to health according to the ICESCR, it includes not only physical and mental health, but other conditions that are required for individuals to fulfill their highest attainable standard of health.

Public health law is the study of the legal powers and duties of the state, in collaboration with its partners, for example health care, business, the community, the media, and academia, to ensure the conditions for people to be healthy, and of the limitations on the power of the state to constrain for the common good and autonomy, privacy, liberty, proprietary, and other legally protected interests of individuals. (Lawrence O. Gostin, 2007) Several themes emerge from this definition government power and duty, coercion and limits on state power, government's partner in the public health system, the population focus, communities and civic participation, the prevention orientation, and social justice for expecting the population from benefiting from a public health system. (Material of Georgetown Summer Program, 2012)

The prime objective of public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values

of social justice. (Lawrence O. Gostin, 2010) Public health law provides a legal and administrative means that assure social conditions in which people can be healthy. It is a critical component in public health that suggests directions or grants authority for the society to carry out or forbid activities in order to promote people's health. The adoption of new law is not an end in itself but can provide the administrative basis for the development and management of health systems and programs. Whether the public health threat is bioterrorism, pandemic influenza, obesity, or lung cancer, law is an essential tool for addressing the problem. (W.E. Parmet, 2009)

Appropriate legislation is fundamental to improving public health. At the national level countries continuously need to review and update health legislation to protect and promote the health of their populations; sustain their health policies and programs; prevent ill health resulting from unsafe products and unsafe living conditions; fight new and re-emerging communicable diseases; support the development of health systems; and combat continuing poverty, inequities in health and discrimination.

(WHO homepage, URL http://www.who.int/hhr/health_law/healthlaw/en/)

Despite such significance of public health laws and legislations, many developing countries still lack adequate public health legislation or have legislation that is outdated which fails to address people in contemporary health issues of their people. Recent interest in public health legal preparedness - which encompass evaluating current public health laws, amending and supplementing those laws, and training the persons who implement, interpret, and study public health law indicates the need to carry out a concerted action in developing and developed countries alike.

Law can be an essential tool for creations to enable people to live healthier and safer lives. (Lawrence O. Gostin, 2005) Law and the legal process is the inseparable companion of the public health process, the history of public health has in many respects been a legal history, law has always been and continues to be an important component of public health. It is important for

public health practitioners to see how the law sits as an integral component of public health practice. (Christopher Reynolds, 2004)

Public Health incorporates the interdisciplinary approaches of epidemiology, biostatistics and environmental health, community health, behavior health, health economics, public policy, social insurance and occupational health and other important subfield. Currently the international landscape and nature is dramatically changing and appreciating the IHDL should be following this stream. IHDL is no longer a domestic adaptation, but an international obligation. Possible requires a more interdisciplinary approach to address health law issues in-country.

From the strong belief that law could be one of the tool for public health, the Health Law team in WHO was established in 1948 and initiated the IDHL intended for all who are interested in the administrative and legislative aspects of public health, and its ultimate scope and character was determined by such evidence as the WHO could obtain of its utility since 1948. (IDHL Vol S.1-2, 1948-1950). Orientations of the Health Law team have been deliberated upon by the World Health Assembly and Executive Board in several supportive resolutions over the years. Under this constitutional responsibility, WHO has operated a vigorous program of technical cooperation and information transfer for more than 60 years.

(WHO homepage, URL http://www.who.int/hhr/health_law/healthlaw/en/)

Since 1948, the IDHL has provided an invaluable compendium of the health legislation of the world, by country and subject matter in English and French. (The American Public Health Association, 2001) WHO decided in the summer of 1999 to end the publication of the IDHL as a printed quarterly journal and publish health legislation on the internet. The IDHL is unique in providing original texts of the health laws and accurate summaries of such legislation, constituting a rich resource readily available for development of health policy and research on comparative legislation. (Roemer R., 1998) WHO has made health legislation validated worldwide over the past half-century

without cost the user. The IDHL has become an invaluable tool for government officials, academics, industry, and other entities as a source of legislation.

However, on-line publication of health legislation does not maintain the same high quality as it has long provided in its printed quarterly, and specifically that legislative texts and summaries of legislation be presented by country and by subject matter so as to be readily available globally. Getting importance of governance on health, global society recognizes the importance of legislation as a foundation for public health programs and as a strategy for developing health systems.

In terms of the notions of upstream, midstream, and downstream, global health has been focusing on downstream and midstream. Downstream factors are micro level factors that include the effect 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 consensus on upstream investments are directed at fundamental causes of poor health and inequities. Upstream factors are macro level factors that comprise social structural influence on health and health systems, government policies and the social, physical, economic and environmental factors that determine health. The one of major upstream factor is legal approach. It means that law can be the strong tool for public health from now on.

Role of the law in the field of public health is implementation of legal rules within the system. Laws play at least two essential roles in public health including law as infrastructure and interventional norms. The first element is law or legal authorities, and it can be defined as the implementers of legal rules within the system. These provisions are used to create agencies, public health authorities, or to provide broad powers to these public health agents. The second kind of provision is called interventional norms, and those are specifically directed to regulate specific threats, for example to limit the danger posed by specific threats to health. (Material of Georgetown Summer Program, 2012)

One of the cornerstones of public health is the ability of governments to efficiently implement a range of effective health protection measures to guard their citizens against potential or actual health hazards and risks. Legislation is a necessary part of the framework that enables Member States to effectively detect, assess and respond to public health threats, including those aspects necessary to fulfill commitments under the International Health Regulations (2005).

4.1.2. Importance of Global Health Governance

Global health has been evolving; getting important on issues such as global spread of infectious disease, HIV and access to essential medicines, global trade in dangerous products, and migrant health. (IOM, 2009) In addition, by explosion of interest in global health in academic centers and leading think-tanks and re-conceptualization of health as more than a technical and humanitarian concern and as central to the vital security interests of states, new and unprecedented legal regimes to provide a framework for global health cooperation are emerging.

Global Health Governance is defined as "the management of the structural and normative aspects of the determinants and outcomes of global health". (Gilles Dussault, 2012) Our world becomes more interconnected everyday. However, more interconnection means increased threats to global public health due to more globalization, economic interdependence and, and movement of people and products across the world. (Obijiofor Aginam, 2005)

For example, in 2003, SARS spread worldwide through close person to person contact. The first case was reported in Asia in February 2003 and spread to more than two dozen countries in North America, South America, Europe, and Asia within a few months. Approximately 8,098 persons were sick and 774 persons died. In 2009, H1N1 Flu also spread through close person to person contact. First case was reported in North America in April 2009, spread to 74

countries by June 2009, and more than 214 countries confirmed cases by May 2010. (Sophie Harman, 2012)

In legal public health areas, infectious diseases are usually categorized negative rights. For example, isolation or quarantine measures may affect human rights such as right to liberty and security of person, right to autonomy and right to privacy. Possible tension between individual rights and community interests, for example population health, should be resolved in light of preestablished principles and guiding tools. The 'Siracusa Principles on the Derogation of Civil and Political Rights', are recognized as a legal standard for measuring valid limitations on human rights in accordance with the law, based on a legitimate objective, strictly necessary and democratic society, least restrictive and intrusive means available, and not arbitrary, unreasonable, or discriminatory.

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. 63% of all deaths were contributed by NCDs. Increasingly affecting people in low income countries, 9 million out of the 36 million people who died from chronic disease in 2008.

In legal public health areas, NCDs are usually projected in positive rights. Governments need to act in order to ensure that the conditions are given for people to live healthier lives, for example regulating industry or incentivizing healthier behaviors. Also, fulfillment of the right to health has two components including health services and essential medicines and technologies. Underlying social, economic, cultural, and political determinants of health and structural barriers, poverty, gender equality, ethnicity, economic exclusion, stigmatization, non-discrimination and other socially determined barriers are important. (Material of Georgetown Summer Program, 2012)

Like this, globalization has exacerbated inequality across the world, threatening global health. Growing needs for public health law to address basic

needs and strengthen health systems, accountability, transparency, and enforcement are needed for global health governance.

4.1.3. Global Health Architecture and Role of WHO

In WHO's Constitution, it is described that the objective of WHO shall be the attainment by all peoples of the highest possible of health. (Article 1) Health is a state of complete, physical, mental and social well-being and not merely the absence of infirmity or disease. (Preamble) In order to achieve its objective, the functions of the Organization shall be: (a) To act as the directing and coordinating authority on international health work; (c) To assist Governments, upon request in strengthening health services; (f) To establish and maintain such administrative and technical services as may be required, including epidemiological and statistical services; (g) To stimulate and advance work to eradicate epidemic, endemic and other diseases; (j) To promote cooperation among scientific and professional groups that contribute to the advancement for health; (k) To propose conventions, agreements and regulations, and make recommendations with respect to international health matters, and to perform such duties as may be assigned thereby to the Organization and consistent with its objective; (n) To promote and conduct research in the field of health; (v) Generally to take all necessary action to attain the objective of the Organization. (Article 2)

WHO's core functions are technical assistance and cooperation, directing and coordinating authority in international health, research, normative activities including secretarial generated norms and standards, and instruments adopted by the World Health Assembly such as Recommendations (Article 23), Regulations (Article 21), and Conventions (Article 19).

However, the WHO financial crisis of 2011 has stimulated wide spread debate about reorganizing the priorities of the organization while others have suggested that an entirely new institution should be created. In the crowded landscape of global health governance today, what the role of WHO should be and what are priorities were raised.

Due to sustained political attention on global health concerns, health on foreign policy agenda's rise. New actors including foundations such as Bill and Melinda Gates Foundation, Non-governmental Organizations (NGOs) such as Medicines Sans Frontieres (MSF), public-private partnerships such as the Global Fund to combat AIDS, TB and Malaria, the Global Alliance for Vaccine and Immunization (GAVI) have been proliferating as well as billions of additional funds from state and non-state actors emerged. (Taylor AL, 2002)

Under global health architecture, WHO initiated a reform process. WHO's reform aims to position the organization to better address the increasingly complex challenges of health in the 21st century. By establishing clear priorities, combined with adopting better management and governance practice, WHO can better serve the global health community. WHO reform enables to more effectively fulfill WHO's constitutional mandate as the 'directing and coordinating authority on international health work'. Based on criterias including the current health situation, needs of individual countries, international agreed instruments, the existence of evidence-based, cost-effective interventions, and the comparative advantage of WHO, public health areas are categorized as communicable disease, non-communicable disease, health throughout the life cycle, health system, preparedness surveillance and response, and corporate services and enabling functions. (WHO Newsletter on WHO reform, 2012)

Within the health system category there are three priorities. Firstly an emphasis on National Policies, Strategies and Policies (NHPSP) which plays an essential role in defining a country's vision, priorities, budgetary decisions and course of action for improving and maintaining the health of its people. Second is integrated health service delivery for reaching universal health coverage. Integrated health services encompasses management and delivery of quality and safe health services so that people receive a continuum of health promotion,

disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care services, through the different levels and sites of care within the health system, and according to their needs throughout the life course. (WHO homepage, URL http://www.who.int/nationalpolicies/en/) The last priority is regulatory framework. However, specific concept and directions for the latter are not defined yet.

4.1.4. 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 required international innovation and collaboration through legal systems. (James G. Hodge, Jr., 2011)

At the international level, contemporary global health challenges reveal our inter-dependence, and demand collective consensus and collective action; national and international health laws are mutually supportive, and are vital to protect and promote health; and the importance of health legislation is reflected in many national Constitutions and in the WHO Constitution. Under Article 63 of the WHO Constitution, each Member State is required to communicate promptly to the Organization important laws, regulations pertaining to health which have been published in the State concerned.

Recent Developments in Global Health saw the development and acceptance of law binding instruments that include: WHO Framework Convention on Tobacco Control (2003), International Health Regulations (2005), United Nations Convention on Disabilities (2006), United Nations (failed) negotiations on a proposed convention on reproductive cloning, WHO Global Code of Practice on the International Recruitment of Health Personnel (2010), WHO Pandemic Influenza Preparedness Framework (2011) and Protocol on Illicit Trade in Tobacco Products (2012). Also, non-binding instruments such as Resolutions, declarations, codes of conduct, guiding principles relating to health or particular populations or global public health concerns have been emerging;

for example WHO Global Strategy and Plan of Action on Health, Innovation and Intellectual Property (2008) and WHO Global Code of Practice on the International Health Worker Recruitment (2010).

Over 30 new global health treaties have been proposed in the last few years. These include: Framework convention on infectious diseases, Framework convention on alcohol control, Framework convention on obesity, Framework convention on biomedical technology, Framework convention on global health, Framework convention on nanotechnology, Framework convention on R & D, Framework convention on occupational safety and health, Framework convention on health worker migration for the Caribbean, Binding instrument on marketing unhealthy foods and beverages to children, Treaty on global health, Protocol on polio, Treaty to reduce child deaths by 2025, Essential health and biomedical R & D treaty, Treaty on health technology cost-effectiveness evaluation and competitive tender, and Treaty on R & D for neglected diseases. The proliferation of global health treaty proposals in the last few years reflects the pervasive influence of the perceived success of the FCTC. However, widespread enthusiasm for new lawmaking has not always been accompanied by sound legal and political analysis of the context and circumstances.

Following the Statute of International Court of Justice (ICJ) Article 38.1, the Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply international conventions, whether general or particular, establishing rules expressly recognized by the contesting states, and international custom as evidence of the general practice accepted as law. A treaty is a form of contract between states and represents the express legal rights and obligations to which parties have agreed. As a general rule, treaties are binding only upon states that have consented to them. In Vienna Convention on the Law of Treaty, Treaty defined as an international agreement concluded between states in written form and governed by international law. (Article 2(1)) Every State possesses capacity to conclude treaties. (Article 6) Every treaty in force is binding upon the parties to it and must be performed in

good faith. (Article 26) Also, state may not invoke provisions of internal law as a justification of failure to perform a treaty. (Article 27)

With regards to global health governance, treaties are preferred. The preference for binding instruments reflects the widely held view that non-binding instruments are weak, inferior and ineffective in stimulating national compliance. Credibility of binding instruments is that hard law is seen as raising the moral, political and legal stakes of compliance and the fact that treaties need to go through a process of domestic ratification further bolsters the credibility of binding commitments.

Non-binding instruments adopted under auspices of international organizations such as resolutions, declarations, codes of conduct, guiding principles. Generally intended to be instruments expressing the common interests of many states in a specific area of international cooperation typically make recommendations to governments. Most declaratory resolutions have limited political impact. However, resolutions have been effective, at times, in establishing normative standards that influence the behavior of governments. Significance of non-binding instruments in state practice has encouraged some commentators to refer to non-binding instruments as soft law such instruments are thought of as a half-way house in a legislative process. (Material of Georgetown Summer Program, 2012)

4.1.5. Domestication of International Health Law

International lawmaking is one of the strong tools for global governance. Governments are increasingly working together through transnational networks outside of formal international organizations to respond to the challenges of interdependence. However, sovereignty and equality of states represent the basic constitutional doctrine of the law of nations. (Andre den Exter. 2011) Corollaries of sovereignty contains states have international legal personality and principle of non-intervention.

Kofi Annan said that "state sovereignty is being redefined by the forces of globalization, the state is now widely understood to be the servant of the people and not visa versa. At the same time, individual sovereignty has been enhanced by a renewed consciousness of the right of every individual to control his or her own destiny".

In regard to sovereignty and the nature of International Law, International law is largely voluntary. To a great extent the responsibility to develop and apply legal rules lies with states themselves. In the international system, there is no supranational authority to 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 managing compliance although there remains considerable interest in enforcement mechanisms. (Material of Georgetown Summer Program, 2012)

These are based on doctrine of the supremacy of international law over municipal law under relation between international law and municipal law. (Edwin M. Borchard., 1940)

4.1.6. Global Regulatory Frameworks including WHO

International organizations are institutions created by sovereign states to accomplish mutual goals. International organizations have rights and duties under international law. In regard to nature and scope of legal authority of international organization, a core principle of international organizations is that the powers of organizations are generally limited to those attributed to them by states. International organizations may not generate their own powers. Those powers necessary to give effect to existing powers are essential to the performance of an organization's functions. Whether or not an organization is legally competent to undertake a particular decision or activity depends upon interpretation of the organization's constituent instrument, typically its constitution.

As per the WHO's Constitution, the World Health Assembly (WHA) shall have the authority to adopt conventions or agreements with respect to any matter within the competence of the Organization (Article 19). The WHA shall have the authority to adopt regulations concerning (a) Sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) Standards with respect to diagnosis of diseases, (d) Standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce, (e) Advertising and labeling of biological, pharmaceutical and similar products moving in international commerce (Article 21). Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice (Article 22).

However, global lawmaking is not easy. Due to need for state consent, which is sovereign issues, international laws are usually of Universally Lowest Common Denominator Standard. There is no international legislature and no rational approach to law creation, no international executive authority, nor an effective international judiciary. Severe problems in international legislative processes and treaty compliance were raised with expense and slowness of the lawmaking process. (John Tobin., 2012) Also, there is a shortage of capacity to monitor the public health law situation and legal system in countries being in line with international health law or common global health consensus. (John G. Culhane., 2011) So, analyzing public health law and legal system in countries for supporting global health governance is useful at this point.

4.1.7. Usefulness of In-Country Analysis on Legal System

During the academic conferences, key issues and problems arising from globalization throughout the world were identified included 1) human rights and

health, 2) communicable disease management and the role of IHR 2005, 3) medical technology innovation and adoption, and 4) international trade and patent law, and negotiation strategies. Through exploring of existing structures and approaches to responding to these key issues and problems, cases and examples how nations are responding to the issue and problems in health, international health law, public health governance, and policies were illustrated and law development and also shown how governance strategies can bridge the divide between health and law, global health and human rights. Also, existing and future gaps in the legal framework, governance mechanisms, and policies for addressing the challenges of health globalization were identified and a dialogue that leads to possible strategies for monitoring and developing the laws, governance frameworks was suggested.

In the summer program in Georgetown Law School, an overview of global health law and governance, international law and international organization, as well as an introduction to national health law and comparative health system were provided with themes such as global health governance, national and global health law, international law and international organization in global health, and comparative health system and legal system. Most of the speakers and participants were sympathetic to the importance of understanding the gaps between international and national public health law standards.

In the expert consultations on public health law, the meeting participants noted that, while countries have public health law 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 improve the utilization of public health law in the health sector. Those addressed the need for routine monitoring of public health law, feedback to improve public health law quality, and appropriate and coordinated technical support to be managed by countries themselves with support from international agencies. While a public health law could be improved by reviewing the indications it generates,

international society should support the development and prioritization of indicators.

Therefore, developing a tool for assessing country-level public health law and legislation is a vital step in promoting public health legal preparedness and ultimately improving the health and welfare of the people.

4.2. Ways for Improving Application of the Framework

4.2.1. Country Assessment Results

In-depth analysis of public health laws could be very useful to countries. It would assist health officials in understanding both their international commitments and the range of domestic laws, identifying possible gaps that would need further public health and other legislation, and determining the comprehensiveness of a country's health law through a series of questions and identifying the gaps through the absence of relevant law. Through this process, one can expect to find recommendations as to what each country needs to do with regard to public health law.

4.2.1.1. Public Health Law in Republic of Korea

One legal expert who is professor in department of medical law and ethics in College of medicine undertaken the pilot test in the Republic of Korea.¹

The Republic of Korea does have constitutional provisions related to health and many acts relating to health. The "Framework Acton Health and Medical Services" comprises general aspects of Health including rights and duties of the nation, formulation and implementation of plans development of health, management of resources for health, system of provision, lifelong health care for citizens, managing major diseases, and support and development of health and medical services etc. This law is like the constitution of public health. One of the major health laws, "Medical Service Act", regulates qualification and licenses, rights and duties, and restriction of medical persons, establishment of medical institutions and medical corporations, evaluation of new medical technology, advertisement of medical service, conciliation of disputes. Korea also has the "Medical Technicians etc Act".

35

¹ Dr SoYoon Kim, Asian Institute of Bioethics and Health Law, College of Medicine, Yonsei University, 134 Shinchon-Dong, Sedaemun-Gu, Seoul 120-752, South Korea.

Besides, there are many health related acts. "National Health Insurance Act" covers health insurance system and financing of health, "Medical Care Assistance Act" for beneficiary who is eligible for medical care, "National Health Promotion Act" for ensuring healthy lifestyle and healthy environment, "Pharmaceutical Affairs Act" for pharmacists and pharmacies and drugs. The "Regional Public Health Act" states the responsibilities of state and local governments as well as establishment of regional public health and medical care plan. Also, the "Emergency Medical Service Act" specifies for the protection of lives and health of the emergency patient. The "Framework Act on Health Examination" is for conducting national health examination conducted by the state and local governments; the "Mother and Child Health Act" for contributing the improvement of national health by protecting the lives and health of mothers and infants.

Furthermore, the "School Health Act" is to protect and promote the health of students and teaching staff, "Infant Care Act" for fostering infants to healthy members of the society, the "Act on Long-term Care Insurance for the Aged" for elderly citizens, the "Bioethics and Safety Act" and the "Internal Organs Transplant Act" for bioethics issues, the "Environmental Health Act" for protecting and maintaining national health and ecosystem, the "Occupational Safety and Health Act" for maintaining and promoting the safety and health of workers by preventing industrial accidents. For injury prevention, Korea does have the "Radioactive Rays and Radioisotope Use Promotion Act" and the "Traffic Safety Act".

With regards to infectious disease control issues, Korea has the "Communicable Disease Control Prevention Act", the "Quarantine Act", the "Act on the Prevention of Contagious Animal Disease" and the "Tuberculosis Prevention Act". The "Prevention of Acquired Immunodeficiency Syndrome Act" is for contributing to the protection of national health by prescribing necessary matters for prevention and control of AIDS. Most of the tobacco

control is regulated by the "National Health Promotion Act" and the "Tobacco Business Act". (see Table 1)

Table 1. Profiling the Health Laws in the Republic of Korea

Mod ule	Code	Name	Туре	Number	Enactment/ Revision	For mat	Lang uage s
Mod	1-1	Constitution of the Republic of Korea	Cor	stitution	1948/1987	Нуре	Kore
ule 1	1-2	Framework Act on Health and Medical Services	Act	9034	2000/2008	rlink to an	an & Engli
	1-3	Medical Service Act (Enforcement Decree of the Medical Service Act)	Act	10387	1962/2010	onlin e data	sh
	1-4	National Health Insurance Act (Enforcement Decree of the National Health Insurance Act)	Act	10682	1999/2011	base & elect	
	1-5	National Health Promotion Act	Act	10327	1995/2010	ronic	
	1-6	Pharmaceutical Affairs Act (Enforcement Decree of the National Health Insurance Act)	Act	10324	1953/2010	docu ment <u>http:</u>	
	1-7	Regional Public Health Act	Act	8423	1956/2007	<u>//ela</u>	
	1-8	Emergency Medical Service Act	Act	9305	2000/2008	w.klr	
	1-9	Communicable Disease Control and Prevention Act	Act	9932	1954/2010	i <u>.re.k</u> r/kor ser	
	1-10	Quarantine Act (Enforcement Decree of the Quarantine Act)	Act	9932	1963/2010	ser vice/ main do	
	1-11	Prevention of Acquired Immunodeficiency Syndrome Act	Act	9932	1987/2010	<u>.uo</u> _	
	1-12	Act on the Prevention of Contagious Animal Disease (Enforcement Decree of the Act on the Prevention of Contagious Animal Disease)	Act	10310	1961/2008	•	
	1-13	Tuberculosis Prevention Act	Act	9963	1967/2008	-	
	1-14	Framework Act on Health Examination	Act	10333	2008/2010	-	
	1-15	Dental Health Act	Act	9932	2000/2010	_	
	1-16	Framework Act on Healthy Homes	Act	9932	2004/2010	_	
	1-17	Mother and Child Health Act	Act	9932	1973/2010	_	
	1-18	School Health Act (Enforcement Decree of the National Health Insurance Act)	Act	9932	1967/2010	_	
	1-19	Infant Care Act	Act	9511	1991/2009	_	
	1-20	Act on Long-Term Care Insurance for the Aged	Act	9693	2007/2009	_	
	1-21	Employment promotion and Vocational Rehabilitation of Disabled Persons Act	Act	9932	1990/2010	_	
	1-22	Mental Health Act (Enforcement Decree of the Mental Health Act)	Act	10387	1995/2010	_	
	1-23	Tobacco Business Act (Enforcement Decree of the Tobacco Business Act)	Act	9932	1988/2010	_	
	1-24	Act on the Control of Narcotics etc.	Act	9932	2000/2010	_	
	1-25	Bioethics and Safety Act	Act	9100	2004/2008	_	
	1-26	Internal Organs, Etc. Transplant Act	Act	8852	1999/2008	_	
	1-27	Criminal Procedure Act	Act	9765	1954/2009	-	
	1-28 1-29	Medical Devices Act Environmental Health Act	Act	10564 8946	2003/2010 2008	-	
	1-30	Occupational Safety and Health Act	Act	10339	1981/2010		

(Enforcement Decree of the

		Occupational Safety and Health Act)			
	1-31	Industrial Accident Compensation Insurance Act	Act	10339	1963/2010
	1-32	Radioactive Rays and Radioisotope Use Promotion Act	Act	10774	2002/2011
	1-33	Traffic Safety Act	Act	9966	1979/2009
	1-34	Sports Industry Promotion Act	Act	8852	2007/2008
	1-2	Framework Act on Health and Medical Services			
	1-7	Regional Public Health Act	·	•	
	1-4	National Health Insurance Act			
Mod -	1-5	National Health Promotion Act			
ule 2	2-1	Medical Care Assistance Act	Act	8852	2001/2008
uie z	1-3	Medical Service Act			
	1-6	Pharmaceutical Affairs Act			
	2-2	Medical Technicians, etc. Act	Act	8852	1995/2008
	1-9	Communicable Disease Control and Prevention Act	Act	9932	1954/2010
Mod	1-9	Communicable Disease Control and Prevention Act			
ule 3	1-10	Quarantine Act (Enforcement Decree of the Quarantine Act)	Act	9932	1963/2010
	1-5	National Health Promotion Act			
Mod ule 4	1-23	Tobacco Business Act (Enforcement Decree of the Tobacco Business Act)	Act	9932	1988/2010

4.2.1.2. Public Health Law in Philippines

One legal expert who is physician lawyer was performed pilot test in Philippines.² Philippine laws have had various nomenclature designations at different periods in the history of the Philippines, as shown in the following table 2 (see Table 2)

Philippines does have constitutional provisions related to health. The major health laws are the "Philippines Health Insurance Act of 1995", the "Medical Act of 1959", the "Philippine Nursing Law of 2002", the "Philippines Midwifery Law", "The Magna Carta of Public Health Workers", the "Hospital Licensure Law", the "Code of Sanitation of the Philippines". (see Table 3)

⁴ Mr David Clarke, Director, Allen and Clarke Policy and Regulatory Specialist Limited 8 Park Street, Thorndon PO ox 10 730, Wellington 6143, New Zealand.

² Dr Bu Castro, Physician Lawyer, Philippines Hospital Association, No.44-A, Acayan St. 14th Avenue, East Tapinac, Olongapo City, Philippines.

Table 2. Nomenclature Designation used for Laws in Philippines

Nomenclature Designation	Abbreviation	Form of Government	Dates
Act	Act	Philippine Government under United States Rule	1900-1935
Commonwealth Act	CA	Philippine Commonwealth	1935-1946
Batas Pambansa	BP	Modified Parliamentary Republic	1978-1985
Presidential Decree	PD	Republic under Martial Law/Fourth Republic	1972-1986
Presidential Proclamation	PP	Republic under Martial Law	1972-1986
Executive Order	EO	Republic under 1986 Provisional Constitution	1986-1876
Presidential Proclamation	PP	Republic under 1986 Provisional Constitution	1986-1987
Republic Act	RA	Republic	1946-72,
Republic Act	NA .	Republic	1987-present

Reference: URL http://en.wikipedia.org/wiki/List of Philippine laws

Table 3. Profiling the Health Laws in Philippines

Mod ule	Code	Name	Туре	Number	Enactment/ Revision	For mat	Lang uage s
Mod	1-1	Philippine Constitution	Constitu	ution	1987		
ule 1	1-2	Philippine Health Insurance Act of 1995	Republic Act	RA 7875	1995	-	
	1-3	Executive Order	Executive Order	EO 784	1982	_	
	1-4	Medical Act of 1959	Republic Act	RA 2382	1959	_	
	1-5	Philippine Nursing Law of 2002	Republic Act	RA 9173	2002		
	1-6	Philippine Midwifery Law	Republic Act	RA 7392	1992	_	
	1-7	The Magna Carta of Public Health Workers	Republic Act	RA 7305	1992	_	
	1-8	Hospital Licensure Law	Republic Act	RA 4226	1965	="	
	1-9	Code of Sanitation of the Philippines	Presidential Decree	PD 856	1975	_	
	1-10	Philippine AIDS Prevention and Control Act of 1998	Republic Act	RA 8504	1998	_	
	1-11	Blood Bank Law				="	
	1-12	Anti-Graft Corrupt Practices Act					
	1-13	Organ Donation Law			•	-	
	1-14	Philippine Dental Act of 2007	Republic Act	RA 9484	2007	=" =:	
	1-15	Family Code				= =	
	1-16	General Act				_	
	1-17	Mandatory Infants and Children Health Immunization Act of 2011	Republic Act	RA 9484	2011	_	
	1-18	Newborn Screening Act of 2004	Republic Act	RA 9288	2004	_	
	1-19	Child Abuse Law	Presidential Decree	PD 603			
	1-20	Expanded Senior Citizens Act of 2003	Republic Act	RA 9257	2004	_	
	1-21	Tobacco Regulation Act of the Philippines	Republic Act	RA 9211	2003	_	
	1-22	Dangerous Drugs Act of 2002	Republic Act	RA 9615	2002		
	1-23	Code of Ethics of Medical Profession	Presidential Decree			_	
	1-24	Regulation of Practice of Nutrition and Dietetics in the Philippines	Presidential Decree	PD 1286	1978	_	
	1-25	The Consumer Act of the Philippines	Republic Act	RA 8394	1992	_	
	1-26	Food, Drug, and Cosmetic Act	Republic Act	RA 3720	1963	_	
	1-27	Traditional and Alternative Medicine Act of 1997	Republic Act	RA 8423	1997	=	
	1-28	Medical Technology Law			•	-	

				·	
	1-29	Label, Sale and Distribution of Hazardous Substances	Presidential Decree	PD 881	1976
	1-30	Occupational Health and Safety	Presidential Decree	PD 442	1974
	1-31	Philippines Clean Air Act of 1999	Republic Act	RA 9849	1999
	1-32	Creating Radiation Health Office	Presidential Decree	PD 480	1974
	1-33	Granting the Metropolitan Manila Commission Powers Related to Traffic Management	Presidential Decree	PD 1605	1978
	1-34	The Philippine Sports Commission Act	Republic Act	RA 6748	1990
	1-2	Philippine Health Insurance Act of 1995	Republic Act	RA 7875	1995
	2-1	Government Service Insurance Act of 1997	Republic Act	RA 8291	1995
	2-2	Social Security Act of 1997	Republic Act	RA 8282	1997
Mod ule 2	2-3	Medical and Dental Services, Book four of the Labor Code of the Philippines	Presidential Decree	PD 442	1974
	1-7	The Magna Carta of Public Health Workers	Republic Act	RA 7305	1992
	2-4	Universally Accessible Cheaper and Quality Medicines Act of 2008	Republic Act	RA 9502	2008
	1-26	Food, Drug, and Cosmetic Act	Republic Act	RA 3720	1963
	1-17	Mandatory Infants and Children Health Immunization Act of 2011	Republic Act	RA 10152	2011
	3-1	Law on Operation of Quarantine Service	Republic Act	RA 123	1947
	3-2	Quarantine Act of 2004	Republic Act	RA 9271	2004
	1-17	Mandatory Infants and Children Health Immunization Act of 2011	Republic Act	RA 10152	2011
Nod ile 3	1-9	Code of Sanitation of the Philippines	Presidential Decree	PD 856	1975
	2-30	Occupational Health and Safety	Presidential Decree	PD 442	1974
	3-3	Department of Health Administrative Order	Executive Order	EO 02	2005
	3-1	Tax Rates Imposed on Alcohol and Tobacco Products	Republic Act	RA 9334	2995
lod le 4	1-21	Tobacco Regulation Act of the Philippines	Republic Act	RA 9221	2003
	3-2	Tariffs and Customs Law of the Philippines	Presidential Decree	PD 1464	1978

4.2.1.3. Public Health Law in Samoa

One legal expert who has the expertise in Samoa Health Law was performed pilot test in Samoa. Samoa conducted the pilot test using a two step process. First, the tool was filled out using internet sources such as the Pacific Islands Legal Information Institute's website (http://www.paclii.org) and the Samoa Parliament's legislation website. Second, a quality control check was performed with key officials in the Samoa Government.

Samoa does have constitutional provisions related to health. The major health laws are the "National Health Services Act", "The Ministry of Health Act", "The Healthcare Professions Registration and Standard Act", the "Nursing and Midwifery Act", the "Pharmacy Act", the "National Kidney Foundation of Samoa Act", The Accident Compensation Act", "The National Provident Fund Act", "The Oceania University of Medicine Act", "The Medical Practitioners Act", the "Dental Practitioners Act", "The Samoa Water Authority Act", "The Immigration Act", "The Disaster and Emergency Management Act", "The Mental Health Act", "The Tobacco Control Act", "The Accident Compensation Act", "The Food and Drugs Act", the "Narcotics Act 1967", the "Births, Deaths and Marriages Registration Act" and "The Occupational Safety and Health Act" etc. (see Table 4)

Table 4. Profiling the Health Laws in Samoa

Mod ule	Code	Name	Туре	Number	Enactment / Revision	Format	Languages
Mod ule 1	1-1	The Constitution of the Independent State of Samoa	Cons	titution	2008		
	1-2	National Health Services Act	Act	20	2006		
	1-3	The Ministry of Health Act	Act	19	2006	-	
	1-4	The Healthcare Professions Registration and Standards Act	Act	7	2007	•	
	1-5	The Nursing and Midwifery Act	Act	8	2007		
	1-6	Pharmacy Act	Act	6	2007	•	
	1-7	The National Kidney Foundation of Samoa Act	Act	12	2005	•	
	1-8	The Accident Compensation Act	Act	36	1989	-	
	1-9	The National Provident Fund Act	Act	1	1972	•	
	1-10	The Oceania University of Medicine (Samoa) Act	Act	2	2002	-	
	1-11	The Medical Practitioners Act	Act	29	2007	•	
	1-12	Dental Practitioners Act	Act	11	2007	•	
	1-13	The Health Ordinance	Ordinan ce	19	1959	•	
	1-14	The Samoa Water Authority Act	Act	13	2003		
	1-15	The Immigration Act	Act	4	2004	•	
	1-16	The Disaster and Emergency Management Act	Act		2007		
	1-17	The Mental Health Act	Act	5	2007	-	
	1-18	The Tobacco Control Act	Act		2008		
	1-19	The Accident Compensation Act	Act	36	1989	•	
	1-20	The Infants Ordinance	Ordinan ce	7	1961	_	
	1-21	The Education Act	Act	9	2009		
	1-22	The Labour and Employment Act	Act	12	1972	-	
	1-23	The Food and Drugs Act	Act	6	1967		

	1-24	The Excise Tax Rates Act	Act	17	1984
	1-25	The Liquor Act	Act		1971
	1-26	The Customs Act	Act		1977
	1-27	Narcotics Act 1967.	Act	3	1967
	1-28	Births, Deaths and Marriages Registration Act	Act	17	2002
	1-29	Coroners Ordinance	Ordinan ce	5	1959
	1-30	Burials Ordinance	Ordinan ce	4	1961
	1-31	Consumer Information Act	Act	5	1989
	1-32	The Poisons Act	Act		1968
	1-33	The Waste Management Act	Act	13	2010
	1-34	The Occupational Safety and Health Act	Act	5	2002
	1-35	Lands Surveys and Environment Act	Act	33	1989
	1-36	Water Resources Management Act	Act	31	2008
	1-37	Samoa Water Authority Act	Act	13	2003
	1-38	Ports Authority Act	Act	34	1998
	1-39	Planning and Urban Management Act	Act	5	2004
	1-40	Fisheries (Ban of Driftnet Fishing) Act	Act	12	1999
	1-41	The Forests Act 1967			1967
	1-42	Marine Pollution Prevention Act	Act	2	2008
	1-43	National Parks and Reserves Act	Act	19	1974
	1-44	Sports Disputes Resolution Act	Act	13	2008
	1-45	South Pacific Games (Taxation Incentives) Act	Act	14	2007
	1-46	Samoa Sports Facilities Authority Act	Act	24	2007
	1-47	Youth, Sports and Cultural Affairs Act	Act	8	1993-1994
	1-48	The Statistics Act	Act		1971
	1-3	The Ministry of Health Act	Act	19	2006
	1-12	Dental Practitioners Act	Act	11	2007
	1-5	The Nursing and Midwifery Act	Act	8	2007
	1-8	The Accident Compensation Act	Act	36	1989
	1-7	The National Kidney Foundation of Samoa Act	Act	12	2005
Mod	1-9	The National Provident Fund Act	Act	1	1972
ule 2	1-4	The Healthcare Professions Registration and Standards Act	Act	7	2007
	1-11	The Medical Practitioners Act	Act	29	2007
	1-6	Pharmacy Act	Act	6	2007
	1-23	The Food and Drugs Act	Act	6	1967
	1-17	The Mental Health Act	Act	5	2007
	1-16	The Disaster and Emergency Management Act	Act		2007
Mod	1-13	The Health Ordinance	Ordinan ce	19	1959
ule 3	3-1	The Quarantine (Biosecurity) Act	Act	22	2005
	3-2	Immigration Act	Act	4	2004
	3-3	Sea Carriage of Goods Ordinance	Ordinan ce	5	1960
Mod	1-24	The Excise Tax Rates Act	Act	17	1984

4.2.1.4. Public Health Law in Vanuatu

One legal expert who is lecturer in law school undertaken the pilot test in Vanuatu.⁵ Vanuatu adopted a team approach, whereby a law professor, a local consultant who is lawyer, a government official in the Ministry of Health and a group of law students worked together to fill out the tool.

Table 5. Profiling the Health Law in Vanuatu

Mod ule	Code	Name	Туре	Number	Enactment/ Revision	Format	Langua ges
	1-1	Constitution of Vanuatu	Consti	tution			
_	1-2	Public Health Act	Act	Cap 234			
_	1-3	Health Committees Act	Act	Cap 296		_	
		The Environmental				="	
	1-4	Management and Conservation Act	Act	Cap 283		_	
	1-5	Vanuatu National Cultural Council Act	Act	Cap 186		_	
	1-6	The Health Practitioners Act	Act	Cap 164		_	
	1-7	The Nurses Act	Act	Cap 262		_	
	1-8	The Mental Hospital Act	Act	Cap 38		=	
	1-9	The Health Committees Act	Act	Cap 296			
_	1-10	The Quarantine Act	Act	Cap 1		='	
Mod	1-11	Health Practitioners Act	Act	Cap 164	•	_	
ule 1	1-12	The Tobacco Control Act	Act		2008	_	
ule 1	1-13	The Liquor Licensing Act	Act	Cap 52	•	_	
_	1-14	The Dangerous Drugs Act	Act	Cap 12			
	1-15	The Burials Act	Act	Cap 101		="	
	1-16	The Food Control Act	Act	Cap 228		=" _	
	1-17	Food Control Regulation	Regulation		2007	= <u>-</u>	
	1-18	The Sale of Medicines (Control) Act	Act	Cap 48		_	
	1-19	The Pesticides (Control) Act	Act	Cap 226	•	=	
	1-20	The Health and Safety at Work Act	Act	Cap 195		_	
	1-21	The Employment Act	Act	Cap 160			
	1-22	The Road Traffic Control Act	Act	Cap 29			
	1-23	The Vanuatu National Sports Council Act	Act	Cap 208		_	
Mod	1-2	Public Health Act	Act	Cap 234	· · · · · · · · · · · · · · · · · · ·	-	
ule 2	1-6	The Health Practitioners Act	Act	Cap 164	•	_	
ule 2	1-7	The Nurses Act	Act	Cap 262		=" _	
Mod	3-1	Civil Aviation Act	Act	Cap 258		_	
ule 3	1-2	Public Health Act	Act	Cap 234		_	
aic 3	1-10	The Quarantine Act	Act	Cap 1		_	
Mod	1-12	The Tobacco Control Act	Act		2008	_	
ule 4	4-1	Criminal liability for breaches of the Act	Act				

⁵ Ms Anita Louse Jowitt, Lecturer in Law, University of the South Pacific, PO Box 9070, Port Vila, Vanuatu.

Vanuatu does have constitutional provisions related to health. The major health laws are the "Public Health Act", the "Health Committees Act", "The Health Practitioners Act", "The Nurses Act", "The Mental Hospital Act", "The Health Committees Act", "The Quarantine Act", "Health Practitioners Act", "The Tobacco Control Act", "The Food Control Act" and others (see Table 5)

4.2.1.5. Public Health Law in the Kingdom of Cambodia

One local researcher who is Medical Doctor and having the working experience in Ministry of Health in Cambodia conducted the implementation pilot test in the Kingdom of Cambodia. There is legal hierarchy in Cambodia, as shown in the following table. (see Table 6).

Table 6. Legal Hierarchy in the Kingdom of Cambodia

Name	Explanation
The Chhbab (Law)	The actual law which is passed by the vote of the National Assembly and then the Senate, having been approved previously by the Council of Jurists and the Council of Ministers. Thus the Chhbab is subject to the most rigorous Parliamentary process and, in this respect, can be contrasted with Kret and Anu-Kret, which require only the approval of the Council of Ministers. Often Chhbab are confused with the Kram which is the Royal Decree of Promulgation of the Chhbab, the Kram being signed by the King.
The Reach Kret (Royal Decree)	It is used by the King in the exercise of his constitutional powers i.e. powers of appointment upon proposals made by the Council of Ministers and by the Supreme Council of the Magistracy.
The Kret (Decree)	These are signed by the King upon proposals of the Prime Minister after they have been adopted by the Council of Ministers. Kret are countersigned by the Prime Minister.
The Anu-Kret (Sub-Decree)	After adoption by the Council of Ministers, the Anu-Kret are signed by the Prime Minister and countersigned by the Minister or Ministers in charge of the execution of the Anu-Kret. The Anue-Kret can also be used by the Prime Minister in the framework of the Prime Minister's own regulatory executive powers.
The Prakas (Proclamations)	The Prakas are made by Ministers to provide a framework to their own regulatory powers.
Sechdei Sanrech (Decision)	Sechdei Sanrech are individual decisions of the Prime Minister, a Minister or a office Governor. Again, they are used as part of the holder framework of the regulatory powers of the particular.
The Sarachor (Circulars)	The Sarachor are generally used by the Prime Minister, as head of government, and by Ministers, as officials of their Ministry, either to explain or clarify certain legal or regulatory measures, or to provide instructions on implementation.
Deka	Theses are Provincial Proclamations which are used by Provincial Governors within the geographical limit of their Provinces. Again, they are an instrument to provide a regulatory framework.

The Chhbab is the actual law which is passed by the vote of the National Assembly and then the Senate, having been approved previously by the Council of Ministers. The Royal Decree is used by the King as of exercise of his constitutional powers. There also are signed by the King upon proposals of the Prime Minister after they have been adopted by the Council of Ministers. A Decree is countersigned by the Prime Minister. After adoption by the Council of Ministers, the Sub-Decree is signed by the Prime Minister and countersigned by the Minister or Ministers in charge of the execution of the Sub-Decree. The Prakas are made by Ministers to provide a framework to their own regulatory powers. Decisions, Circulars and Dekas are existing, an implementation tools.

The Kingdom of Cambodia does have constitutional provisions related to health. The major health laws are the "Law on the Management of Private Medical, Paramedical, and Medical Aid Services (2000)", the "Law on Abortion (1997)", the Law on Management of Pharmaceuticals (1996)", the "National Disability Law", the "National Lab Control Law", the "Law on Control of Addictive Drugs", the "Land Traffic Law", and the "Law on Social Security Schemes for Persons Defined by the Provision of the Labor Law". In terms of Royal Decrees, there are the "Establish of Calamette Hospital", the "Establishment of Cambodia National Medical Council", the "Categorization of Staff", and the "Promulgating the Law on Approving Cambodia to be a Party of the Framework Convention on Tobacco Control". With respect to the Sub-Decree, there are the "Establishing and Functioning of the MoH", the "Establishment of the National Ethics Committee for Health Research on Human Beings", the "Printing Health Warning on Cigarette Package", the "Advertising of Tobacco Products", the "Drug Registration", the "Code of Ethics for Doctors", the "Production and Importation of Traditional Medicines", and the "Classification of Poisonous Drugs". (see Table 7)

Table 7. Profiling the Health Law in the Kingdom of Cambodia

/lod ule	Code	Name	Туре	Number	Enactment / Revision	For mat	Langua ges
/lod le 1	1-1	Constitutions of the Royal Government of Cambodia	Constitu	ution	1993	PDF Hard Copy PDF	Khmer/ English
	1-2	United Nations Charter	International Instrument				
	1-3	Universal Declaration of Human Rights	International Instrument				Khmer
	1-4	International Covenant on Civil and Political Rights (1996)	International Instrument				Khmer
	1-5	International Covenant on Economic, Social and Cultural Rights (1966)	International Instrument				
	1-6	Convention on the Rights of the Child (1989)	International Instrument				
	1-7	Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography (2000)	International Instrument				
	1-8	Law on adoption of international treaty against use of dope in sport 2007	Law		2007	PDF	Khmer
	1-9	Sub-decree No.67 on establishment and functioning of MOH	Sub-Decree	67			Khmer
	1-10	Royal Decree dated 28 February 1996 on Establishment of Calamette Hospital	Royal-Decree		28 Feb. 1996		Khmer
-	1-11	Law on Financial System	Law			PDF	Khmer
	1-12	Taxation Law	Law			PDF	Khmer
	1-13	Law on Social Security Schemes for Persons Defined by the Provisions of	Law			PDF	Khmer
	1-14	Sub-decree No. 592 on Establishment of National Ethics Committee for Health Researcher in Human Being	Sub-Decree	592		PDF	Khmer
	1-15	Law on the Management of Private Medical, Paramedical, and Medical Aid Services (2000)	Law		2000	PDF	Khmer
	1-16	Sub-decree No. 21	Sub-Decree	21			
	1-17	Royal Decree on Establishment of Cambodia National Medical Council	Royal-Decree				Khmer
	1-18	Law on Abortion (1997)	Law		1997	PDF	Khmer
	1-19	Law on Marriage and Family 1989	Law		1989	PDF	Khmer
	1-20	Labour Law 1997	Law		1997	PDF	Khmer
	1-21	Prakas issued by MoH stipulates that disabled people receive free health care of public health facilities	Parakas		2004		
	1-22	The Royal Kram No. SN/RKM/0106/002 dated January 18, 2006 promulgating the Law on Approving Cambodia to be a Party of the Framework Convention on Tobacco Control	Royal Kram	No. SN/RKM/0 106/002	18 Jan. 2006		Khmer
	1-23	Sub-Decree on Printing Health Warning on Cigarette Packages	Sub-Decree		20 Oct 2009	PDF	Khmer
	1-24	Sub-Decree on Advertising of Tobacco Products	Sub-Decree		24 Feb. 2010	PDF	Khmer
	1-25	Parakas on the Implementation of Printing Health Warning Message on Cigarette Packages	Parakas			PDF	Khmer
	1-26	Parakas on Measures for the Banning of Tobacco Product Advertising	Parakas		1 April. 2011	PDF	Khmer
		The Council of Ministers Letter	Circular	No.1270	19 Aug.	PDF	Khmer

		No.1270 A. dated August 19, 1994 on Smoke Free Policy			1994		
	1-28	Decision on Establishment of the Committee to evaluate and legalize degree and certificate	Decision	No.34	9 April 1999	Hard Copy	Khmer
	1-29	Law on the Prevention and Combat against the Spread of HIV/AIDS (2002)	Law		2002	PDF	Khmer
	1-30	National Disability Law	Law	•			
	1-31	Land Traffic Law	Law		8 Feb. 2007	Hard Copy	Khmer
	1-32	Law on Management of Pharmaceuticals (1996)	Law	•	1996	PDF	Khmer
	1-33	Sub-Decree No.44 on Drug Registration	Seb-Decree	No.44	10 Aug. 1994	Hard Copy	Khmer
	1-34	Sub-Decree No.61 Code of Ethics for Doctor	Sub-Decree	No.61	28 Aug. 2003	Hard Copy	Khmer
	1-35	Standard Operating Procedure 2008			2008	Hard Copy	English/ Khmer
	1-36	Sub-Decree No.23 dated 28 April 1998 on Production and Importation of Traditional Medicines	Sub-Decree	No.23	28 April 1998	Hard Copy	Khmer
	1-37	Parakas No.364 on implementation of drug registration	Parakas	No.364		Hard Copy	Khmer
	1-38	Law on Control of Addictive Drugs	Law			Hard Copy	Khmer
	1-39	Classification of Poisonous Drugs	Sub-Decree	No.37	16 June 2000	Hard Copy	Khmer
Mod ule 2	2-1	Sub-Degree No. 67 on Establishment and Functioning of MoH	Sub-decree	No. 67	October 22, 1997	hard copy	Khmer
	2-2	Royal Decree No. 50 dated 10 June 1999 on Establishment of Council for Administrative Reform (CAR)	Royal decree	No. 50	June 10, 1999	pdf	Khmer
	2-3	Sub-decree No. 21	Sub-decree	No. 21			Khmer
	2-4	Civil servant law	Law		October 21, 1994	hard copy	Khmer
	2-5	Decision of the National Medical Council to determine types doctors	decision	No. 030/11	July 13, 2011	hard copy	Khmer
	2-6	Royal decree on categorization of staff?	Royal Decree				
	2-7	PRAKAS on TOR of Health workforce?	Parakas				
	2-8	Law on the Management of Private Medical, Paramedical, and Medical Aide Services (2000)	Law		November 30, 2000	Pdf/ hard copy	Khmer
	2-9	Royal Kram promulgating Law on the Management of Private Medical, Paramedical, and Medical Aide Services (2000)	Royal Kram	No.1100/1 0			
	2-10	Law on Management of Pharmaceuticals (1996)	Law		2006	hard copy	Khmer
	2-11	National Lab Control					
	2-12	Procurement Law	Law				
	2-13	Rectangular Strategy of the Royal Government of Cambodia	Strategy			pdf	Khmer
	2-14	MoH Health Strategic Plan 2008-2015	Strategic Plan		2008-2015	pdf	Khmer
	2-15	Guideline for Development of Operational District	Guidelines		1997	hard copy	Khmer/ English
	2-16	Strategic Framework for Health Financing	Strategy		2008-2015	pdf	Khmer/ English
	2-17	MPA Guidelines	Guideline				Khmer/ English
	2-18	CPA Guidelines	Guideline				Khmer/ English
	2-18 2-19	CPA Guidelines Health Financing Strategic Plan	Guideline Strategic plan				

	4-11	National Strategic Plan on Tobacco	Strategic plan		2011-2015	pdf	English/
	4-10	FCTC		,	2005	hard copy	English
	4-9	Notice of ratification of FCTC Instrument of Ratification on WHO	law		2005	сору	/Khmer
	4.0	Control			2005	hard	English
	4-8	Statement of drafted law promulgating the law approving Cambodia to be part of the Framework Convention on Tobacco	Statement	No. 70	2005	hard copy	Khmer
	4-7	PRAKAS issued by the Ministry of health ON THE IMPLEMENTATION OF PRINTING HEALTH WARNING MESSAGES ON CIGARETTE PACKAGE	Prakas			pdf	English & Khmer
	4-6	SUB-DECREE dated October 20, 2009 ON PRINTING HEALTH WARNING ON CIGARETTE PACKAGES	Sub-decree		October 20, 2009	pdf	Khmer
	4-5	Circulars issued by ministries	Circulars			Pdf	English/ Khmer
	4-4	The Council of Ministers letter No. 1270 A. dated August 19, 1994 on Smoke Free Policy in workplaces and meeting halls	Circular	No. 1270 A	August 19, 1994	Pdf	Khmer
	4-2	Law on Taxation 1997 The Royal Kram No. SN/RKM/0106/002 dated January 18, 2006 promulgating the Law on Approving Cambodia to be a Party of the Framework Convention on Tobacco Control	Law Royal decree	No. SN/RKM/0 106/002	1997 January 18, 2006	PDF Pdf	Khmer
ule 4		Tobacco Tax		-	2011		Khmer
Mod	4-1	Cambodia Parakas dated October 24 2011 on Establishment of Working Group on	Parakas	898	24 Oct	Copy	Khmer English/
	3-9	Agreement between Vietnam and	Instrument Agreement			Hard	English/
	3-8	amended sub-decree64 WHO International Health Regulation	International		2005		English/
	3-7	Letter No. 1557 dated 20 September 2005 approving MOH be part of	Letter	No.1557	20 Sep 2005	Hard Copy	Khmer
	3-6	Amended Sub-Decree No.64	Sub-Dcree			Hard Copy	Khmer
Mod ule 3	3-5	Sub-Decree No.64	Sub-Decree	No.64		Hard Copy	Khmer
	3-4	Guidelines for quarantine officer at the point of entry	Guildelines		1939	Hard Copy	Khmer
	3-3	Parakas No.193 dated 19 May 1999 on ToR for Quarantine Office	Parakas	No.193	19 May 1999	Hard Copy	Khmer
	3-2	Parakas No.985 dated September 29 2003 putting quarantine office under responsibility of CDC department	Parakas	No.985	29 Sep 2003	Hard Copy	Khmer
	3-1	Sub-Decree No.67	Sub-Decree	No.67		Hard Copy	Khmer
	2-26 2-27	Rational drug use Essential Drug Lists	Guidelines				
	2-25	Treatment protocol for referral hospital	Protocol			•	
	2-24	Operational Guideline for Clients' rights and Providers' rights and duties	Guidelines			•	
	2-22	Guidelines Master Plan for Quality Improvement	Master Plan				
	2-21	Health Workforce Development Plan Special Operating Agency (SOA)	Plan Guidelines				
		Fund, Vouchers, Exemption System		,	2010-2015		
		based health insurance, Health Equity					

		Education and Reduction 2011-2015				Khmer
	4-12	WHO FCTC	International Convention	2003	hard copy	Khmer
	4-13	SUB-DECREE dated 24 February 2011 ON ADVERTISING OF TOBACCO PRODUCTS	Sub-decree	February 24, 2011	pdf	Khmer
	4-14	PRAKAS dated 01 April 2011 ON MEASURES FOR THE BANNING OF TOBACCO PRODUCT ADVERTISING	Prakas	April 24, 2011	pdf	Khmer

4.2.2. Pilot Test Results: Appropriateness of the Tool and Potential for Use

The pilot test was intended to check whether the tool (see Annex 1) is usable, identifying the difficulties using the tool, exploring how the tool can be improved, and how the analysis tool can be used in the future.

4.2.2.1. Appropriateness of the Tool

Initial analysis shows that the tool was useful to provide an overview of a country's existing public health law and legislation. All individual four teams that performed the initial pilot test agreed that the tool was fairly useable. Results of the pilot test showed that the analysis tool was generally usable, but there was important feedback regarding the purpose, uses, structure, wording, appropriateness and the need for qualitative aspects of the tool.

There was an initial feeling that the tool was too detailed for cross country comparison. On the other hand, for academic analysis, it was felt that the tool was not specific enough and had too much space for interpretation. However on the positive side, the tool was seen as being very useful for capacity building and education purposes. Finally, the experts came to a consensus that a WHO implied non-compliance to international standards could be risky and controversial. As such, it was agreed that the tool would be neutral, general and broad, and just be a tool to assess the public health law situation in countries.

4.2.2.2. Suggestions for Improving the Tool

For its purpose, the experts agreed that the term 'public health law' would encompass law, legislation and subsidiary legislation, which would include regulations but not policies. Most of the experts agreed that someone with legal competency or a team with legal expertise should fill out the tool initially. However, they also argued that government officials should double-check the contents of the tool once it was filled out. Responsible officers in the government may or may not have a legal background, so a team approach or a stepwise approach was considered adequate. Development of a user's guide which would help the users in filling out the tool as well as in guiding the possible uses of the tool was supported by all. It was also suggested that the public and private sectors should simultaneously go over the tool to avoid bias. The suggestion to engage consultants to fill out the tool was dismissed because it was not aligned with the additional goal of the tool which is to build the capacity of in-country officials.

In terms of structure and contents of the tool, the simple 'yes or no' format of the analysis tool was raised as an issue. It was uncertain whether 'no' should be interpreted as 'no law regarding the issue' or 'don't' know'. As such, the questionnaire should be modified to allow further explanation or clarification. It was also noted that similar questions were posed in various part of the tool. Tidying up the redundancies and clarifying the wording of the questions were deemed necessary. The experts agreed that the contents of the tool was comprehensive overall, covering many of the vital issues in public health and international health agendas. How the information collected through this analysis tool could be transformed into a codified set of information would be discussed in subsequent consultations.

4.2.2.3. Possible Use of the Tool

The main goal and purpose of the tool would be to assist countries to assess their own laws and regulations, enable cross-country comparisons of public health law (once sufficient data is collected) and assess compatibility of a nation's public health law with international policies and values. Also, the tool would be a guide for supporting countries in assessing the scope, completeness and adequacy of their public health law, hopefully increasing their ownership of it. The tool is also meant to help people learn about both international and domestic law and identify possible gaps. Lastly, it can also be used for capacity building of the officials, students, and other relevant personnel.

The initial analysis of the pilot test was presented during a 2nd expert meeting and thereafter further adjusted for subsequent implementation in other countries. Feedback from the experts was reflected in the revised assessment tool, which was shared among the experts for future review. The concept of the public health law assessment tool was successfully presented at the public health law session of the 43rd Asia Pacific Academic Consortium for Public Health (APACPH) on 20 October 2011, thereby promoting awareness among countries in the region.

4.2.2.4. Suggestions for Establishing the Assessment Process

The questionnaire tool does not specify who is expected to undertake the completion and/or from what discipline such as health or law that person was expected to come. If it is envisaged that this questionnaire is to be completed by Ministry of Health (MoH) personnel, a number of things need to be considered and clarified. In terms of scope, it needs to be articulated as to whether MoH personnel should confine themselves only to those laws administered by their Ministry or if they are expected to identify and refer to (health and other) legislative provisions from other areas, such as criminal law, environmental law, immigration law, etc. Through the test we considered a team approach.

There are also a number of capacity issues that arise during the implementation of the tool. First, the questionnaire is in English but is almost certain to be completed by a non-native English speaker. In addition, the questionnaire presumes a high level of familiarity with legal provisions, where to find them and how to read them in order to identify which specific sections apply in each particular case. And it is important to note that public health legislation is likely to be scattered in other places, some of which might be quite obscure. This is borne out by comments received from the Director of Public Health. (WHO/WPRO 1st Expert Consultation Meeting Report, 2011) Within the department they have copies of the main pieces of legislation such as the Public Health Act but not other pieces of legislation that also contain public health provisions for example, the Employment Act or the Immigration Act.

Even as a legal research exercise, the tool was found to be quite cumbersome and time consuming. This was particularly because the process is made more complex and laborious by having to refer to the different parts of the information in order to ascertain the meaning of the question or to determine what information is required. Even with referral to the attached information it was sometimes difficult to ascertain the meaning of the question and different people may answer the same question differently due to differences in interpretation.

As a consequence, to facilitate the use of the tool in other countries some considerations may need to be given to providing for assistance to help countries to complete the tool. First, preparing a simple user's guide to the tool which explains in a step wise way how to go about completing the tool including explaining what is required for the more complex questions. Second, it would be better to complete the first cut of the tool using internet resources before testing the results with the country. This should speed up the process for the country and should be less time consuming for officials in-country. Third, using the opportunity and resources provided by another project, for example another

WHO assignment dealing with countries public health legislation as an opportunity to complete the tool for a country.

4.2.3. Implementing Test Results: Developing the Assessment Process Model

For testing the assessment process model, the Kingdom of Cambodia was designated as pilot study country because the government of Cambodia and the WHO Cambodia country office were favorable for this assessment. First of all, to get concurrence, the WHO Regional office sent an official letter to the WHO Representative in Cambodia to ask him to communicate with the Ministry of Health. This letter included the 1) introduction of the tool, 2) a description of the use of the tool and how it will benefit the country, 3) a request to designate an academic institution for supervising the whole process, 4) specifications for the qualification of the local researcher, and 5) asked the government to recommend a possible candidate for the local researcher position. (see Figure 2)

Asking Asking WHO concurrenc concurrenc WRs MoH **WPRO** Noticing MoH's Acceptant Letter acceptance APW for in-country Designating the LR after analysis discussion Accepting by WPRO **Academic** Communicating with LR Desk Review of Tool Local • Filed Visit Research Compile the list of Local Researcher Institute Consultants Arrange the meetings between SE, LC Communication continuously Designated Local Local Local **Expert** Consult Consult Consult

Figure 2. Flow Chart for the Team Process of Implementation Test of the Kingdome of Cambodia

Meanwhile, WHO Regional Office engaged with an academic research institution to conduct a literature search, interact with senior country officials and write a synopsis of information into a short readable report focusing on the specialist public health law area. For selection of the institution, it needed to have the following competencies, 1) expertise in public health law in more than one country, 2) ability to effectively search the internet for the country's health law materials, 3) experience in communicating with senior officials of different countries and cultures, 4) proven record in synthesizing information expecially on health systems and health law situation in countries into a short readable product, 5) capacity to document process and lessons learned from experience, and 6) excellent written and oral English.

Subsequently, between the designated academic institution and recommended local researcher by Ministry of Health and WHO Country office there will be an official contract with specific terms of reference. The local researcher should have strong background in public health legislation. Although legal training is not essential, the local researcher should be familiar with the country's laws in general, such as constitutional or civil or criminal codes that relate to public health. The local researcher may be affiliated with an institute or a university working with public health law and policy. Moderate to good English proficiency would be preferable.

Under supervision of designated academic institution, the local researcher will initially respond to the questions in the assessment tool to the best of the local researcher's knowledge with assistance from (the) expert(s) in the academic institution. Then the local researcher will identify those parts of the assessment tool where the academic expert will need to interview other legal experts in the country for further discussion.

After that, the local researcher will arrange for interviews between the academic expert and other local expert in the country as necessary including compiling a list of the other legal experts by name, title and organization, date,

time, and location of the meeting, contact information including telephone, e-mail, and street address both for experts and their administrative assistants, and reason why they have been selected to be interviewed. Other local experts who should possess superior knowledge of public health legislation in the country, as well as involvement in the legislative process, policy-making, and enforcement, may include senior government officials or members of professional associations and academic or training institutions. When designated academic expert visit the country, local researcher assist the designated academic expert with verbal translations during the interviews if necessary.

Lastly, the local researcher is expected to 1) compile a list of the relevant legislation pertaining to the responses in the assessment tool including primary legislation and subsidiary regulations, 2) obtain physical and electronic copies of law(s) itself, in English where available and web links to the relevant legislation, and 3) assist the designated academic expert with for the analysis of the date collected in the tool. The final results should be reviewed by government officials in the Ministry of Health for quality control.

4.2.4. Identified Challenges though Analysis Process and Suggesting for future assessment

4.2.4.1. Importance of Getting Concurrence from Government

Most difficult thing during the whole process was getting the concurrence from the Ministry of Health and WHO Country Office (CO). Due to WHO's diplomatic protocols, the Regional office cannot communicate with the government directly but has to pass through the CO. However, the CO has a lot of other projects to implement so the in-country assessment in public health law may not be their priority. So, one needs to convince them first before proceeding with the communication with the Ministry of Health. In this process, many stakeholders including officers in MoH, counterparts in WHO Country

office, staffs in WHO Regional Office, and the designated academic institution were involved in communication just to all stakeholders understand and agree with the assessment activity before it starts.

The agreement with and from the Ministry of Health is essential. During the process, the local researcher has to rely on the government officers' help to discuss or fill the tool; called upon in government as there are many different areas where legislation could exists in the Ministry of Health. Not only for the process of the assessment but also later on for the practical use and review of the result one needs to involve the MoH. After finalizing the in-country assessment, the synthesized results of public health law status and gaps in country should be fed back to the government to inform them what has been collected and further improvement if necessary. If there is no consent for such procedures, the results may not be approved by the government later. Finally, agreement from the MoH is essential because it is the official host to the WHO and the WHO is an intergovernmental organization serving the Ministry of Health in member countries.

Therefore receiving the government concurrence from government is of the essence though it requires much time and effort; it is indispensable for a successful outcome of the assessment.

4.2.4.2. Quality Control of Local Researcher

The reason for the involvement of a local researcher rather than solely leaving it to the designated academic institution was that a local person can grasp much better the country situation including its culture, social, and political background. Also, the local researcher will understand the local legislative process better. From conducting the process implementation test in Cambodia, it was confirmed that the local researcher's qualification and ability to quality control the answers are very important.

In the previous pilot tests, health law experts who already familiar with health law were involved. However, in Cambodia the local researcher was not a public health law expert, but a public health specialist. In terms of local researcher, ideally it should be a public health law expert who has knowledge and experience of public health and legal issues. However, it is recognized that finding such qualified experts may be difficult in many developing countries. Such persons may only be found in local academic institutions.

Another useful qualification for the local researcher (as found in Cambodia), was having experience in or with the Ministry of Health. During the assessment process, the engagement of government officials is essential. If the local researcher has no experience or connection with government officers in Ministry of Health, support from the government may be difficult. Also, the local researcher's English proficiency is essential. The tool is made in English, related information for filling the tool such as International Digest of Health Legislation (IDHL), International Health Regulation (IHR), and Framework Convention on Tobacco Control (FCTC) are also written in English. In addition, if possible the English version of the country's laws should be collected aside from the local language versions. So, if local researcher has poor English, processing would be difficult.

Lastly, a pre-training program for local researchers was raised. Even when the designated academic expert had communicated extensively by e-mail with the local researcher in Cambodia before visiting the field, the local researcher did not understand what the purpose of the tool was, the scope of the law, and the process of the assessment. So, before starting the in-country analysis in the field, it is recommended that a training program should be provided for local researchers to improve their general understanding of this assessment. The program may contain: 1) understanding of public health law and international health law, 2) purpose, vision, and goal of the tool, 3) contents of the tool and methods to filling it up, 4) the assessment process, and 5) reporting of the final result, including quality control of the output.

4.2.4.3. Role of the Academic Institution and Local Researcher

Initially, most of the responsibility for the pilot test was imposed onto the designated academic institution. They would play the leading role in assessment and the local researcher was there just to support the academic institution. However, though the implementation test, it was found that the local researcher should play a much quarter role. The local researcher can understand the country situation much better than a foreign academic institution. Also, through this process the local researcher can improve their understanding of the health law situation in country, while at the same time contribute to capacity building and upgrade legal literacy in the country.

So, conducting the in-country assessment including desk review, interviewing or meeting with local experts, and preparing a synthesized report by local researcher is recommended. As academic institution, they can provide a training program for local researchers and supervise the local researchers when they have questions or face difficulties during the assessment process. Academic Institutions' country visits can therefore also be minimized for these reasons. However, field visits may still be required in some cases, where there is a serious problem for conducting the assessment.

4.2.4.4. Standardizing the Reporting Form and Result Template

To assist local researchers with compilation of the results standardizing the final report among countries, there was forward to be a need for a reporting form [Annex 2] and final results template [Annex 3]. Those two forms contain similar contents, but the purpose and period when to use are different. The reporting form is made in an Excel file for the local researcher to fill-in the tool and related information during the assessment process. The result template is used for feedback to government in country after finalizing the assessment. It contains synthesized results including profiling the health laws and most important gaps in the country.

The reporting form includes the background, objective and purpose of the analysis, legal system in specific country, total process of the analysis, and result of the analysis. In background, there is a description of 1) general public health law situation in specific country, 2) advanced research or history of similar analysis in the specific country, 3) necessity and meaning of public health law analysis, and 4) expected outcome and impacts of assessment. In addition, the total process of the analysis including timeframe, participants, consultation process, data collection process, desk review method including analytical methods, related website references, completion percentage of the tool should be described.

4.2.4.5. Importance of Gathering Human Resources Information

Considering the purposes of the framework both collecting the law and networking between health legal related persons, i.e. human resource information should be added to the reporting contents. Especially in cases where the local researcher cannot find local experts or is unfamiliar with certain aspects of the tool or with some legal issues, it may be useful to find and identify relevant resource persons that can later be used for networking or more detailed meetings. Specifically, if a health legislation officer in the Ministry of Health exists in the country, s/he may be a useful contact for close collaboration

For profiling such expert human resources for health law in countries, name and contact number as well as specific questions for gathering such an experts list is needed. For example, such specific questions could be 1) Is there a person who in charge of the law in the Ministry of Health in your country?, 2) Is there a person who in charge of the public health in the Ministry of Justice in your country?, 3) Does your country have the health related committee in parliament?, 4) Is there a institution working on public health law?, 5) Is there a academic consortium for public health law?, 6) Are there lawyers or legal professionals who are specialized in health?, and 7) Is there a department related to medical law or health law in the university?

4.2.4.6. Importance of Gathering Country Background

The initial tool focused on the existence of health related legislation, but less so on the background information. However, understanding a synthesized public health law situation in a country needs prerequisite understanding of basic information of the country including its social, political, legal system. General information contains 1) general information of the legal system, 2) categorization of the legal system such as civil law, common law, religious law, or combination law system, 3) unique history about country's legal system. In terms of government structure: 1) basic forms of government, 2) government structure such as con-federal, federal, imperial, or unitary, 3) perceived power sources such as democracy, monarchy, and oligarchy, and 4) the administrative, legislative and judiciary systems can be included.

Because there are both primary and secondary sources of law in a country, each jurisdiction will have its own hierarchy or legislation. In order to assess the legislative level required for new legislation, it is necessary to examine the hierarchy and to appreciate: what forms of legislation can be created at each level; who has the power to create such legislation and how such legislation is to be created.

This background information can also help to increase understanding of how laws are crafted, which might be of use to multiple countries in the region. Systems of law can generally be classified as being either a civil law system or a common law system. The characteristics of the two systems differ and they have different sources of law. A source of law refers to a source in the particular legal system that has the authority to declare a rule to be a law. Understanding the legal system in countries is also essential. It includes 1) major characteristic of the country's legal system, 2) legal hierarchy, 3) legislative branch or lawmaking process, 4) name and explanation in each basic code, 5) description of other forms of laws, and 6) relationship between international law and treaties and domestic laws. These processes help to understand a country's situation in

public health law making and its organization which be used in grouping when analyzing the results among countries.

4.2.4.7. Receiving Feedback for Tool Itself and Assessment Process

The in-country assessment process and the development of the assessment tool are not yet finished but part of an ongoing process. Upgrading the tool and developing other modules are needed, as well as finding a more efficient and effective way for conducting the assessment project should be identified continuously. So, getting feedback from involved persons such as local researchers and local experts would be helpful in this process on 1) the suitability or appropriateness of the tool, 2) difficulties using the tool, 3) how the tool should be improved, 4) how the analysis tool can be used, and 5) other possible comments.

4.2.5 Comparative Analysis Results: Focusing the Existence of Law

The framework can assist in assessing the laws of countries, in conducting cross-country comparisons of public health law, and in accessing the compatibility of the nation's public health law with its policies and values. The primary purpose of the in-country analysis is for understanding the public health law situation including the most important gaps with international standard or policies in each country. In this case, a report for each country can be made for understanding the specific country situation, feedback for government and public information disclosure. For this kind of the result application, i.e. comparison, it is important to establish an essential health legislation list.

Another way is for using it as cross country comparison. First of all, a 'yes or no' based country comparison is possible. (see Table 8) Here it is

focused on the definition of the answer 'no' which means that a country does not have any legal background in specific issues or matter. Secondly, a legal system based comparison can be undertaken by grouping countries by legal system for using enacting or legislating process, or process for enacting primary legislation. Thirdly, one can group it on the basis of public health law coverage in high, medium or low coverage countries.

To illustrate, as a horizontal comparison perspective, with regards to the existence of constitutional provisions related to health, three countries including Republic of Korea, Philippines and Kingdom of Cambodia responded yes, and two countries Samoa and Vanuatu responded no. In respect to existence of law relating to health research for example government support or permit, three countries including Republic of Korea, Philippines, and Samoa said yes, and Vanuatu and Kingdom of Cambodia answered they don't have any related provision or articles in their law.

Similarly one can take a vertical comparison perspective, where e.g. the Republic of Korea has laws covering almost each legal area. However, Philippines indicated less health law coverage than Republic of Korea. Especially, Philippines has no legal ground for 1) human reproduction and population control, 2) care of the disable and rehabilitation, 3) mental health, 4) death and dying, and 5) health information. Through such a perspective, the focus area in the Philippines can be easily identified.

Table 8. Comparative Analysis Result – Yes/No Box

MODULE 1: International Digest of Health Legislation							
	Questions	ROK	PHL	SAM	VAN	CAM	
1.	Does your country have constitutional provisions relating to health?	O	O	Х	Х	0	
2.	Does your country have law(s) relating to human rights and other fundamental rights that pertain to health?	O	•	X	X	0	
3.	Does your country have law(s) relating to international treaties and other international instruments that pertain to health? (If so, please provide a brief overview of your legal system and explain how such international obligations are incorporated into the system. Also, please list the	•	•	?	?	•	

	international treaties and instruments to which your country is a signatory.)					
4.	Does your country have law(s) relating to the organization and/or administration of health care (e.g., general governmental health and public health agencies, including ministries, boards, councils)?	O	•	•	O	O
5.	Does your country have law(s) relating to health financing (e.g., taxation, social security, health insurance, cost containment)?	•	•	•	O	O
6.	Does your county have law(s) relating to health research (e.g., government support, permits)	O	O	O	Х	Х
7.	Does your country have law(s) relating to health education (e.g., information the public, health promotion, access to information)	0	?	0	x	х
8.	Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)?	O	O	0	•	•
9.	Does your country have law(s) relating to health care facilities, related institutions, and/or services?	O	O	O	O	O
10.	Does your country have law(s) relating to communicable diseases?	O	O	O	•	0
11.	Does your country have law(s) relating specifically to HIV/AIDS, including criminal laws, immigration laws, and/or family laws?	•	•	•	O	O
12.	Does your country have law(s) relating to organ transplantation and/or human tissues, including blood and blood products?	0	O	?	?	х
13.	Does your country have law(s) relating to non- communicable diseases?	O	O	O	X	X
14.	Does your country have law(s) relating to oral health (e.g., fluoridation)?	O	O	O	Х	х
15.	Does your country have law(s) relating to family health (e.g., family counseling, genetic counseling, maternal health and care programs, prenatal care, prenuptial examinations, sex education)?	O	O	Х	•	O
16.	Does your country have law(s) relating to child health (e.g., abuse of children, adolescent health, child labor, daycare facilities, infant care, school health program)?	•	•	O	O	O
17.	Does your country have law(s) relating to human reproduction and/or population control?	O	X	X	X	•
18.	Does your country have law(s) relating to care of the elderly (e.g., basic care arrangements, geriatric programs, old-age homes)?	O	O	X	x	O
19.	Does your country have law(s) relating to care of the disable and/or rehabilitation (e.g., basic care arrangements, mobility and access arrangements, sheltered workshops)?	O	X	O	•	O
20.	Does your country have law(s) relating to mental health?	O	X	\mathbf{O}	\mathbf{O}	X
21.	Does your country have law(s) relating to the control of smoking and/or use of other tobacco products?	O	O	O	O	•
22.	Does your country have law(s) relating to the control of alcohol use?	0	Х	O	O	Х
23.	Does your country have law(s) relating to the control of drug abuse (e.g., control of narcotics and other illegal substances, addition treatment, criminalization)?	O	O	0	O	O
24.	Does your country have law(s) relating to biomedical ethics and/or professional responsibility (e.g., research ethics, confidentiality, advertising, codes of conduct, disciplinary	O	O	O	X	O

	measures, civil and/or criminal liability for wrongdoing)?		•					
25.	Does your country have law(s) relating to death and dying (e.g., euthanasia, living wills, determination of death, registration of death)?	0	Х	O	X	x		
26.	Does your country have law(s) relating to post-mortem examinations?	O	O	O	O	X		
27.	Does your country have law(s) relating to the disposal of the dead?	O	O	O	O	х		
28.	Does your country have law(s) relating to nutrition (e.g., food fortification, infant foods, malnutrition, nutritional services and education)?	O	O	X	X	•		
29.	Does your country have law(s) relating to food safety (e.g., adulteration and additives, inspection, irradiation, import and export controls, packaging and advertising, pesticides and veterinary pharmaceutical residues, handling and distribution)?	•	•	•	0	•		
30.	Does your country have law(s) relating to the safety of consumer products (e.g., toys, kitchen utensils, appliances, ceramics)?	O	0	O	Х	•		
31.	Does your country have law(s) relating to pharmaceuticals and/or related products?	O	O	O	O	•		
32.	Does your country have law(s) relating to traditional medicines?	O	O	0	X	•		
33.	Does your country have country law(s) relating to medical devices?	O	O	?	?	•		
34.	Does your country have law(s) relating to poisons and/or other hazardous substances?	O	O	O	O	•		
35.	Does your country have law(s) relating to occupational health and safety?	O	O	0	O	0		
36.	Does your country have law(s) relating to environmental protection as it pertains specifically to human health (e.g., sanitary standards for housing, water/air quality, pollution, waste disposal)?	•	0	O	•	O		
37.	Does your country have law(s) relating to radiation protection?	O	O	C	Х	0		
38.	Does your country have law(s) relating to accident prevention (e.g., health requirements for drivers, educational programs, road safety, safety in air travel)?	0	0	0	0	•		
39.	Does your country have law(s) relating to sports and recreation (e.g., doping, safety/hygiene of swimming pools, sports medicine)?	O	0	0	0	•		
40.	Does your country have law(s) relating to health information (e.g., vital statistics, notification of disease), including provisions relating to the role of the private sector in obtaining and/or maintaining such information and statistics?	•	х	O	х	х		
MODULE 2: Health Systems based on Primary Health Care Values								
	Questions	ROK	PHL	SAM	VAN	CAM		
1	 Does your country have law(s) mandating health authority to develop national health plans, policies, strategies, and/or frameworks? 	O	Х	O	Х	•		
2	Does your country have law(s) mandating health authority to implement and monitor nation health plans, policies, strategies, and/or frameworks?	O	Х	O	X	•		
3	Does your country have law(s) mandating health authority to engage in coalition-building with stakeholders outside the health sector?	0	Х	•	х	х		

4.	Does your country have law(s) relating to the provision of health financing (e.g., taxation, social security, health insurance, cost containment)?	0	0	•	O	x
5.	Does your country have law(s) relating to the provision of minimum health services for your citizens?	X	O	X	?	X
6.	Does your country have law(s) relating to safety-net mechanisms for your citizens to protect them from financial disaster due to health expenditures?	0	•	•	X	x
7.	Does your country have law(s) relating to maintaining numbers of health workers (e.g., production, deployment and retirement, international recruitment)?	O	•	x	Х	х
8.	Does your country have law(s) relating to classification among various types of health workers?	0	O	•	Х	0
9.	Does your country have law(s) relating to the distribution of health workers?	0	X	Х	Х	O
10	 Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)? 	O	х	•	O	O
11	Does your country have law(s) relating to the protection of patients as health consumers (e.g. patient bill of rights, including access to services and medical technologies, right to receive health interventions at a time and location of their choosing)?	?	?	•	x	x
12	2. Does your country have law(s) relating to monitoring the performance of your health system (e.g., quality control of services)?	0	X	•	X	x
13	Does your country have law(s) relating to the access of essential medicines?	0	O	•	X	0
14	Does your country have law(s) relating to quality control, cost effectiveness, safety, efficacy of medicines and medical technologies?	0	•	•	Х	•
15	 Does your country have law(s) relating to the access of vaccines? 	O	O	X	X	X
16	Does your country have law(s) relating to quality control of vaccines (e.g., cold chain requirements)?	?	?	Х	Х	X
17	7. Does your country have law(s) relating to the use of information technology in health care?	O	X	X	X	X
	MODULE 3: International Health Re	gulatio	ns (20	05)		
	Questions	ROK	PHL	SAM	VAN	CAM
	Does your country have law(s) relating to the designation or establishment of a National IHR Focal Point? (See Article 4)	O	X	Х	Х	0
	Does your country have law(s) relating to the designation of the authorities responsible for public health risks and public health emergencies of international concern? (See Article 4)	•	X	x	x	O
	Does your country have law(s) relating to the capacities for surveillance and notification of public health risks and public health emergencies of international concern? (See Articles 5-10, Annex 1)	•	х	•	х	х
	Does your country have law(s) relating to the capacities for public health response to public health risks and public health emergencies of international concern? (See Article 13, Annex 1)	•	X	O	x	x
	Does your country have law(s) relating to the capacities for public health response at designated points of entry, including airports, ports, and ground crossings? (See Articles 19-22. Annex 1)	•	•	•	0	х

6.	Does your country have law(s) relating to health measures for travelers? (See Articles 23, 30-32, 35, 42-43)	O	O	0	0	Х
7.	Does your country have law(s) relating to certificates of vaccination or other prophylaxis for travelers? (See Article 36)	O	O	O	X	х
8.	Does your country have law(s) relating to charges for health measures regarding travelers? (See Article 40)	0	X	Х	0	х
9.	Does your country have law(s) relating to health measures for baggage, cargo, containers, conveyances, goods, postal parcels, and/or human remains? (See Articles 23, 33, 35, 43)	•	O	O	Х	х
10.	Does your country have law(s) relating to charges for health measures regarding baggage, cargo, containers, conveyances, goods, postal parcels, and/or human remains? (See Article 41)	•	X	•	•	х
11.	Does your country have law(s) relating to the application of health measures on containers and/or container loading areas? (See Article 34)	O	O	O	X	х
12.	Does your country have law(s) relating to the responsibilities of conveyance operators with respect to health measures? (See Articles 23, 24, 35, 42-43)	O	O	O	O	х
13.	Does your country have law(s) relating to health measures for conveyances in transit? (See Articles 23, 25-26, 27, 42-43)	O	?	O	O	х
14.	Does your country have law(s) relating to health measures for conveyances at points of entry? (See Articles 23, 27, 28-29, 35, 37-39, 42-43)	O	O	X	O	x
15.	Does your country have law(s) relating to health documents for conveyances? (See Articles 37-39)	0	O	Х	Х	х
16.	Does your country have law(s) relating to collaboration and assistance with other States Parties and/or WHO with regard to public health risks and public health emergencies of international concern? (See Article 44)	•	O	O	x	?
17.	Does your country have law(s) relating to the treatment of personal data received from another State Party and/or WHO with regard to public health risks and public health emergencies of international concern? (See Article 45)	x	x	x	x	x
18.	Does your country have law(s) relating to biological substances, reagents, and materials for diagnostic purposes with regard to public health risks and public health emergencies of international concern? (See Article 46)	•	•	х	х	х
	MODULE 4: Framework Convention o	n Toba	ссо Со	ntrol		
	Questions	ROK	PHL	SAM	VAN	CAM
1.	Does your country have law(s) relating to national tobacco control strategies, plans, or programs? (See Article 5)	X	?	?	?	?
2.	Does your country have law(s) relating to the pricing and/or taxation of tobacco products? (See Article 6)	O	O	O	X	0
3.	Does your country have law(s) relating to the protection from exposure to tobacco smoke? (See Article 8)	O	C	O	O	C
4.	Does your country have law(s) relating to the regulation of the contents of tobacco products? (See Article 9)	O	C	O	X	Х
5.	Does your country have law(s) relating to the regulation of tobacco product disclosure? (See Article 10)	O	C	O	O	Х
6.	Does your country have law(s) relating to the packaging and labeling of tobacco products? (See Article 11)	O	O	O	O	O
7.	Does your country have law(s) relating to education, communication, training, and/or public awareness of tobacco issues? (See Article 12)	O	O	X	X	O

8.	Does your country have law(s) relating to tobacco marketing, including advertising, promotion, and sponsorship? (See Article 13)	0	O	O	O	0
9.	Does your country have law(s) relating to tobacco dependence and cessation? (See Article 14)	X	•	X	X	?
10.	Does your country have law(s) relating to illicit trade in tobacco products? (See Article 15)	O	O	O	X	•
11.	Does your country have law(s) relating to sales to and by minors? (See Article 16)	O	0	0	O	х
12.	Does your country have law(s) relating to the provision of support for economically viable alternatives for tobacco workers, growers, and/or individual sellers? (See Article 17)	O	O	Х	х	х
13.	Does your country have law(s) relating to the protection of the environment and the health of persons in respect of tobacco cultivation and manufacture? (See Article 18)	O	O	Х	x	x
14.	Does your country have law(s) relating to criminal and/or civil liability, including compensation, with respect to tobacco products? (See Article 19)	O	O	Х	O	х
15.	Does your country have law(s) relating to research, surveillance, and exchange of information with respect to tobacco consumption? (See Articles 20-22)	•	?	Х	х	х

4.2.5.1. Health Law Coverage in the Republic of Korea

In Korea, all areas in the International Digest of Health Legislation (IDHL) are covered. "Constitution of the Republic of Korea" describe that all citizens shall have the right to a healthy and pleasant environment. The contents of the general provisions in IDHL are found in the "Framework Act on Health and Medical Services", the "Medical Services Act", the "National Health Insurance Act", and the "National Health Promotion Act". (Q.1-7)

Health Manpower section is mainly in the "Medical Services Act" and the "Regional Public Health Act". (Q.8) Health care facilities and services can be seen the "Medical Services Act". (Q.9) With regards to disease control and medical care, controlling and prevention of communicable diseases is found in the "Communicable Disease Control and Prevention Act" and the "Prevention of Acquired Immunodeficiency Syndrome Act"(Q.10-11) Also controlling and preventing the non-communicable disease is found in the "Framework Act on Health and Medical Services", the "National Health Promotion Act" and the "Framework Act on Health Examination".(Q.13) The "Internal Organs

Transplant Act" regulates the procedures includes blood transfusion, organ and tissue transplantation. (Q.12)

The "Dental Health Act" covers the section 5 of IDHL for oral health. (Q.14) With regards to family health and human reproduction issues, Korea has the "Framework Act on Healthy Homes", the "Mother and Child Health Act", the "School Health Act" and the "Infant Care Act". (Q.15-17). The "Act on Long-Term Care Insurance for the Aged" describe the care of the elderly, the "Employment Promotion and Vocational Rehabilitation of Disabled Person Act" specifies the responsibilities of the state and local governments on rehabilitation. (Q.18-19) The section 9 of the IDHL, mental health, is covered by the "Mental Health Act". (Q.20)

Control of smoking, alcoholism, and drug abuse can be seen in the "National Health Promotion Act", the "Tobacco Business Act" and the "Act on the Control of Narcotics, etc.". (Q.21-22) The "Bioethics and Safety Act" and "Internal Organs Transplant Act" state the ethical issues and professional responsibility (Q23-24) and death and related issues (Q.25-27). For nutrition and food, Korea has the "Framework Act on Food Safety" and some articles in the "Framework Act on Health and Medical Services" and the "National Health Promotion Act".(Q.28-29) With regards to consumer protection, there are the "Framework Act on Consumers" and some articles including rights of patients and health medical services personnel, and the right to know about health and medical services in the "Framework Act on Health and Medical Services". (Q.30)

Pharmaceuticals section is mainly in the "Pharmaceutical Affairs Act" and the "Medical Service Act" (Q.31-32), and Medical Device is covered by the "Regional Public Health Act". (Q.33) Section 16 of the IDHL, poisons and other hazardous substances is specified in the "Environmental Health Act" (Q.34), and Section 17, occupational health and safety is covered by the "Occupational Safety and Health Act". (Q.35) Also, Environmental protection is in the "Environmental Health Act" (Q.36), the "Radioactive Rays and Radioisotope Use Promotion Act" for radiation protection (Q.37), the "Traffic Safety Act" for

accident prevention(Q.38), and the "Sport Industry Promotion Act" for sports and recreation section(Q.39). The last question for health information and statistics, there are related articles in the "Framework Act on Health and Medical Services" and the "Medical Services Act".(Q.40)

4.2.5.2. Health Law Coverage in Philippines

In Philippines, most of the areas in the International Digest of Health Legislation (IDHL) are covered. The "Philippine Constitution" describes that the state shall protect and promote the right to health of the people and health consciousness among them as well as protect and advance the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature. (Q.1-2) Treaty or international agreements shall be valid and effective if concurred. (Q.3) The organization and administration of health care is mainly in the "Philippine Health Insurance Act 1995" including the Philippine Health Insurance Corporation and the Local Health Insurance Office. (Q.4) The contents of health financing is in the "Philippine Constitution" describing that the state shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost, and in the "Philippines Health Insurance Act 1995" specifying the National Health Insurance Fund. (Q.5) The health research related provision can be seen in "Executive order 784" about the Philippine Council for Health Research and Development. (Q.6)

Health Manpower is mainly described in the "Medical Act of 1959", the "Philippines Nursing Law of 2002", the "Philippine Midwifery Law" and "The Magna Carta of Public Health Workers". (Q.8) Health care facilities and services can be found the "Hospital Licensure Law". (Q.9) With regards to disease control and medical care, controlling and prevention of communicable diseases is in the "Code of Sanitation of the Philippine" and the "Philippine AIDS Prevention and Control Act of 1998"(Q.10-11) the "Blood Bank Law", the "Anti-Graft Corrupt Practices Act" and the "Organ Donation Law" regulates

the procedures includes blood transfusion, organ and tissue transplantation. (Q.12) Also controlling and preventing the non-communicable disease is found? (Q.13)

The "Philippine Dental Act of 2007" covers section 5 of IDHL for oral health. (Q.14) With regards to family health and child health, Philippines has the "Generic Act", the "Mandatory Infants and Children Health Immunization Act of 2011", the "Newborn Screening Act of 2004" and the "Child Abuse Law" (Q.15-16). Although, Philippine doesn't have the human reproductive related law yet, the "Reproductive Health Bill" and the "Responsible Parenthood Bill" is still being debated in the House of Representatives and the Senate (Q.17). The "Expanded Senior Citizens Act of 2003" describes the care of the elderly (Q.18), but there is no active in suggesting laws on rehabilitation medicine (Q.19). However, because the "Philippine Constitution" includes the article that there shall be priority for the needs of the under-privileged sick, elderly, disabled, women, and children, it can be expected to enact the law for disabled person's care.

The section 9 of the IDHL, mental health, isn't covered by the current laws but, there is a pending Bill in the House Representatives entitled the "Early Detection and Intervention Services for Children with Mental illness (House Bill no. 2609) (Q.20) Control of smoking and drug abuse can be seen in the "Tobacco Regulation Act of the Philippines" and the "Dangerous Drugs Act of 2002". (Q.21-23) With regards to control of alcohol use, there is a pending legislative bills in the legislative body entitled the "Anti-Drunk Driving Act" (Q.22).

For biomedical ethics and professional responsibility, Philippines has the related section in the "Medical Act of 1959" as well as the "Code of Ethics of Medical Profession" which is not a law but internal rules of each health care profession (e.g. Nurses) except the medical profession (doctor) which in the law. (Q.24) The "Code of Sanitation of the Philippines" states the death and related issues (Q.25-27). For nutrition and food, Philippines has the "Regulation of

Practice of Nutrition and Dietetics in the Philippines" and some articles in the the "Philippine Constitution" and the "Code of Sanitation of the Philippines" (Q.28-29) With regards to consumer protection, there are "The Consumer Act of the Philippines" (Q.30).

Pharmaceuticals are mainly covered in the "Food, Drug, and Cosmetic Act" (Q.31), traditional medicine is covered by the "Traditional and Alternative Medicine Act of 1997" (Q.32), and Medical Device is covered by the "Medical Technology Law". (Q.33) Section 16 of the IDHL, poisons and other hazardous substances is specified in the "Label, Sale and Distribution of Hazardous Substance" (Q.34), and Section 17, occupational health and safety is covered by the Presidential Decree on "Occupational Health and Safety". (Q.35) Also, Environmental protection is in the the "Philippine Clean Air Act of 1999" (Q.36), "Creating Radiation Health Office" for radiation protection (Q.37), "Granting the Metropolitan Manila Commission Powers related to Traffic Management" for accident prevention (Q.38), and "The Philippine Sport Commission Act" for sports and recreation section (Q.39). The last question for health information and statistics, there is no specific law, but Philippine Department of Health has a website on the health information and statistics about health and disease. (Q.40)

4.2.5.3. Health Law Coverage in Samoa

In Samoa, most of the areas in the International Digest of Health Legislation (IDHL) are covered that coverage rate is similar with Philippines. The Constitution of Samoa includes the "right to life" but no explicit provisions relating to health. (Q. 1-2) The organization and administration of health care is mainly in the "National Health Services Act 2006", the "Ministry of Health Act 2006", the "Healthcare Professions Registration and Standards Act 2007", the "Medical Practitioners Act 2007", the "Nursing and Midwifery Act 2007", the "Pharmacy Act 2007", and the "National Kidney Foundation of Samoa Act 2005" (Q.4). The contents of health financing are in the "Ministry of Health Act 2006". The "National Health Services Act 2006" provides for the Ministry of

Health to determine fees and charges for health services. The "Accident Compensation Act 1989" provides for employer and other source of funds. The "National Kidney Foundation of Samoa Act 2005" lists raising funds as a function of the foundation. Lastly, the "National Provident Fund Act 1972" provides for the establishment of a Health Care Scheme (Q.5).

The health research related provisions can be seen in the "Ministry of Health Act 2006" listing health research as a responsibility of the Ministry of Health to provide. The "Oceania University of Medicine Samoa Act 2002" provides that the University is to be a centre of excellence for research in health and medical care. The "Accident Compensation Act 1989" contains provisions for research to reduce the number and severity of accidents, injuries and occupational diseases. The "National Kidney Foundation of Samoa Act 2005" provides for conducting and publishing research relating to the Foundation's purposes. (Q.6) The health education related provision can be seen the "Ministry of Health Act 2006" listing health education as a responsibility of the Ministry of Health. The "Nursing and Midwifery Act 2007" contains provisions for nursing education. The "National Kidney Foundation Act 2005" contains provisions for healthcare education concerning kidney related diseases. The "Oceania University of Medicine Samoa Act 2002" provides for the operation of the University as a training provider. (Q.7)

The Health Manpower section is mainly in the "National Health Services Act 2006" containing provisions for staff and other personnel. Health professional practice is regulated under the "Healthcare Professions Registration and Standards Act 2007", the "Medical Practitioners Act 2007", the "Nursing and Midwifery Act 2007", the "Dental Practitioners Act 2007", and the "Pharmacy Act 2007" (Q.8). Health care facilities and services can be seen the "National Health Services Act 2006", especially Part III 11. Management and arrangement of health services, institutions and bodies, and extensive rules and guidelines are in Part VI (Q.9).

With regards to disease control and medical care, the "Health Ordinance 1959" contains extensive provisions for preventing the spread of communicable diseases, including requirements for dwellings and buildings (Part II), nuisances that are dangerous to health (Part III), and Part IV Infectious Diseases. The "Education Act 2009" provides for the exclusion of students with diseases or infestations from school. The "Samoa Water Authority Act 2003" provides powers for the Director-General of Health with regards to the water supply in Samoa. The "Immigration Act 2004" places requirements on operators of conveyances to provide information. The "Disaster and Emergency Management Act 2007" provides for emergency powers to deal with matters which include disease outbreaks. (Q.10) Though there are provisions in the Health Ordinance which have general application to communicable disease including HIV as well as to the Ministry of Health's functions in terms of health education, health promotion and disease prevention, UNDP, SPC and UNAIDS have undertaken a stock take of Samoan legislation to assess the legal environment relating to HIV in Samoa. (Q.11)

Controlling and preventing the non-communicable disease related provision is mainly in the "National Kidney Foundation of Samoa Act 2005", the "Mental Health Act 2007", the "Tobacco Act 2008", and the "Accident Compensation Act 1989 (3rd Schedule Section 25)". (Q.13) The "Dental Practitioners Act 2007" covers the section 5 of IDHL for oral health. (Q.14) With regards to child health, Samoa has the "Infants Ordinance 1961" providing for the protection of children (Part III). The "Accident Compensation Act 1989" provides special provisions for young persons. The "Health Ordinance 1959" provides for the medical examination of school children. The "Education Act 2009" provides for the exclusion of students with diseases or infestations, provisions regarding employment of school-aged children, student welfare in schools and early-childhood education centers. The "Labor and Employment Act 1972" provides that it is unlawful to employ a child under the age of 15 years except in safe and light work suited to his/her capacity. The "Disaster and

Emergency management Act 2007" provides for plans by educational institutions to protect the welfare of students in a disaster and emergency. (Q.16)

Samoa doesn't have the law or provisions related to human reproduction and care of the elderly. (Q.17-18) However, with regards to care of the disable and rehabilitation, the "Accident Compensation Act 1989" includes provisions for rehabilitation, including provision of artificial limbs as well as the "Education Act 2009" contains provisions for establishing the suitability of education for children with special needs. (Q.19) The "Mental Health Act 2007" provides for the care, support, treatment and protection of persons with a mental disorder. (Q.20) Control of smoking and use of other tobacco products are mainly in the "Tobacco Control Act 2008". The "Food and Drugs Act 1967" provisions relating to drugs apply to tobacco, cigars and cigarettes and the "Excise Tax Rates Act 1984" provides for taxes on tobacco products. (Q.21) Control of alcohol use is mainly in the "Liquor Act 1971". The "Excise Tax Rates Act 1984" provides for taxes on alcohol, and the "Customs Act 1977" contains provisions for the importation of brandy, whisky and rum. The "Customs Act 1977" also contains a range of provisions regarding methylated spirit, its importation and use (Part VII Methylated Spirit). (Q.22)

The "Narcotics Act 1967" and the "Food and Drug Act 1967" cover the control of drug abuse. (Q.23) The "Healthcare Professions Registration and Standards Act 2007" contains provision for standards and Codes of Conduct for healthcare professions (Part III), including legal and human rights of patients. It provides for each Council of Professions to ensure that their respective professional standards take account of the determinations and procedures on ethical matters of any relevant association of healthcare professionals. The "Medical Practitioners Act 2007", the "Dental Practitioners Act 2008", the "Pharmacy Act 2007", and the "Nursing and Midwifery Act 2007" all contain provisions for professional standards for health care workers. (Q.24)

The "Births, Deaths and Marriages Registration Act 2002", the "Coroners Ordinance 1959", and the "Burials Ordinance 1961" states the death

and related issues. The "Health Ordinance 1959" enables the Chief Executive Office of the Ministry of Health to order post-mortem examinations as well as provides for burial of a person who has died in such a state as to be dangerous to health (Q.25-27). For nutrition and food issues, the "Food and Drugs Act 1967" exist, but the new Food Bill deals with nutrition issues including the fortification of foods. When finished, it will replace those parts of the 1967 Act that deal with food regulation (Q.28-29). With regards to consumer protection, there is the "Consumer Information Act 1989". The "Food and Drugs Act 1967" contains a number of provisions for consumer protection including provisions for labeling, advertising, content, and composition of food and drugs sold in Samoa. The new Food Bill also includes controls designed to protect consumers. (Q.30)

The "Pharmacy Act 2007" deals primarily with the administration of the pharmacy profession in Samoa but does contain provisions for Regulations relating to dispensing, processes of approval for drugs. The "Food and Drugs Act 1967" contains a range of provisions for new drugs, changes to drugs, testing, distribution, labeling and sale of drugs. (Q.31) The "Healthcare Professions Registration and Standards Act 2007" lists traditional healers and traditional birth attendants as allied health professionals and provides for regulation of these professions. (Q.32) Section 16 of the IDHL, poisons and other hazardous substances is specified in the "Poisons Act 1968". Not only the "Waste Management Act 2010" has provisions relating to toxic or hazardous wastes, but also the "Accident Compensation Act" contains provisions relating to compensation for injury/disease from hazardous substances. (Q.34) Also, Section 17 occupational health and safety is covered by the "Occupational Safety and Health Act 2002", the "Accident Compensation Act 1989", and the "Labor and Employment Act 1972". (Q.35)

In terms of Environmental protection, the "Lands Surveys and Environment Act 1989" contains extensive provisions. Else, the "Water Resources Management Act 2008", the "Waste Management Act 2010" have the

related provision. The "Samoa Water Authority Act 2003" includes provisions to assist in protecting, managing and conserving Samoa's water resources. The "Ports Authority Act 1998" contains offences for pollution of waters of a port. The "Fisheries Act 1988" states it is an Act for the conservation, management and development of Samoan fisheries. The "Forests Act 1967" provides for conservation, protection and development of natural resources of Samoa, especially soil, water and forest. (Q.36)

Health care professionals using diagnostic regulation are regulated under the "Healthcare Professions Registration and Standards Act 2007", the "Medical Practitioners Act 2007", and the "Dental Practitioners Act 2008". (Q.37) the "Accident Compensation Act 1989" contains provisions relating to prevention, including the functions and duties of the Corporation. The "Occupational Safety and Health Act 2002" also contains provisions for prevention, including measures to minimize accidents and injuries. (Q.38) Sports and recreation related provisions can be seen in the "Sports Disputes Resolution Act 2008", the "South Pacific Games (Taxation Incentives) Act 2007", "Samoa Sports Facilities Authority Act 2007" and the "Youth, Sports and Cultural Affairs Act 1993-1994". For the last question on health information and statistics is mainly covered by the "Ministry of Health Act 2006". The "Accident Compensation Act 1989" includes statistical records as a function of the Corporation. The "Statistics Act 1971" provides for health statistics to be collected in the Census. (Q.40)

4.2.5.4. Health Law Coverage in Vanuatu

In Vanuatu, approximately half of the areas in the International Digest of Health Legislation (IDHL) are covered. The organization and administration of health care is mainly in the "Public Health Act" establishing public health administration, and the "Health Committee Act" establishing community level administration. (Q.4) The contents of health financing is in the "Public Health Act" specifically section 112 established the Public Health Fund. (Q.5) There is

no general law relating to health research. However, the "Environmental Management and Conservation Act" part 4 division 1 controls bio-prospecting, which includes taking genetic resources. Permits are needed in order to do this. The "Vanuatu Cultural Research Policy" made pursuant to the "Vanuatu National Cultural Council Act" requires permits for any research with cultural dimensions. (Q.6) The World Health Organization Framework Convention on Tobacco Control has been ratified in Vanuatu. (Q.7)

The "Health Practitioners Act" provides for registration of doctors and ancillary health professionals. It also provides a procedure for complaints and establishes a disciplinary committee. The "Nurses Act" also provides for registration and provides a procedure for complaints. It also provides a process for accrediting nursing training courses. (Q.8) There is no general law area for health care facilities and services. However, the "Mental Hospital Act" was adopted from the UK and establishes a mental hospital in which people can be involuntarily detained. Also, the "Health Committees Act" gives health committees the duty to maintain local health facilities, but there is no further regulation of these facilities. (Q.9)

The "Public Health Act" Part 3 regulates notifiable diseases. These are, primarily, communicable diseases although some poisoning (fish poisoning pesticide poisoning) also appear on the list. The "Quarantine Act" allows incoming vessels with signs of communicable diseases to be quarantined. (Q.10) HIV/AIDS appears on the schedule of notifiable diseases under the "Public Health Act" Part 3. There are no further specific HIV/AIDS related laws. (Q.11) Dentists are regulated under the "Health Practitioners Act" but there are no specific laws relating to oral health. (Q.14) Vanuatu has ratified CEDAW "Convention on the Elimination of all Forms of Discrimination Against Women (Ratification) Act" but no specific laws relating to family planning have been passed pursuant to this. (Q.15) Vanuatu has ratified the Convention on the Rights of the Child (Ratification) Act" but no specific laws relating to child health have been passed

in accordance with this. Part 12 of the "Public Health Act" permits the Minister to make regulations to promote breastfeeding and control baby formula and infant feeding aids. No regulations have been made pursuant to this. (Q.16)

Vanuatu has the "Convention on the Rights of Persons with Disabilities (Ratification) Act 2008" but has not made specific laws in this area. (Q.19) The "Mental Hospital Act" was adopted from the UK and establishes a mental hospital in which people can be involuntarily detained. (Q.20) The "Tobacco Control Act 2008" is a fairly comprehensive law related to control of smoking. (Q.21) The "Liquor Licensing Act" requires suppliers of alcohol to be licensed. It prohibits the supply of alcohol to under 18 year olds but does not control the supply of alcohol to already intoxicated people. (Q.22) The "Dangerous Drugs Act" regulates the import, sale and possession of various drugs that have the potential to be abuse and criminalizes breaches of the act. (Q.23)

While the "Health Practitioners Act" and the "Nurses Act" provide procedures for complaints there is no specific statute law on medical ethics. This is, instead, governed by common law (case law principles). (Q.24) There are no laws in areas such as euthanasia. (Q.25) The "Public Health Act" section 9(2)(i) allows for postmortems to be ordered in the event of a suspected notifiable disease. (Q.26) The "Burials Act" provides for the issuing of licenses to inter. The "Public Health Act"s 9(1)(c) gives the Minister very broad powers in respect of notifiable diseases. Whilst there is nothing specific about disposing of the dead the ministerial power is broad enough to allow for orders relating to disposal of bodies following a post mortem to be made. (Q.27)

Part 12 of the "Public Health Act" permits the Minister to make regulations to promote breastfeeding and control baby formula and infant feeding aids. No regulations have been made pursuant to this. There are no other nutrition laws. (Q.28) Food safety issues are covered by the "Food Control Act" and the "Food Control Regulations 2007" (Q.29) There are no specific laws relating to health services consumers protection. There are also no specific product safety laws. However, there are laws relating to labeling pesticides S 16

Pesticides (Control) Act. Food labeling is dealt with under the "Food Control Act" and the "Food Control Regulations 2007". (Q.30)

The "Sale of Medicines (Control) Act" regulates the distribution of pharmaceuticals. (Q.31) Traditional medicine practitioners are excluded from the "Health Practitioners Act". There is no control of traditional medicines. (Q.32) Section 16 of the IDHL, poisons and other hazardous substances is specified in the "The Pesticides (Control) Act", but there is no general law on poisons. (Q.34) The "Health and Safety at Work Act" is the principal law in occupation health and safety area which is section 17 in IDHL. The "Employment Act" also contains some provisions about sanitation and ventilation at work. (Q.35) The "Public Health Act" regulates domestic hygiene and housing (Part 10) nuisances affecting health (part 4) water supply (part 7) and sanitation and waste disposal (part 8). (Q.36)

The "Health and Safety at Work Act" imposes duties on employers and employees to minimize the risk of accidents at work. The "Road Traffic Control Act" provides a number of general rules aimed at minimizing road accidents. Other aspects are not legislated. (Q.38) The "Vanuatu National Sports Council Act" sets up a Council with broad functions, that could include issues such as drug abuse in sport and sports medicine, but there are no specific laws in these areas. (Q.39) There are no specific laws on health information and statistics. (Q.40)

4.2.5.5. Health Law Coverage in the Kingdom of Cambodia

In the Kingdome of Cambodia, most of the areas in the International Digest of Health Legislation (IDHL) which is similar with Philippines and Samoa are covered. The "Constitutions of the Royal Government of Cambodia" describes duty to care for children and elderly parents (Article 47), ban and severe punishment relating to illicit drugs, counterfeit or expired goods (Article 64), Health guarantee and rights to free medical consultations at public hospitals, and maternities for poor citizens (Article 72), Children and mother health

(Article 73), Assistance to disabled (Article 74) and Social security system (Article 75) (Q.1-2). The organization and administration of health care is mainly in the "Sub-decree 67 on establishment and functioning of MoH", the "Royal Decree dated 28 February 1996 on Establishment of Calamette Hospital", and the "Royal Decree on Establishment of National Medical Council". (Q.4)

The contents of health financing is in the "Law on Financial System", the "Taxation Law", the "Law on Social Security Schemes for Persons Defined by the Provisions of the Labor Law", the "Health Financing charter" and the "Health Financing Strategic plan 2008-2015". (Q.5) The health research related provision can be seen in the "Sub-decree No. 592 on establishment of the National Ethics Committee for Health Research ". The National Institute of Public Health (NIPH) established to support MoH to conduct research in public health for policy development. (Q.6) Health Manpower is mainly described in the "Law on the Management of Private Medical, Paramedical, and Medical Aide Services 2000", the "Sub-decree No. 21", the "Royal Decree on Establishment of Cambodia National Medical Council" and the "Decision No. 34 dated 9 April 1999 on Establishment of the Committee to evaluate and legalize degree and certificate". (Q.8) Health care facilities and services can be seen in the "Law on the Management of Private Medical, Paramedical, and Medical Aide Services 2000". (Q.9)

MoH has established CDC Department, National Centre for Tuberculosis, National Centre for Malaria, and the National Institute for Public Health to support MoH in control and eradication of communicable diseases. (Q.10) Controlling and prevention of communicable diseases is regulated by the "Law on the Prevention and Combat against the Spread of HIV/AIDS 2002". (Q.11) Cambodia doesn't have the law related organ transplantation and/or human tissues, including blood and blood products, but MoH has established the National Blood Bank and the Hemo-Dialysis Centre. It is noted that Cambodia has no capacity to do organ transplantation. (Q.12) Cambodia also does not have the law related non-communicable disease, but MoH has established the

Department of Health Prevention whose role is to manage the non-communicable diseases. (Q.13)

The section 5 of IDHL for oral health cannot be seen in Cambodia regulation, but MoH has established the Department of Health Prevention in which oral health is part of its activities. (Q.14) Under the "Law on Abortion 1997" and the "Law on Marriage and Family 1989", the National Centre for Mother and Child Health was established. (Q.15) With regards to family health and child health, Cambodia has the "Labor Law 1997". (Q.16) In the constitution, Duty to care for children and elderly parents (Article 47) is described for human reproductive issue. The Cambodian government has signed the Madrid International Plan of Action on Ageing (MIPAA) but not yet ratified. Policies, the National Strategic Development Plan, the Health Strategic Plan, the Drafted National Social Protection Strategy for the Poor and Vulnerable, and the National Strategy for Prevention and Control of Non Communicable disease, mention the elderly but implementation is unclear. (Q.18) Also, assistance to disabled (Article 74) provision is included in the Constitution. Under the "National disability law", Prakas issued by MoH in 2004 stipulates that disabled people receive free health care at public health facilities. (Q.19) The section 9 of the IDHL, mental health, isn't covered by the current laws, but a National mental health plan 2003-2020 exist. (Q.20)

Control of smoking can be seen in the "Royal Kram No. SN/RKM/0106/002 dated January 18, 2006 promulgating the Law on Approving Cambodia to be a Party of the Framework Convention on Tobacco Control", the "Sub-Decree on printing health warning on cigarette package", the "Prakas on the implementation of printing health warning messages on cigarette packages", and the "Prakas on measures for the banning of tobacco product advertising". (Q.21) With regards to control of alcohol use, there is the "Land Traffic Law" Chapter 3 Article 9, Paragraph 10 limits the maximum level of blood alcohol concentration (BAC) when driving a vehicle. (Q.22) Control of drug abuse can be seen in the "Law on Management of Pharmaceuticals 1996",

the "Sub-decree No. 44 on drug Registration 1994", the "Prakas No. 364 on implementation of drug registration", the "Law on control of addictive drugs", and the "Sub-decree No. 37 on classification of poisonous drugs". (Q.23)

For biomedical ethics and professional responsibility, Cambodia has a related section in the "Standard Operating Procedure 2008" and the "Sub-decree No. 61 Code of Ethics for Doctor" as well as the "Ethical Guidelines for Health Research 2002" and the "National Ethic Committee for Health Research" which are not a law but internal rules. (Q.24) There is no formal system of medicolegal death investigation in Cambodia. Complete medico-legal post mortem examinations are not performed. There is no functional morgue/autopsy room facility and there is a major cultural aversion to autopsy and cold-storage of bodies. The main death investigators are the Judicial Police who are not medically qualified. 95% of Cambodian people are Buddhist. The rest are Muslim and Christian . Their funeral rites are recognized by the Constitution of the Royal Government of Cambodia. (Q.25-27)

For nutrition and food, Cambodia has the "Cambodian Nutrition Investment Plan (CNIP) 2003-2007", the "Health Strategic Plan (HSP) 2003-2007 and HSP 2008-2015", and the "National Program on Nutrition". The law on the quality and safety of products, goods and services as adopted in 21 June 2000. (Q.28-29) With respect to consumer protection, importation of some toys and other consumer products are restricted. (Q.30) Pharmaceuticals are mainly described in the "Law on management of pharmaceuticals and related products dated on June 17, 1996" and the "Sub-decree on pharmaceutical counterfeit products control". (Q.31) Traditional medicine is covered by the "Sub-decree No. 23 dated 28 April 1998 on Production and Importation of Traditional Medicines". (Q.32) There is no law on the medical devices. However, there need to be licensed from MoH and MEF for any import of medical devices. (Q.33)

Section 16 of the IDHL, poisons and other hazardous substances is specified in the "Sub-decree No. 37, dated 16 June 2000, on Classification of Poison in Health Sector" (Q.34), and Section 17, occupational health and safety

as well as environmental protection is governed by the Department of Occupational Health and Safety and Ministry of Labor and Vocational Training. (Q.35-36) The "Law on road traffic" is described about the accident prevention (Q.38), and the "Law on adoption of international treaty against doping in sport 2007" for sports and recreation section(Q.39). The last question for health information and statistics, there is no specific law, but regulations and guideline on health information related to CDC and MoH, Department of HIS and Statistics of MoH and private sector exist. (Q.40)

4.2.6 Comparative Analysis Results: Focusing the Type of Laws

Legislation is law that is written down. Legislation may be created by the main legislative body, often a parliament, or by another body, holder of office or authority that is given the power to create it. First, law that is created by a parliament can be classified as primary legislation. The power to make law for a particular jurisdiction (a country, collection of countries or a geographical area such as a region) may be given to a parliament by a Constitution (which may actually be a piece of legislation of another jurisdiction). Laws created by parliaments are generally called Acts of Parliament or statutes. The World Act merely refers to the fact that the parliament has acted in its capacity as the legislature. Primary legislation may delegate power to another body to create more detailed sub-law on the subject, known as subordinate legislation. Subordinate legislation is legislation that is subordinate to primary legislation, and is made under a delegated power contained in a law. Such legislation may also be referred to as secondary or subsidiary legislation cannot be contrary to the primary legislation. (WHO/WPRO, 2004)

Table 9. Law Typology

	Big Category	Specific Category	Examples
1	Constitutional Provision	adopted by the government	Constitution
2	Primary legislation	enacted by the main law-making body of the government (e.g., parliament)	act, codes, statutes, law
3	Subsidiary legislation	promulgated by executive bodies (ministries, agencies)	resolution, regulations, orders, decrees, decision, directive, circular, multiple circular,
4	By-laws	issued by local authorities (city councils, district offices)	ordinance, Official document
5	International instruments	signed and ratified by country	treaties, conventions
6	Do not have any laws	Do not have a	ny laws

In other way, a multivariable system using 'yes or no' for existence of legislation and the 'hierarchy of the regulation or law typology' is thus also possible like Table 9. Law can be categorized in 1) constitutional provision which is 1) constitutional provisions (e.g., bill of rights) adopted by the government, 2) primary legislation (e.g., acts, codes, statutes) enacted by the main law-making body of the government (e.g., parliament), 3) subsidiary legislation (e.g., regulations, orders, decrees) promulgated by executive bodies (e.g., ministries, agencies), 4) by-laws (e.g., ordinances) issued by local authorities (e.g., city councils, district offices), and 5) international instruments (e.g., treaties, conventions) signed and ratified by your country. (see Table 9)

In multivariable systems, rating or imposing color code methods are possible. Comparative analysis result of module one for International Digest of Health Legislation (IDHL) (see Table 10), comparative analysis results of module two for Health Systems based on Primary Health Care (PHC) valued (see Table 11), comparative analysis results of module three for International Health Regulation (2005) (Table 12), and comparative analysis results of module four Framework Convention on Tobacco Control (FCTC) (see Table 13) in five countries: Republic of Korea, the Philippines, Samoa, Vanuatu, and Cambodia are provided as examples below in tables 10-13.

Table 10 describes the comparative law analysis result of Module 1 based on the type of laws. In the Republic of Korea, most of the items in IDHL are covered by the Constitution and primary legislation. In the Philippines, 9 items among 40 questions were covered by constitutional provision, 19 items were covered by primary legislation and 4 items were covered by subsidiary legislation. In Samoa, 27 items among 40 questions were covered by primary legislation and 3 items were covered by by-laws. In Vanuatu, 19 items among 40 questions were covered by primary legislation and 3 items were covered by international instruments. In Cambodia, 4 items for constitutional provision, 7 items for primary legislation, and 18 items were covered by subsidiary legislation. (see Table 10)

Table 10. Comparative Law Analysis Result of Module 1

	MODULE 1: International Digest of Health Legislation					
	Questions ROK PHL SAM VAN				VAN	CAM
1.	Does your country have constitutional provisions relating to health?	O	O	х х		O
2.	Does your country have law(s) relating to human rights and other fundamental rights that pertain to health?	O	O	X	X	O
3.	Does your country have law(s) relating to international treaties and other international instruments that pertain to health? (If so, please provide a brief overview of your legal system and explain how such international obligations are incorporated into the system. Also, please list the international treaties and instruments to which your country is a signatory.)	O	0	?	?	•
4.	Does your country have law(s) relating to the organization and/or administration of health care (e.g., general governmental health and public health agencies, including ministries, boards, councils)?	0	O	O	0	O
5.	Does your country have law(s) relating to health financing (e.g., taxation, social security, health insurance, cost containment)?	O	O	O	O	O
6.	Does your county have law(s) relating to health research (e.g., government support, permits)	0	0	O	Х	х
7.	Does your country have law(s) relating to health education (e.g., information the public, health promotion, access to information)	0	?	O	X	x
8.	Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)?	0	0	O	O	0
9.	Does your country have law(s) relating to health care facilities, related institutions, and/or services?	O	O	O	O	O
10.	Does your country have law(s) relating to communicable	O	C	O	O	0

Cananaih						
	have law(s) relating specifically to g criminal laws, immigration laws, and/or	O	0	•	•	0
	have law(s) relating to organ d/or human tissues, including blood and	O	O	?	?	x
13. Does your country communicable dis	have law(s) relating to non- eases?	0	?	O	Х	х
14. Does your country fluoridation)?	have law(s) relating to oral health (e.g.,	C	O	O	Х	X
family counseling,	have law(s) relating to family health (e.g., genetic counseling, maternal health and enatal care, prenuptial examinations, sex	0	0	x	•	0
abuse of children,	have law(s) relating to child health (e.g., adolescent health, child labor, daycare re, school health program)?	O	O	O	O	0
	have law(s) relating to human for population control?	O	Х	X	Х	0
	have law(s) relating to care of the elderly rangements, geriatric programs, old-age	O	0	X	X	0
and/or rehabilitati	have law(s) relating to care of the disable on (e.g., basic care arrangements, as arrangements, sheltered workshops)?	O	X	0	O	O
20. Does your country	have law(s) relating to mental health?	0	Х	0	0	Х
21. Does your country	have law(s) relating to the control of se of other tobacco products?	O	O	O	0	O
22. Does your country alcohol use?	have law(s) relating to the control of	O	Х	O	O	х
abuse (e.g., contr	r have law(s) relating to the control of drug ol of narcotics and other illegal on treatment, criminalization)?	0	0	0	0	0
and/or profession confidentiality, ad	have law(s) relating to biomedical ethics al responsibility (e.g., research ethics, vertising, codes of conduct, disciplinary d/or criminal liability for wrongdoing)?	O	0	•	x	O
	have law(s) relating to death and dying iving wills, determination of death, th)?	0	х	O	х	x
26. Does your country examinations?	have law(s) relating to post-mortem	0	O	0	O	Х
	have law(s) relating to the disposal of the	0	O	0	0	х
	have law(s) relating to nutrition (e.g., infant foods, malnutrition, nutritional ation)?	O	O	X	X	O
29. Does your country adulteration and a export controls, pa	have law(s) relating to food safety (e.g., dditives, inspection, irradiation, import and ckaging and advertising, pesticides and ceutical residues, handling and	O	0	0	•	•
	have law(s) relating to the safety of se (e.g., toys, kitchen utensils, appliances,	O	O	O	Х	0
31. Does your country	have law(s) relating to pharmaceuticals	O	O	O	O	O

and/or related products?					
32. Does your country have law(s) relating to traditional medicines?	0	O	O	Х	0
33. Does your country have country law(s) relating to medical devices?	0	O	?	?	0
34. Does your country have law(s) relating to poisons and/or other hazardous substances?	0	O	O	O	O
35. Does your country have law(s) relating to occupational health and safety?	0	O	O	O	0
36. Does your country have law(s) relating to environmental protection as it pertains specifically to human health (e.g., sanitary standards for housing, water/air quality, pollution, waste disposal)?	•	0	0	•	0
37. Does your country have law(s) relating to radiation protection?	0	O	0	X	0
38. Does your country have law(s) relating to accident prevention (e.g., health requirements for drivers, educational programs, road safety, safety in air travel)?	•	0	0	O	O
39. Does your country have law(s) relating to sports and recreation (e.g., doping, safety/hygiene of swimming pools, sports medicine)?	•	0	0	O	O
40. Does your country have law(s) relating to health information (e.g., vital statistics, notification of disease), including provisions relating to the role of the private sector in obtaining and/or maintaining such information and statistics?	0	x	O	x	x

Table 11 describes the comparative law analysis result of Module 2 based on the type of laws. In the Republic of Korea, most of the items are covered by the primary legislation. In the Philippines, 7 items among 17 questions were covered by primary legislation and 1 item was covered by constitutional provision. In Samoa, 10 items among 17 questions were covered by primary legislation and 1 items were covered by constitutional provision. In Vanuatu, only 2 items among 17 questions were covered by primary legislation. In Cambodia, 4 items were covered by primary legislation and 2 items were covered by subsidiary legislation. (see Table 11)

Table 12 describes the comparative law analysis result of Module 3 based on focusing the type of laws. In the Republic of Korea, most of the items are covered by the primary legislation. In the Philippines, 10 items among 18 questions were covered by primary legislation and 1 item was covered by subsidiary legislation. In Samoa, 11 items among 18 questions were covered by primary legislation. In Vanuatu, only 4 items among 18 questions were covered

by primary legislation. In Cambodia, only 2 items were covered by primary legislation (see Table 12)

Table 11. Comparative Law Analysis Result of Module 2

	MODULE 2: Health Systems based on Primary Health Care Values					
	Questions	ROK	PHL	SAM	VAN	CAM
1.	Does your country have law(s) mandating health authority to develop national health plans, policies, strategies, and/or frameworks?	O	x	O	X	•
2.	Does your country have law(s) mandating health authority to implement and monitor nation health plans, policies, strategies, and/or frameworks?	0	X	0	X	0
3.	Does your country have law(s) mandating health authority to engage in coalition-building with stakeholders outside the health sector?	0	x	0	X	x
4.	Does your country have law(s) relating to the provision of health financing (e.g., taxation, social security, health insurance, cost containment)?	0	0	0	0	x
5.	Does your country have law(s) relating to the provision of minimum health services for your citizens?	X	O	X	?	Х
6.	Does your country have law(s) relating to safety-net mechanisms for your citizens to protect them from financial disaster due to health expenditures?	O	0	0	X	х
7.	Does your country have law(s) relating to maintaining numbers of health workers (e.g., production, deployment and retirement, international recruitment)?	O	O	x	X	x
8.	Does your country have law(s) relating to classification among various types of health workers?	0	O	O	X	0
9.	Does your country have law(s) relating to the distribution of health workers?	O	X	X	X	O
10.	Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)?	O	X	O	O	0
11.	Does your country have law(s) relating to the protection of patients as health consumers (e.g. patient bill of rights, including access to services and medical technologies, right to receive health interventions at a time and location of their choosing)?	?	?	0	x	х
12.	Does your country have law(s) relating to monitoring the performance of your health system (e.g., quality control of services)?	O	X	O	X	х
13.	Does your country have law(s) relating to the access of essential medicines?	C	O	O	X	0
14.	Does your country have law(s) relating to quality control, cost effectiveness, safety, efficacy of medicines and medical technologies?	0	0	O	X	O
15.	Does your country have law(s) relating to the access of vaccines?	O	O	X	X	Х
16.	Does your country have law(s) relating to quality control of vaccines (e.g., cold chain requirements)?	?	?	X	Х	Х
17. 	Does your country have law(s) relating to the use of information technology in health care?	O	X	X	X	X

Table 12. Comparative Law Analysis Result of Module 3

	MODULE 3: International Health Regulations (2005)					
	Questions	ROK	PHL	SAM	VAN	CAM
1.	Does your country have law(s) relating to the designation or establishment of a National IHR Focal Point? (See Article 4)	O	X	X	Х	0
2.	Does your country have law(s) relating to the designation of the authorities responsible for public health risks and public health emergencies of international concern? (See Article 4)	•	X	X	×	0
3.	Does your country have law(s) relating to the capacities for surveillance and notification of public health risks and public health emergencies of international concern? (See Articles 5-10, Annex 1)	•	x	0	x	x
4.	Does your country have law(s) relating to the capacities for public health response to public health risks and public health emergencies of international concern? (See Article 13, Annex 1)	•	X	0	X	х
5.	Does your country have law(s) relating to the capacities for public health response at designated points of entry, including airports, ports, and ground crossings? (See Articles 19-22, Annex 1)	•	0	0	•	х
6.	Does your country have law(s) relating to health measures for travelers? (See Articles 23, 30-32, 35, 42-43)	O	O	O	O	Х
7.	Does your country have law(s) relating to certificates of vaccination or other prophylaxis for travelers? (See Article 36)	0	O	O	Х	x
8.	Does your country have law(s) relating to charges for health measures regarding travelers? (See Article 40)	0	X	X	0	х
9.	Does your country have law(s) relating to health measures for baggage, cargo, containers, conveyances, goods, postal parcels, and/or human remains? (See Articles 23, 33, 35, 43)	O	O	O	Х	х
10.	Does your country have law(s) relating to charges for health measures regarding baggage, cargo, containers, conveyances, goods, postal parcels, and/or human remains? (See Article 41)	0	X	0	•	х
11.	Does your country have law(s) relating to the application of health measures on containers and/or container loading areas? (See Article 34)	0	O	O	х	х
12.	Does your country have law(s) relating to the responsibilities of conveyance operators with respect to health measures? (See Articles 23, 24, 35, 42-43)	0	0	0	O	х
13.	Does your country have law(s) relating to health measures for conveyances in transit? (See Articles 23, 25-26, 27, 42-43)	0	0	O	0	х
14.	Does your country have law(s) relating to health measures for conveyances at points of entry? (See Articles 23, 27, 28-29, 35, 37-39, 42-43)	0	0	X	0	х
15.	Does your country have law(s) relating to health documents for conveyances? (See Articles 37-39)	0	0	X	Х	х
16.	Does your country have law(s) relating to collaboration and assistance with other States Parties and/or WHO with regard to public health risks and public health emergencies of international concern? (See Article 44)	O	O	O	х	?
17.	Does your country have law(s) relating to the treatment of personal data received from another State Party and/or WHO with regard to public health risks and public health	X	x	X	х	х

emergencies of international concern? (See Article 45)					
18. Does your country have law(s) relating to biological substances, reagents, and materials for diagnostic purposes with regard to public health risks and public health emergencies of international concern? (See Article 46)	•	0	X	×	x

Table 13. Comparative Law Analysis Result of Module 4

	MODULE 4: Framework Convention on Tobacco Control					
	Questions	ROK	PHL	SAM	VAN	CAM
1.	Does your country have law(s) relating to national tobacco control strategies, plans, or programs? (See Article 5)	X	?	?	?	?
2.	Does your country have law(s) relating to the pricing and/or taxation of tobacco products? (See Article 6)	0	O	0	X	0
3.	Does your country have law(s) relating to the protection from exposure to tobacco smoke? (See Article 8)	O	O	O	O	O
4.	Does your country have law(s) relating to the regulation of the contents of tobacco products? (See Article 9)	0	O	0	X	х
5.	Does your country have law(s) relating to the regulation of tobacco product disclosure? (See Article 10)	O	O	O	O	X
6.	Does your country have law(s) relating to the packaging and labeling of tobacco products? (See Article 11)	0	0	O	0	O
7.	Does your country have law(s) relating to education, communication, training, and/or public awareness of tobacco issues? (See Article 12)	0	0	X	X	0
8.	Does your country have law(s) relating to tobacco marketing, including advertising, promotion, and sponsorship? (See Article 13)	O	O	O	O	•
9.	Does your country have law(s) relating to tobacco dependence and cessation? (See Article 14)	X	O	X	X	?
10.	Does your country have law(s) relating to illicit trade in tobacco products? (See Article 15)	O	O	O	X	O
11.	Does your country have law(s) relating to sales to and by minors? (See Article 16)	O	O	O	0	х
12.	Does your country have law(s) relating to the provision of support for economically viable alternatives for tobacco workers, growers, and/or individual sellers? (See Article 17)	O	O	X	X	x
13.	Does your country have law(s) relating to the protection of the environment and the health of persons in respect of tobacco cultivation and manufacture? (See Article 18)	O	O	X	X	x
14.	Does your country have law(s) relating to criminal and/or civil liability, including compensation, with respect to tobacco products? (See Article 19)	0	O	X	0	x
15.	Does your country have law(s) relating to research, surveillance, and exchange of information with respect to tobacco consumption? (See Articles 20-22)	•	?	X	X	X

Table 13 describes the comparative law analysis result of Module 4 based on focusing the type of laws. In the Republic of Korea and the Philippines, most of the items are covered by the primary legislation. In Samoa, 8 items among 15 questions were covered by primary legislation. In Vanuatu, 5 items among 15 questions were covered by primary legislation and 1 item was covered by by-laws. In Cambodia, 6 items were covered by subsidiary legislation. (see Table 13)

4.2.7. Assessing the Results, Providing the Final Analysis: Points for Attention

Reviewers could and should not make judgement about the quality of the law or provide policy options, as these actions could be controversial and open for different interpretations. For example is the absence of a law on human resource worse than a regulatory administrative system for the training and distribution of health staff? Also WHO can not be seen as a 'policing officer' when there is certain non-compliance to international standards implied; this may be dangerous for its relationship with the government.

In terms of evaluation methods, the current 'yes or no' format of the analysis tool provides only quantitative information regarding the availability or presence of a certain law. Where the law was actually implemented, enforced or enforceable is another important issue that has to be evaluated. In reality, many countries in the region may have a law but do not actually enforce the law or do not have the capacity to implement the law. As such, the experts collectively felt a need to expand the questions in the tool to allow such quantitative evaluation. However, they were also concerned that responses to questions about a law's enforcement or enforceability may not be readily assessable and may be very subjective. It was suggested to test the feasibility of the qualitative evaluation in certain countries as part of the ongoing tool improvement process.

The analysis framework may eventually generate interaction between countries which increases the necessity of the study on comparison of the public health law, regulation, and legislative process among countries. While research and study using analytical methods establishes important ground and structure for improving and/or developing the law, it is also known that most of lawmakers select comparative legal methods to develop their legislative direction in their own country based on similar situation in other countries. The reasons why similarities and difficulties of the law are analyzed are for improving law in countries. However, comparative methods may also have limitations as 1) unified methods do not exist due to differences between academic areas or study purpose, 2) comparable objectives for laws are actually different, 3) practical comparison is impossible as a country does not allow its system to be studied and 4) it is simple too difficult due to comprehensiveness and/or complication of law making procedures to learn lessons to be adopted in another country.

4.3. Models for Monitoring Domestic Public Health Law and Legal System Supporting Global Health Governance

4.3.1. Analytical Results on WHO Historical Legal Activities

To establish a possible basis for critical legislation development, an inventory of health law, legislation and regulation issues as reflected in resolutions taken during the World Health Assembly (WHA) and the (WPRO) Regional Committee Meetings (RCM) was undertaken. The review of the WHA Resolutions from 57th to 65th and RCM Resolution from 1st to 62nd showed that several health law related issues were being discussed on a regular basis but that very little follow-up was done in terms of acceptance and application incountry.

In WHA Resolutions, Obsolete Pesticides and Other Obsolete Chemicals issues were developed in 63rd WHA resolution 26, Worker's Health in 60th resolution 26, Road Safety and Health in 57th resolution 10, Infant and Child Nutrition in 65th resolution 6 and 58th resolution 32, Female Genital Mutilation in 61st resolution 16, Drug Dependence and Alcoholism in 61st resolution 4, Aging in 58th resolution 16, Cancer in 58th resolution 22, Mental Health in 65th resolution 4, Malaria, Filariasis and other Parasite Disease in 64th resolution 17 and 69 the resolution 20, Sexually Transmitted Diseases and HIV/AIDS in 59th resolution 19 and 57th resolution 15, Tuberculosis in 62nd resolution 15, Antimicrobial Resistance in 58th resolution 27, Sustainable Health Financing and Universal Coverage in 58th resolution 33, and Nursing and Midwifery in 64th resolution 7 and 59th resolution 27, Essential Medicine in 61st resolution 21, 60th resolution 16 and 20, Traditional Medicine in 62nd resolution 13, Patient Safety in 55th resolution 18, Biomedical research in 60th resolution 15, Blood and Blood Products in 63rd resolution 12, Food and Non-Alcohol Beverage to Children in 63rd resolution 14, Human Organ and Tissue Transplantation in 63rd resolution 22, and International Trade and Health in 59th resolution 26.

In the RCM Resolutions were developed as follow: Environmental Health in 56th resolution 7, International Code of Marketing of Breast-milk Substitutes in 51st resolution 4 and 34th resolution 18, Non-communicable Diseases in 62nd resolution 2 and 51st resolution 6, Drug Dependence and Alcoholism in 26th Resolution 11, WHO FCTC in 55th resolution 7, 54th resolution 8, 52nd resolution 6, 48th resolution 10, 45th resolution 15, and 43rd resolution 6, Malaria, Filariasis and other Parasite Disease in 53rd resolution 4 and 12th resolution 4, Dengue Fever and Dengue Hemorrhagic Fever in 59th resolution 7, Sexually Transmitted Diseases and HIV/AIDS in 59th resolution 19 and 57 resolution 15, Tuberculosis in 53rd resolution 1, Cholera in 22nd resolution 10 and 13th resolution 5, Smallpox Eradication in 10th resolution 18, IHR in 61st resolution 5, 58th resolution 3, and 57th resolution 3, Food Safety in 62nd resolution 6 and 52nd resolution 2, Antimicrobial Resistance in 53rd resolution 5, Health Emergency and Disaster Management in 64th resolution 10, 60th resolution 22, and 59th resolution 22, Nursing and Midwifery in 57th resolution 8, Traditional Medicine in 62nd resolution 5 and 36th resolution 6, Health Laboratory Services in 60th resolution 6, and Blood and Blood Products in 37th resolution 15.

WHO has compiled and disseminated health-relevant legislation as a service to countries. In 1948, WHO established the International Digest of Health Legislation (IDHL). It represents the latest stage in the evolution of a service which began in 1909 with the publication of the first issue of the 'Bulletin menuel de'Office international d'Hygiene publiques'. Making it available for a wider audience reflected the need to devise new means of providing this information, but also of the frequency of adoption, amendment, and repeal of legislative provision for individual countries. The IDHL contains a selection of national and international health legislation. Texts of legislation are summarized in English or mentioned by their title. The current electronic version of the IDHL supersedes the printed version, which was published from 1948 to 1999. Where possible, links are provided to other websites that contain

full texts of the legislation in question.. The database provides materials by selecting a country, subject, volume, issue, and by looking for a specific keyword.

Using the IDHL subject categories and scope notes, the current status of IHDL adoption by countries in Western Pacific Region was checked. Among the 37 countries and areas, 15 countries were up-to-date However, 9 countries including Brunei Darussalam, Cambodia, French Polynesia, Lao PDR, Malaysia, Mongolia, Nauru, Palau, and Philippines were not open. 6 other countries including China, Hong Kong China, Republic of Korea, Marshall Islands, New Zealand, and Viet Nam were not updated. In 7 Countries including American Samoa, Guam, Macao China, New Caledonia, Pitcain Islands, and Wallis and Futuna, the information was limited due to fact that local persons who are in charge of updating it were absent and thus management of IDHL was poor.

The results of the review of public health law activities by WHO, using many publications from Headquarters and regional offices from 2001 to 2012, showed that the most popular issues were communicable disease preparedness with IHR and tobacco control with FCTC. In addition, mental health, human rights, fight against obesity, and food safety were also regularly covered in publications. SEARO was the only regional office that uniquely undertook a cross-country comparison for specific themes such as tobacco control, and patent legislation among some countries in region. WPRO on the other hand was the only regional office that focused on general law issues with publications such as 'Enhancing Health Policy Development: A practical guide to understanding the legislative process (2004)' and Enforcement of Public Health Legislation (2006). However, it has to be concluded in the final analysis that there was not cross comparison publication on domestic public health law and legal systems which would have been more broaden that the specific areas mentioned above.

4.3.2. Basic Principal and Timeline of the WHO Regulatory Framework

Through analyzing the WHO's historical legal activities, basic lessons were drawn for the further development of regulatory frameworks in countries. Firstly, there is need to establish appropriate monitoring mechanisms. Many resolutions in the WHA or RCM contain health law issues, but either due to unclear phrasing or lack of monitoring these had been not being followed up. Secondly, regulation is a function of governance, which is one of the six building blocks for health systems strengthening as promoted by WHO. So, developing regulatory frameworks means that also governance issues need to be addressed concurrently. Leaving it broad and vague as in the IHDL should be avoided and hence this project is taking it further by developing a comparative law web site that is assisting in the further development of the domestic public health law framework. Figure 2 shows the timeline of the development for public health law analytical framework.

Stage II

Team
Building
Making Specific Analysis Tool

Stage I

Making Fundamental Draft

2010
2012
2014
2016

Figure 3. Timeline of the Development for Public Health Law Framework

Stage I started by reaching a consensus of the vision, goal, and the various steps of the assessment/analysis process, making the fundamental draft of the tool as well as initial team-building of responsible officers and/or professionals in selected countries. Stage II continued with the testing of the tool in one more country as well as team-building and networking of responsible officers and/or professionals in selected countries. In 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 with specific analyses tools for specific legal areas, making a comparative international law website, and disseminating the approach to other regions (see Table 14)

Table 14. Timeline of the Development for Public Health Law Framework

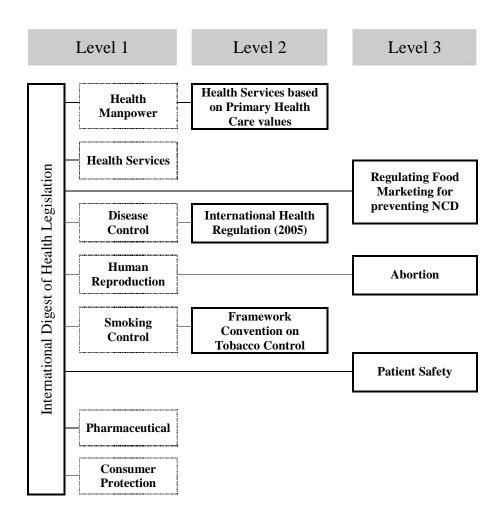
Stage	Time	Tasks
Stage I.	2 years (September 2010 – August 2012)	Team building Making fundamental draft of assessment tool and analysis framework Consensus of Vision & Goal, and steps of the assessment Process
Stage II.	2 years (September 2012 – August 2014)	Additional specific analysis tool making about Needed Agenda Specification and Verification of Operating System Confirmation of Team building through workshop, education etc.
Stage III.	2 years (September 2014 – August 2016)	Developing specific analysis tools for different areas Making a Comparative International Law Web Site Disseminate the system to other areas

4.3.3. Model 1 – Assessment tool development

Following 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 and hence the further development of the tool along the lines of so-called 'Levels' Level 1 is based on IDHL which is WHO's framework on categorizing laws in countries for last 60 years. However, the categorization of the themes do

not reflect current global health trends and the monitoring and updating system is poorly developed. However, IDHL is at the moment the only one tool for covering most of the health issues from a public health law perspective. So, headings from the International Digest of Health Legislation, which would be more complete but perhaps less accessible to those without legal backgrounds is inevitable to embrace the width and breadth of themes in public health law. (see Figure 4)

Figure 4. Developing the 'Level' Concept for the Assessment Tool



The subject categories in IDHL were divided into 1) general provision including organization and administration of health care, health care financing, health research, health education, and international treaties and other legal instruments, 2) health manpower, 3) health care facilities and services including hospitals and related institutions, and services, 4) disease control and medical care including communicable diseases, communicable disease HIV/AIDS, noncommunicable disease, and procedure, 5) oral health, 6) family health including child health, 7) human reproduction and population policies, 8) care of the elderly and rehabilitation including care of the elderly and geriatrics, and care of the disabled, 9) mental health, 10) control of smoking alcoholism, and drug abuse, 11) ethical issues and professional responsibility including professional and personnel issues, 12) death and related issues including death and dying, post-mortem examinations, and disposal of the dead, 13) nutrition and food, 14) consumer protection, 15) pharmaceutical and medical devices including traditional medicines, 16) consumer protection, 17) pharmaceuticals and medical devices, 18) poisons and other hazardous substances, 19) occupational health and safety, 20) environmental protection, 21) radiation protection, 22) accident prevention, 23) sports and recreation, and 24) health information and statistics.

Because the current module 2 to 4 are fairly specific and different from the broad IDHL issues, detailed health system issues, IHR and FCTC issues can be categorized as level 2. Criteria to designate them as level 2 include: 1) they are among the big categories in IDHL, 2) there is a need for the development of legal instrument or legal improvement by specific area experts or specialist and hence a more detailed assessment, or 3) being an emerging and/or important immediate agenda as assessed by the local legal experts or local researchers. Simply giving priority to the assessment of established law such as the Framework Convention on Alcohol Control (FCAC) can be considered.

Level 3 subjects for the assessment tool are those arising from emerging agendas which as yet have no real legal implications but which may evolve in

the coming years, such as patient safety and quality control issues, or are of more limited specific agendas, the IHDL framework, such as antimicrobial resistance, food marketing for children, and abortion issues.

In summary, it is recommended that the assessment tool should be changed to adopt the level (1-3) concept.

4.3.4. Model 2 – Making the results of the assessment visible

Having compiled and analyzed the data collected from the assessment tool, there is a need to make it more comprehensible and visual. There are several options proposed below.

First, like 'Achieving the Health-Related MDGs in the Western Pacific Region', a comparison table could be developed using colored score. For example, the health MDG scorecard for Low-and middle-income countries (LMICs) highlights some of the key MDG indicators. For eleven LMICs countries, health related MDG indicators are described with specific numerical values and color codes including "on track" for green, "insufficient progress" for orange, and "off track" for red. (see Figure 5) In this way it provides a quick overview of the results scores from the quantitative assessment and also allowing for comparison between groups of countries, i.e., high coverage group, middle coverage group, and lower coverage group as per a specific color code.

Figure 5. Health MDGs scorecard for LMICs in the Western Pacific Region

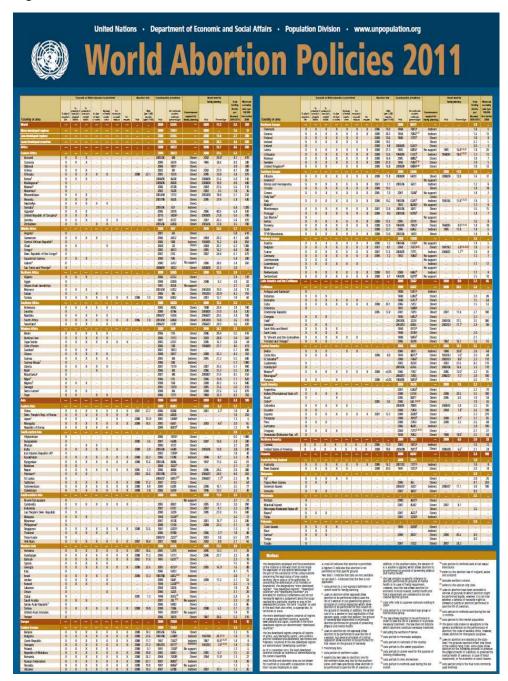
Health MDGs scorecard for LMICs* in the Western Pacific Region (with population ≥ 250 000)

		Cambodia	China	Fiji	Lao PDR	Malaysia	Mongolia	Papua New Guinea	Philippines	Solomon Islands	Viet Nan
	Infant mortality rate per 1000 live births	69	18	16	48	6	33	53	26	30	12
₩.	Under–5 mortality per 1000 live births	89	21	18	61	6	41	69	32	36	14
	Measles immunization % coverage	92	99	72	59	95	94	58	88	60	97
	Maternal mortality per 100 000 live births	290	38	26	580	31	65	250	94	100	56
\$	Skilled birth attendant % births	44	98	99	20	100	100	39	60	43	88
	Contraceptive use % married women aged 15—49	40	87	:=	32		66	-	51	-	79
	HIV/AIDS prevalence % adults aged 15—45	0.8	0.1	0.1	0.2	0.5	0.1	0.9	<0.1	-	0.5
•	Malaria mortality per 100 000 population	1.9	<0.1		0.1	0.1	==	9.2	<0.1	10.2	<0.1
	TB treatment success rate %	94	94	81	92	72	89	39	89	92	92
À.	Underweight % among children five years of age	29	7	-	32	=	5	18	21	12	20
ge'	Water % using improved sources	61	89	(a)	57	100	76	40	91	70	94
₩'	Sanitation % using improved facilities	29	55	-	53	96	50	45	76	32	75

Reference: WHO WPRO, Achieving the Health-Related MDGs in the Western Pacific Region Progress Report 2010, 2010 p.10.

Secondly a chart could be developed that lists/ranks all the countries on a specific subject, like 'The World Abortion Policies 2011' wall chart by the United Nations. It contains legal grounds on which undetected abortion is permitted for each of the 192 Member and three non-Member States of the United Nations. The wall chart also includes information on national estimates of abortion rate, fertility rate, maternal mortality ratio, levels of contraceptive use, unmet need for family planning, and government support for family planning, as well as regional estimates of unsafe abortion. (see Figure 6) Using a wall-chart one can get e.g. all information of public health law situation in all countries..

Figure 6. World Abortion Policies 2011



Reference: United Nations, Department of Economic and Social Affairs, Population Division, World Abortion Policies 2011 Wall chart, 2011. URL: www.unpopulation.org

Thirdly a 'Snapshot' chart can be developed that gives a quick overview of selected laws in each country. An example forwards is provided below: 'Making the Law Work for the HIV Response'. (see Figure 7)

MAKING THE LAW WORK FOR THE HIV RESPONSE A snapshot of selected laws that support or block universal access to HIV prevention, treatment, care and support July 2010 «We can remove punitive laws, policies, practices, stigma and discrimination that block effective responses to AIDS»

Joint Action for Results: UNAIDS Outcome Framework 2009-2011

Figure 7. Making the Law Work for the HIV Response

Reference: UNAIDS, Making the Law Work for the HIV Response: A Snapshop of Selected Laws that Support or Block Universal Access to HIV Prevention, Treatment, Care and Support, 2010.

4.3.5. Model 3 – Establishment of a public health law network

The third model to expand the analysis framework is to establish a Regional Health Law Forum (HLF) consisting of health law experts and specialists, local researchers, policy makers and lawmakers, and government. For example, the Expanded Program on Immunization (EPI) in the Western Pacific Region has been holding annual meetings of the Technical Advisory Group on Immunization Vaccine-Preventable Disease (TAG) for the Western Pacific Region which is a key mechanism to jointly monitor program performance, review technical and programmatic challenges and provide recommendations for strengthening of immunization programs and systems. The participation in an EPI TAG meeting is critical to accurately understand progress and common challenges of national immunization programs. The countries' participation also provides an opportunity for countries and partners to learn from each other's experiences and challenges and receive advice from the EPI TAG with special emphasis on targeted disease control goals, introducing new and underutilized vaccine, strengthening routine immunization systems, vaccines safety and security, and resource mobilization.

Reflecting on the EPI TAG mechanism, the objectives of the HLF meetings are to review progress, identify obstacles and recommend key actions required to 1) establish leadership and governance standards for public health law; 2) identify priority areas for strengthening the regulatory capacity in the region; 3) to review progress, discuss plans, specify critical issues and propose ways forward to accelerate the introduction of essential public health law components in domestic laws frameworks; and 4) to provide partners an opportunity to be updated on progress, challenges, and priority activities, and funding requirements and gaps.

Secondly another form of networking is the establishment of a parliamentary committee of lawmakers in health lead by the WHO Regional Office. In SEARO, the Regional Conference of Parliamentarians has been holding its annual meeting since 1996. It discusses themes such as 'Health and Development' in 1996, 'Women, Health and Environment' in 1997, 'Economic Crisis and Its Impact on Health' in 1998, 'Health of the Vulnerable Population' in 1999, 'Impact of Tuberculosis and Malaria' in 2000, 'Report of the Commission on Macroeconomics and Health' in 2002, 'Legislative and Policy Actions for Promoting Health' in 2007, 'Health Impacts of Climate Change' in 2010, and 'Strengthening of National Public Health Systems for Emerging Health Challenges' in 2012. In 2008 and 2009, EMRO also had a consultation meeting on constituting such a regional parliamentarian forum.

The roles of the parliamentary committee can be: 1) to encourage and promote the formation of national group/committees of health legislation resource groups specific health and legal issues, 2) to support these group and committees to increase awareness and promote understanding between public health and law, 3) to establish through active advocacy with governments, these groups as key stakeholders in all health sector development initiatives at both the policy and service delivery level, 4) to review existing legislation and propose a revised set of legislation for emerging health issues, 5) where appropriate, to provide legislative support to health and development interventions, 6) to identify potential source of funding at country, regional and international level to expand the resource base for health development and establish such financial resources, 7) to promote and facilitate collaboration and networking among groups outside their respective countries and between international (non)governmental organizations though group visits and exchange programs, 8) to collect and document health and development related regional and national good practices, and 9) to facilitate, support, sponsor and organize meetings and conferences of health law related experts, and conduct seminars, workshops, and training program for improving health law capacity in the country.

The third mode of networking is using the Regional Committee Meeting (RCM) annually, where high-level government officers of Ministries of Health in region can present their situation and share their experiences. Through the holding of a public health law session or side meeting in the RCM, sharing information on national legislation and reporting regulation progress are possible. Also, after grouping countries with similar legal systems, status of legal development, health law capacity or having, specific health agendas, side meetings or seminars could be organized to support their effort in upgrading their health law capacity.

4.3.6. Model 4 – Creation of website and data base

The fourth model or product that can be developed as a result of the use of the assessment tool and analysis framework is the establishment of a common website. First, using an existing website is useful to develop related links. Many developed countries have their own English law website. For example, Australia (http://www.public.health.wa.gov.au/2/1056/2/legislation.pm), Japan (http://www.japaneselawtranslation.go.jp/law/?re=02), and the Republic of Korea (http://elaw.klri.re.kr/kor_service/main.do) have their own databases and public website. But it needs to be clear what the legal status is when documents are published on the internet or can be downloaded from databases. For example, 'the Statutes of the Republic of Korea, the Acts and suboriginate statute translated into English shall no be construed as having official authority and shall be used only for reference'.

In the Western Pacific Region, there are some sub-regional databases and information sites existing. Such as the 'PacLII Databases (http://www.paclii.org/databases.html)' which covers 22 countries and areas including American Samoa, Cook Islands, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Fiji Islands, Guam, Kiribati, Marshall Islands, Nauru, Niue, Nouvelle-Caledonie, Pacific Islands Treaty

Series, Palau, Papua New Guinea, Pitcairn Islands, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, and Regional Links of Interest. Also, 'WashLaw' (http://www.washlaw.edu/forint/alpha/p/pacificislands.html) is established for legal research on the web. It includes different sections such as 1) the pacific islands legal information institute, 2) pacific islands law collection, 3) the world legal information institute, and 4) updates to different laws.

Second, websites and databases can be created containing statutes itself, results of analyses, information on seminars and meetings, discussion groups debating the latest information. For example, the European Public Health Law Network was established in 2007 as part of the European Union (EU) co-funded Public Health Law Flu project. When it was created, the EPHLN network, 'to bring together public health law expertise, and facilitate envisaged: communication between the main actors in disease preparedness and control across Europe. The network will be framed to encompass individual membership such as public health professionals and law professionals and, agency membership such as national and European government bodies, and NGOs with responsibility for disease preparedness and control, it will enable posting of information, and individual and group email communication'. The aim of the website consisted of designing an interactive network of specialist information and encouraging an exchange of expertise amongst members. The website sought to appeal to academics, public health professionals and lawyers. These days the network contains over 700 publications divided into 28 public health law categories. News, events, front page content, legislation and the francophone section are updated on a regular basis. The European Public Health Law Network has been a successful and innovative site in the area of public health law. Interest in the site continues to grow. Future funding can contribute to a bigger site with interactive features and pages in a wider variety of languages to attract a wider global audience; see also figure 8. (Basak P., 2011)

Along similar lines, the Western Pacific Public Health Law Network (WPPHLN)' website could be developed. The aim of the WPPHLN would be to develop and coordinate a sustainable Western Pacific network of professionals and stakeholders for whose work public health law has relevant. Target audience would be public health professionals, researchers, lawyers, policy makers, and service delivery professionals. It contains the 1) goal and vision of the WPPHLN, 2) law database(s), 3) comparison analysis result disclosure, 4) research including public access and membership access articles, 5) workshop and events information, and 6) a forum and discussion room.

ABOUT EPHCN

WORKSHOP
EVENTS

PUBLIC ACCESS

MEMBER ACCESS

DISCUSSION 1

CONTACT DETAILS

THAVEL DISCUSSION 2

DISCUSSION 3

GOOGLE MAP

PRIVACY

FAQ

BROWSE PUBLIC ARTICALS

SUCCEED

FAILED

SUBMIT ARTICALS

SUBMIT

SEND

Figure 8. Website Structure of the European Public Health Law Network

Reference: European Public Health Law Network.

4.3.7. Model 5 – Enactment of model law and domestication of international health law

The Last model to be developed is the establishment of an essential health legislation list. For example, WHO Model Lists of Essential Medicines has been updated every two years since 1977. In this way, after developing the essential health legislation list, regular monitoring and information disclosure for domestic public health laws which reflects international law criteria (or not) would be possible.

Secondly, one could consider the development of model public health law(s) for the region. Such a model public health law is defined as public health law(s) or private policies publicly recommended by at least one organization for adoption by government bodies or by specified private entities. (Elias Mossialos, 2010) In view of the powerful contribution that law can make to improved public health, the formulation of standards for model public health laws that reflect and build on such precedents and that incorporate, to the extent practically possible, current knowledge about the effectiveness of law-based public health interventions is recommended. (Dekeely et al, 2007) Developing the model public health law can affect the domestication of international health law which can possibly contribute to the establishment of regulatory frameworks supporting global and domestic health governance.

5. Discussion

The objective of this study was to demonstrate the importance of monitoring domestic public health law and legal system supporting global health governance through the development of framework on analysis tool to assess public health law in the Western Pacific Regional countries. As a result, developing an assessment framework to analyze public health law and legal systems in countries as a tool for global health governance was demonstrated and proved useful. Secondly, the tool added academic value by its applicability in different countries resulting in significant data collection and the ability to provide an overview of the public health law situation in selected WPRO countries.

To present the fundamental basis and demonstrate the usefulness of an analysis framework for public health law and legal system in countries as a tool of global health governance, experts consultation meetings were held, academic workshops attended and literature review on global health governance and public health law undertaken. Through support of the regional office of WHO is was possible to hold experts consultations meeting on public health law in this region to assist with the development of the analysis framework. WPRO has been conducting many health law related activities in 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 on the analysis framework. However, there could have been a selection bias. The number of persons who were invited in the expert consultations was limited and they may not represent a comprehensive health law opinion. Also the expert's group was composed of health law experts, which may have excluded experts who have expertise in global health governance. Due to time and financial constraints, the 1st and 2nd experts consultations were convened only one day each. This was found to be too short to discuss most of the issues.

With regards to attending international conferences, this proved meaningful to check the importance of the developing public health law agendas in academic societies in Asia, United States, and Canada. However, the limitation of attending international conferences was a limitation of English proficiency of the author to understand all information that was provided. In addition, some materials used in conference were not accessible, so only note taking material could be used as evidence.

In terms of literature review, the researcher has been trying to collect as much as it could, but some important materials could be missing.

To identify challenges faced during the demonstration tests and finding methods to improve the application of the analysis framework including academic value for public health law, pilot tests were conducted in four countries, a second expert meeting was held to discuss pilot results, a further implementation pilot test was done in Cambodia, and meetings were held with technical and academic staff. Conducting pilot tests two times before applying the framework and tool to other countries was very meaningful. Pilot tests for several countries were time consuming and costly for just checking the appropriateness of the tool. Finding the appropriate researcher was also not easy. However, health law experts who participated in 1st expert meeting were actively involved in the pilot test. Discussions on the framework and tool by both experts who were conducting the pilot test directly and experts who were not involved in the pilot test or in the initial framework development was also good to get different perspectives.

Through conducting the implementation pilot test in Cambodia, challenges and difficulties during the in-country assessment were identified, and allowed for the tool to be improved which will benefit local researchers in other countries.

The primary purpose of conducting pilot tests was checking the appropriateness of the tool itself. Because the reporting form was too broad, there were limitations for collecting people's ideas. Actually, results among the

health law experts who were involved in the pilot tests varied. For example, some researchers identified appropriateness of the questions itself and suggestions how they can be improved; but other researchers described only the assessment result of countries: e.g. by only including yes, no and explanatory note for existence of regulation. The other challenges were attributed to those views between the researchers who have an academic view and those from WHO. As staff from a member states supporting agency they would concentrate their review more on the synthesized results which can be feedback to the country than checking the appropriateness of the tool.

Only a few technical staffs in WPRO were interviewed. If the interview process had been done before the 1st experts meeting, more information could have been collected for the development and content of the assessment tool.

To suggest future direction and model for measuring domestic public health law and legal systems supporting global health governance, historical health legislation activities and similar analyses were reviewed, to identify strengths and weakness of the proposed analysis framework. In the two experts meetings, the discussions on future direction and model development were not enough. However, as this project was initiated in 2010 and has been conducted for the last 2 years, many materials and data have been collected which will contribute to future process of the project.

The results of this study demonstrated that public health law allows for a legal and administrative systems that assures social conditions in which people can live a healthy life. However, the question of effectiveness of law on public health, for example which methods are more effective between legal approaches versus non-legal approaches can still be raised. Under the current global architecture shape which possibly requires a more interdisciplinary approach to address health law issues in-country, monitoring public health law and legal systems in countries could be the one tool to understand governance that supports the improvement of people's health as a major strategy for WHO/WPRO.

The other questions faced throughout the project was the status of international health law in global health governance differentiating and respecting national sovereign versus implementing international law, and ability for external organizations to undertake such legal monitoring and whether using an unified tool can be used under varied historical and cultural background in countries. Countries that have become signatories to international Conventions are under a binding obligation to incorporate protection provided by such international agreements into their domestic law. Three important documents of this nature are together referred to as the International Bill on Human Rights. They are the Universal Declaration of Human Rights (UDHR), the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). Thus, if a country is a member of the United Nations, it is important to determine whether, and when, it became a signatory to all the documents comprising the International Bill on Human Rights. (J. Stuart Showalter., 2007)

Also, the International Health Regulations (IHR) is an international legal instrument that is binding for all the Member States of WHO. The regulations seek to effectively prevent and respond to acute global health risks by requiring the countries to report disease outbreaks and other public health risks. They also require the countries to improve their public health surveillance and response systems. WHO provides technical guidance and consultations to support such capacity building. (WHO/WPRO 2010) They are a set of global rules supported by WHO that is aimed to heighten national, regional and global public health security. The IHR offer an opportunity to improve global health governance, overcoming the problems of sovereignty and entrenched power. An innovative governance paradigm, based on the new IHR, would include comprehensive data collection, national public health preparedness, human rights safeguards, and sound public health governance. In addition, WHO Framework Convention on Tobacco Control (FCTC) is the first global health treaty negotiated under the

auspices of WHO in response to the global tobacco epidemic. (Lien G, DeLand K., 2011)

The appropriateness and usefulness of the analysis framework and its assessment tool for Public Health Law were confirmed through applying it in selected countries in the Western Pacific Region. Through this process, the tool, its development, possible problems were identified. The pilot tests confirmed that special consideration should be given to its implementation process, such as getting concurrence from government, determining the qualification of the local researchers as well as to the analysis of the assessment, such as the quality control and analysis methods and implication of such to describe the local public health law and regulatory situation in a country. Also, possible future improvements were raised. The analytical framework can be used as a tool to describe domestic public health law, but also capture other parts of the analysis, e.g. human resource availability for the close monitoring, development and implementation of public health laws. Also, the summary form can establish the major gaps in public health law with references to primary and secondary law which is in some countries more prominent and/or significant than in others.

Determining the types of law that would be covered by the tool was also difficult because of the wide range of instruments that could be regarded as "law" or have the effect of law, such as legislation, rules and regulations, administrative order, judicial opinion or other court-based law, as well as public policy and programs, tribal law, customary law. Because of practical concerns, the consensus of the 1st Consultation was to limit the law to legislation, both primary and subsidiary. (Kim SY et al, 2012)

The other question whether such health law assessments can be helpful for changing or improving the real world in public health areas and whether this is a need for an assessment especially when a country is well implementing its health sector program or policies were raised. Where possible, countries should still be encourages to enact missing primary legislation to provide a better legal basis for public health programmes.

In addition, there are already other global surveys, so this analytical framework could be the redundant. But, current global surveys are fragmented by issue. For example, children health status is monitored under a 'Framework for Implementing the Set of Recommendations on the Marketing of Food and Non-alcoholic Beverages to Children', disability issues by "Mapping of the Disability Policy and Program Frameworks in the Pacific', Tobacco control by "Global Tobacco Surveillance System (GTSS)", and IHR by "IHR Core Capacity Monitoring Framework: Questionnaire for Monitoring Progress in the Implementation of IHR Core Capacities in States Parties; Toolkit for implementation in national legislation" which contains questions and answers, legislative reference and assessment tool and examples of national legislation. However, there is no overall monitoring system for the whole spectrum of public health law and legal systems in countries.

Lastly, the future vision for monitoring domestic public health law and legal systems supporting global health governance was proposed that includes 1) further development of the tool to assess health law, 2) sharing experiences by the creation of websites and databases of public health laws, and 3) the establishment of networking to further enhance the analysis and establishment of domestic public health law on the basis of international health laws. Compiling an inventory of all relevant laws, orders and regulations relating to health or having health-related implications could be a useful source 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 contributing to global health governance. For WHO as an intergovernmental organization, this may be useful to assist with legal framework monitoring.

A thesis should contribute to practice, theory or future research. This dissertation was primarily focused on the practice. Development of an Analytical Framework to Assess Domestic Public Health Law Situation is the first successful trial in the real world. In 2006, domestic/national profiling of

population/public health law legislation in comparison with international health law was tried by Asian Institute of Bioethics and Health Law in Yonsei University. The aim of this project was to compile a comprehensive and coherent body of information encompassing all major public health law issues. Through a survey, participating countries provided background and details on their own systems, which was cross referenced with the information provided by others or analyzed at an aggregate level. Thus, public health law of nine countries was compiled but not updated thereafter. In light of this previous practice, this research and its recommendations has provided a much better sustainable future direction, especially with the emphasis on local capacity building and model development.

Finally, there is need for follow-up research. First, the capacity building of local researchers or other people that deal with domestic public health law should be covered. Secondly, improving the current modules is needed. Actually, Module 2 has no legal bases and needs discussion on the outcomes of its assessment by country and possibly by level or functional area (such as the system building blocks). Lastly, taking into account law and the actual world, research should be undertaken how health can be improved through monitoring of the public health law directly, or how legal system factors can be used for improving the health law capacity or coverage.

6. Conclusion

First, the usefulness of analyzing public health law and legal systems in countries as a tool of global health governance was demonstrated. Public health law provides a legal and administrative means that assures social conditions in which people can be healthy. It is a critical component that suggests directions or grants authority for the society to carry out or forbid activities in order to promote people's health. The role of the law in the field of public health is the implementation of legal rules within the health sector. As the world becomes more interconnected everyday, global health governance which is the management of the structural and normative aspects of the determinants and outcomes of global health, is relying more and more on the development of appropriate regulatory frameworks in and above countries.

In the crowded landscape of global health governance today, the role of WHO as an intergovernmental organization, is to protect the public's health and improving individual health outcomes through the promotion of appropriate legal systems. International lawmaking for domestic adoption is one of the strong tools for global governance. However, global law making is not easy and monitoring the public health law situation and legal system in countries being in line with international health law or common global health consensus is severely lacking. So, developing an analytical framework and tools for analyzing public health law and legal system in countries for supporting global health governance is useful at this point.

Second, this study identified methods to improve academic value and application of an analysis framework and a tool to assess public health law, which were subsequently used for data collection in selected countries. Results of country assessment from the Republic of Korea, the Philippines, Samoa, Vanuatu and Kingdom of Cambodia were used to demonstrate that the assessment tool was generally usable. However, by the nature of it being a pilot also received important feedback regarding the purpose, use, structure, wording, appropriateness and the need for qualitative aspects measurement in the tool.

This study recommends that response structure and questionnaire contents, as well as evaluation methods of the tool are further improved. The purpose of the tool was confirmed that contributes to help people learn about both international and domestic law and identifies possible gaps.

Third, the assessment tool implementation test in the Kingdom of Cambodia, showed the importance of getting concurrence from the government, quality control of the local researcher, the role of the academic institution in relation to the local researcher, standardizing of the reporting form and the results template, as well as the importance of gathering human resources information, country background, and feedback on tool itself. Also, analytical and result disclosure methods including cross country comparison and attentive points for interpreting the results were suggested.

Fourth, using an analysis on WHO historical legal activities, basic principles were established that would further enhance the long-term applicability of the tool by expanding from the IHDL into a well established law regulatory framework at local or regional level, through concurrent development of appropriate governance and monitoring capacities.

Fifth, several models were proposed to embed the development of regulatory frameworks as part of domestic and international health agenda's, through refinement of the questionnaire levels of the tool, color-coding of its results, applying different presentation methods, developing model legislation lists, commonly accessible websites and public health law support/discussion groups.

Through the development of an analytical framework to assess domestic public health law situation in western pacific regional countries, importance of monitoring domestic public health law and legal system supporting global health governance were demonstrated.

References

- 1. Andre den Exter. *International Health Law and Ethics Basic Documents* 2nd Revised Edition; Maklu, 2011.
- Basak P. Developmen of an Online Tool for Public Health: the European Public Health Law Network. Public Health 2011 Sep;125(9):600-3.
- 3. Bogdan Buduru, Leslie A. Pal. *The Globalized State: Measuring and Monitoring Governance*. European Journal of Cultural Studies, 2010;13(4):511-530.
- 4. C. Stephen Redhea, Hinda Chaikind, Bernadette Fernandez, Jennifer Staman. ACA: A Brief Overview of the Law, Implementation, and Legal Challenges. 2012.
- 5. Christopher Reynolds. *Public Health Law and Regulation*. Federation Press, 2004.
- DeKeely Hartsfield, Anthony D. Moulton, Karen L. McKie. A Review of Model Public Health Laws. Am J Public Health. April 2007;97(Supplement_1):S56-S61.
- 7. Edwin M. Borchard. *Relation Between International Law and Municipal Law*. 27 Virginia Law Review 137, 1940.
- 8. Elias Mossialos, Govin Permanand, Rita Baeten, Tamara Hervey.

 Health Systems Governance in Europe: The Role of European Union

 Law and Policy. Cambridge University Press, 2010.
- 9. Evgeniya Plotnikova, Sarah E Hill, Jeff Collin. The 'diverse, dynamic new world of global tobacco control'? An Analysis of Participation in the Conference of the Parties to the WHO Framework Convention on Tobacco Control. 9 Dec 2012.
- 10. Gable L, Gostin L, Hodge JG Jr. A Global Assessment of the Role of Law in the HIV/AIDS Pandemic. Public Health 2009 Mar;123(3):260-4.

- 11. Genevieve Howse. *Public Health Law in the Pacific: A Reviewers Companion*. 2012.
- 12. Gilles Dussault. A United Nations Global Health Panel for Global Health Governance: A Commentary on Mackey. Social Sience & Medicine, 2012;1-2.
- Hazarika S, Yadav A, Reddy KS, Prabhakaran D, Jafar TH, Narayan KM. Public Health Law in India: A Framework for Its Application as a Tool for Social Change. Natl Med J India, 2009 Jul-Aug:22(4): 199-203.
- 14. Institute of Medicine (IOM). *The U.S. Commitment to Global Health:**Recommendations for Public and Private Sectors. The National Academies Press, Washington D.C., 2009.
- 15. International Planned Parenthood Federation (IPPF). *Legal Abortion: A Comparative Analysis of Health Regulations*. IPPF/Western Hemisphere Region, New York, 2009.
- James G. Hodge, Jr. Connecting Public Health Law, Practice, Policy and Research. The Journal of Law, Medicines and Ethics, Special Supplement to Volume 39:1, Spring 2011:5-8.
- 17. Jocelyn Downie, Timothy Caulfield, Colleen M. Flood. *Canadian Health Law and Policy 4th Edition*. LexisNexis Canada Inco., 2011.
- 18. John Coggon. What Makes Health Public?: A Critical Evaluation of Moral, Legal, and Political Claims in Public Health. Cambridge University Press, New York, 2012.
- 19. John G. Culhane. *Reconsidering Law and Policy Debates: A Public Health Perspective*. Cambridge University Press, 2011.
- 20. John Tobin. *The Right to Health in International Law*. Oxford University Press, New York, 2012.
- 21. J. Stuart Showalter. *The Law of Healthcare Administration 5th Edition*. Health Administration Press, Chicago, 2007.

- 22. Keith Syrett. Law, Legitimacy and the Rationing of Healthcare: A

 Contextual and Comparative Perspective. Cambridge University Press,
 2007.
- 23. Kim SY, Lee Y, Sohn M, Hahm KH. *Developing a Tool for Assessing Public Health Law in Countries*. Asia Pac J Public Health 2012 Sep;24(5):867-71.
- 24. Laura Westra, Colin L. Soskolne, Donald Spady. *Human Rights and Ecological Integrity: Ethics, Law and Human Rights*. Abingdon, New York, 2012.
- Lawrence O. Gostin. Public Health Law: Power, Duty, Restraint Revised and Expanded 2nd Edition. University of California Press, 2007.
- 26. Lawrence O. Gostin. *Public Health Law and Ethics: A Reader*. University of California Press, 2010.
- 27. Lawrence O. Gostin. *Public Health Law in a New Century Part 1: Law as a Tool to Advance the Community's Health.* JAMA 2000:283(21):2837-2841.
- 28. Lawrence O. Gostin. *Public Health Law in a New Century Part 3:*Public Health Regulation: A Systematic Evaluation. JAMA 2000 Jun 21;283(23):3118-22.
- 29. Lawrence O. Gostin. *General Justifications for Public Health Regulation*. Public Health 2007 Nov;121(11):829-34.
- 30. Lawrence O. Gostin. *Law as a Tool to Facilitate Healthier Lifestyles and Prevent Obesity*. JAMA 2007: 297(1):87-90.
- 31. Lawrence O. Gostin. World Health Law: Toward a New Conception of Global Health Governance for the 21st Century. Yale J Health Policy Law Ethics 2005 Winter;5(1):413-24.
- 32. Lien G, DeLand K. Translating the WHO Framework Convention on Tobacco Control (FCTC): Can We Use Tobacco Control as a Mdodel for Other Non-communicable Disease Control?. Public Health 2011 Dec;125(12):847-53.

- 33. Lukasz Gruszczynski. Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement. Oxford University Press, 2010.
- 34. Martin R. Law as a Tool in Promoting and Protecting Public Health: Always in Our Best Interests?. Public Health 2007 Nov;121(11)846-53.
- 35. Meier, B.M. Transitions in State Public Health Law: Comparative Analysis of State Public Health Reform Following the Turning Point Model State Public Health Act. American Journal of Public Health, 2009;99(3):423-429.
- 36. Michael J. Trevilcock, Mariana Mota Prado. What Makes Poor Countries Poor? Institutional Determinants of Development. Edward Elgar Publishing Limited, 2011.
- 37. Moulton, A.D. The *Scientific Basis for Law as a Public Health Law*. American Journal of Public Health, 2009;99(1):17-23.
- 38. Myongsei Sohn. *Globalization of Public Health Law and Ethics*. Asia-Pacific Journal of Public Health, 2012;24(5):851-855.
- 39. Obijiofor Aginam. *Global Health Governance: International Law and Public Health in a Divided World.* University of Toronto Press, 2005.
- 40. Peter de Cruz. *Comparative Health Law*. Cavendish Publishing Limited, London, 2001.
- 41. Port Kenneth L., Gerald Paul McAlinn. *Comparative Law: Law and the Legal Process in Japan 2nd edition*. 2003.
- 42. Richard B. Saltman, Reinhard Busses, Elias Mossialos. *Regulating Entrepreneurial Behaviour in European Health Care Systems*. World Health Organization, 2002.
- 43. Roemer, R. Health Legislation as a Tool for Public Health and Health Policy, IDHL. 1998;48(1):89-100
- 44. Schlesinger, Rudolf. *Comparative Law: Case-Text Materials* 6th edition. 1998.

- 45. Snezhanna Chichevalieve. *Developing a Framework for Public health Law in Europe*. World Health Organization, EURO, 2011.
- 46. Sophie Harman. Global Health Governance. Abingdon, Oxon, 2012.
- 47. Taylor AL. Global Governance, International Health Law and WHO: Looking Towards the Future. Bull World Health Organ. 2002;90(12):957-80.
- 48. Taylor AL. Making the World Health Organization Work: a Legal Framework for Universal Access to the Conditions for Health. Am J Law Med 1992;18(4):301-46.
- 49. The American Public Health Association. *International Digest of Health Legislation*. American Journal of Public Health. March 2001;91(3)
- 50. The International Development Law Organization (IDLO), World Health Organization (WHO), The O'Neill Institute for National and Global Health Law Georgetown University. *International Expert Consultation on Public Health Law*. Rome, Italy, 26-28 April 2009.
- 51. The International Development Law Organization (IDLO), World Health Organization (WHO), The O'Neill Institute for National and Global Health Law Georgetown University. *International Expert Consultation on the Development of a Public Health Law Manual.* Cairo Egypt, 26-28 April 2010.
- 52. UNAIDS, UNDP, IDLO. *Toolkit: Scaling Up HIV-Related Legal Services*. International Development Law Organization, 2009.
- 53. UNDP HIV/AIDS Group. Global Commission on HIV and the Law: Risks, Rights and Health. UNDP, 2012.
- 54. W.E. Parmet. *Populations, Public Health, and the Law.*, Georgetown University Press, Washington, D.C., 2009.
- 55. World Health Organization (WHO). *International Digest of Health Legislation*, Vol.50, No.1, 1999.
- 56. World Health Organization. International Health Regulation (2005): A brief Introduction to Implementation in National Legislation. 2009,

- 57. World Health Organization. *International Health Regulations* (2005): Toolkit for Implementation in National Legislation. January 2009.
- 58. World Health Organization. WHO Resource Book on Mental Health, Human Rights and Legislation: Stop Exclusion, Dare to Care. 2005.
- 59. World Health Organization. *Newletter on WHO reform: Change@WHO*. November 2012.
- 60. World Health Organization (WHO) Western Pacific Regional Office (WPRO). Expert Consultation on Public Health Law. 5-6 May 2011, Manila, Philippines.
- 61. World Health Organization (WHO) Western Pacific Regional Office (WPRO). Second Expert Consultation on Public Health Law. 18 October 2011, Seoul, Republic of Korea.
- 62. World Health Organization (WHO) Western Pacific Regional Office (WPRO). Western Pacific Regional Strategy for Health Systems Based on the Values of Primary Health Care. 2010.
- 63. World Health Organization (WHO) Regional Office for Western Pacific (WPRO). *Enforcement of Public Health Legislation*. 2006.
- 64. World Health Organization (WHO) Regional Office for Western Pacific (WPRO). Enhancing Health Policy Development: A Practical Guide to Understanding the Legislative Process. 2004.
- 65. World Health Organization (WHO) Regional Office for Western Pacific (WPRO). Using Domestic Law in the Fight Against Obesity: An Introductory Guide for the Pacific. 2003.
- 66. World Health Organization (WHO) Regional Office for Western Pacific (WPRO). Achiving the Health-Related MDGs in the Western Pacific Region Progree Report. 2010.
- 67. World Health Organization (WHO) Regional Office for South-East Asia (SEARO). Meeting the Needs of Persons with Mental Disorders Through Legislation: Proceedings of a Regional Workshop on Mental Health Legislation. Galle Sri Lanka, 24-27 May 2001.

- 68. World Health Organization (WHO) Regional Office for South-East Asia (SEARO). Review of Patent Legislation of India, Indonesia, Sri Lanka and Thailand: Measures to Safeguard Public Health. New Delhi India, September 2004.
- 69. World Health Organization (WHO) Regional Office for South-East Asia (WPRO). A Systematic Approach to Developing and Implementing Mental Health Legislation: Report of a Regional Meeting of Eperts.

 New Delhi India, 6-8 December 2004.
- 70. World Health Organization (WHO) Regional Office for South-East Asia (WPRO). *Tobacco Control Legislation: Report of a Inter-country Workshop*. Colombo Sri Lanka, 4-5 December 2008.
- 71. World Health Organization (WHO) Regional Office for South-East Asia (WPRO). Regional Health Forum WHO South-East Asia Regiona.l Volum 7 Number 2, 2003.
- 72. World Health Organization (WHO) Regional Office for European (EURO). Legislating for Smoke-free Workplaces, European Tobacco Control Policy Series. 2006.
- 73. World Health Organization (WHO) Regional Office for European (EURO). *Housing and Health Regulations in Europe: Summary Document*. 2007.
- 74. World Health Organization (WHO) Regional Office for Africa (AFRO).

 African Parties to the WHO Framework Convention on Tobacco

 Control Prepare to Implement Treaty. 2007.
- 75. World Health Organization (WHO) Regional Office for Africa (AFRO).

 International Health Regulation (2005): Areas of Work for

 Implementation. 2007.
- 76. World Health Organization (WHO) Regional Office for Eastern Mediterranean (EMRO). WHO's Framework Convention on Tobacco Control: A Response to the Global Epidemic. 2010.
- 77. WHO homepage,

URL http://www.who.int/hhr/health_law/healthlaw/en/,

URL http://www.who.int/nationalpolicies/en/,

[Annex 1]

WORLD HEALTH ORGANIZATION WESTERN PACIFIC REGIONAL OFFICE

ANALYSIS TOOL TO ASSESS PUBLIC HEALTH LAW

OVERVIEW

Health law is a central component of every country's attempts to detect, assess and respond to health threats for the improvement and promotion of health for its citizens.

WHO/WPRO has developed a tool to assess health law in countries. The 1st Expert Consultation on Public Health Law convened in May 2011 to review the tool in terms of its goals and objectives, as well as the basic theory and structure. The tool was then pilot tested in four countries: Republic of Korea, Vanuatu, Samoa, and the Philippines. The 2nd Expert Consultation convened in October 2012 to refine the tool based on the results of the pilot test and other relevant resources.

The primary purpose of the tool is to determine the comprehensiveness of a country's health law through a series of questions asking whether law(s) (e.g., legislation, regulation) have been enacted for specific areas relating to health (e.g., HIV/AIDS). Gaps in the country's system may be identified through the absence of relevant law. In addition, the information may be compared across multiple countries. During the process of completing the tool, the relevant provisions of law will also be compiled to build a central database of laws for more detailed analysis. For each country, the final step of implementation will include a report that summarizes the findings and makes recommendations as necessary.

The tool currently comprises 4 modules: Module 1 is based on WHO International Digest of Health Legislation (IDHL); Module 2 concerns Health Systems based on Primary Health Care (PHC) Values; Module 3 concerns the International Health Regulations 2005 (IHR), and Module 4 concerns the Framework Convention on Tobacco Control (FCTC). Because each module has been designed to be self-standing, certain questions may overlap in subject matter across different modules. Additional modules covering different specific areas of health law may later be developed and added to the tool.

For the first phase of implementation, WHO/WPRO has contracted with Yonsei University in the Republic of Korea to apply the tool in four countries, including Cambodia, Lao PDR, Mongolia, and Vietnam. The project will involve of a Designated Expert dispatched by Yonsei University to oversee completing the tool and compiling the laws in cooperation with an appointed Local Researcher in each country.

GUIDELINES

1. For each of the questions in the modules below, please respond by checking the "Y" box with a lower case "x" if your country has law(s) specifically relating to the subject area and currently in force.

The tool is concerned primarily with the following types of law: (i) *constitutional provisions* (e.g., bill of rights) adopted by the government; (ii) *primary legislation* (e.g., acts, codes, statutes) enacted by the main law-making body of the government (e.g., parliament); (iii) *subsidiary legislation* (e.g., regulations, orders, decrees) promulgated

by executive bodies (e.g., ministries, agencies); (iv) *by-laws* (e.g., ordinances) issued by local authorities (e.g., city councils, district offices); and (v) *international instruments* (e.g., treaties, conventions) signed and ratified by your country.

2. If a current law is partially related to a subject area, please respond "Y" and provide further explanation in the box for "explanatory note."

A law that is "partially related" to a subject area may include one or more of the following situations: (i) the law covers certain aspects of the subject area but not all or most of the pertinent aspects as would generally be expected of such a law; or (ii) the subject area is not covered by a law relating exclusively to the subject area per se but instead referenced specifically in a broader law (e.g., framework act) or tangentially related law (e.g., criminal code).

- 3. In the box for "explanatory note," please cite the relevant law(s), including name, year of enactment/revision, and code section, as well as any additional reference markers employed by your legal system.
- 4. Also in the box for "explanatory note," please indicate the format(s) by which the texts of the relevant law(s) may be accessed.

Access may take one or more of the following formats: (i) hyperlink to an on-line database; (ii) electronic document; (iii) electronic scan of the text; or (iv) photocopy of the text.

- 5. Along with the completed tool, please attach hardcopy versions of the texts as appendices following each module.
- 6. Also in the box for "explanatory note," please indicate the language(s) in which the texts are available.

The language(s) may be categorized as one or more of the following: (i) local language; (ii) official English translation sanctioned by the government; (iii) unofficial English translation made for informal research/reference purposes (include information on authorship, source, and date).

- 7. If your country does not have a current law as described above that specifically or partially relates to the subject area, please respond by checking the "N" box with a lower case "x."
- 8. In the box for "explanatory note," please provide additional explanation where appropriate to provide context for the "N" response.

Additional explanation of a "no" response may be helpful in one or more of the following situations: (i) a law relating to the subject area once existed but has since been repealed or otherwise invalidated; (ii) a draft form of law (e.g., bill) relating to the subject area is currently being processed but not yet finalized; (iii) the subject area is covered by a governmental program, policy, or set of procedures that has no direct basis in one of the aforementioned types of law; (iv) the subject area has been addressed in a judicial decision that continues to influence activities and/or has the force of law in the subject area; (v) the subject area is covered by tribal/village/customary law(s) applicable to a limited group of people; or (vi) the subject area is "not applicable" to your country (e.g., maritime issues for a landlocked country).

NOTES to LOCAL RESEARCHER

As described in the Agreement for Performance of Work and Terms of Reference between Yonsei University and you in your capacity as the Local Researcher, you are responsible for completing a preliminary desk review of the tool according to the guidelines above. You are expected to provide accurate responses to the best of your knowledge, making full use of the resources at your disposal. The additional explanations that accompany your responses, where necessary, as well as the citations to and texts of the laws themselves, are also to be considered an essential part of the task. While your responses and explanations may be used in various summaries, analyses, and reports, no direct attribution will be made to the Local Researcher by name.

Upon completion of your desk review, please submit the tool in electronic form to:

- (i) Mr. Sjieuwke POSTMA (Team Leader, HSD unit, WPRO/WHO): hawkenl@wpro.who.int;
- (ii) Ms. Yuri LEE (Technical Officer (Legal), WPRO/WHO): leeyu@wpro.who.int;
- (iii) Dr. Soyoon KIM (Professor, Yonsei University): syoonkim@yuhs.ac; and
- (iv) Dr. Ki-Hyun HAHM (Supervising Expert) (Professor, Ajou University): hahmki@gmail.com.

Upon approval of the desk review by Yonsei University and WHO/WPRO, the tool will undergo a secondary review towards completion under the direct supervision of the Supervising Expert. As the Local Researcher, you are responsible for meeting with the Supervising Expert during the Supervising Expert's visit to your country, arranging and attending additional meetings with other local consultants for information regarding unresolved issues from the desk review, if any, as well as meetings with other persons as necessary, and providing the hardcopy texts of the laws as described above. Finally, you are responsible for drafting the final country report according to the standards set forth in the separate Country Report Template.

Even after final submission of the completed tool, you may be contacted, if necessary, to assist further by providing additional clarification or documentation by the Supervising Expert, Yonsei University, or WHO/WPRO. Your on-going cooperation in this regard will be appreciated.

Please supply information for the following individuals:

Local Researcher

Name	[e.g., Mr./Ms./Dr.] [Given Name] [FAMILY NAME]
Current post/title	[e.g., Professor/Researcher]
Current affiliation	[e.g., Ministry of Health, Health Services Division]
E-mail address	
Telephone	[+country code] [local number]

Additional respondent(s) (other than Local Researcher, persons who completed sections of the tool, if any) (insert additional tables consecutively, one for every additional respondent, if necessary)

Name	[e.g., Mr./Ms./Dr.] [Given Name] [FAMILY NAME]
Current post/title	[e.g., Professor/Researcher]
Current affiliation	[e.g., Ministry of Health, Health Services Division]
E-mail address	
Telephone	[+country code] [local number]
Sections	[e.g., Module 1: questions 21-23, Module 4: all]

Local consultant(s) (persons consulted as resources of information in completing the tool and/or acquiring texts of laws, if any) (insert additional tables consecutively, one for every additional expert, if necessary)

Name	[e.g., Mr./Ms./Dr.] [Given Name] [FAMILY NAME]
Current post/title	[e.g., Professor/Researcher]
Current affiliation	[e.g., Ministry of Health, Health Services Division]
E-mail address	
Telephone	[+country code] [local number]
Sections	[e.g., Module 1: questions 21-23, Module 4: all]

<u>Module 1:</u> International Digest of Health Legislation

- The objective of this module is to assess each country's breadth of coverage for laws pertaining to health and health-related issues vis-à-vis the WHO *International Digest of Health Legislation* (IDHL).
- For convenience, the order, content, and wordings of the questions below generally follow the subject headings of the IDHL, though certain subject areas have been broken down into more specific sub-issues (e.g., (Question 10) communicable diseases and (Question 11) HIV/AIDS) or merged into a single question (e.g., (Question 24) biomedical ethics and professional responsibility).
- The IDHL (in English) is available on-line at: http://apps.who.int/idhl-rils/frame.cfm?language=english. See also Annex 1.

	MODULE 1: International Digest of Health Legislation				
	Question	Y	N	Explanatory Note	
1.	Does your country have constitutional provisions relating to health?				
2.	Does your country have law(s) relating to human rights and other fundamental rights that pertain to health?				
3.	Does your country have law(s) relating to international treaties and other international instruments that pertain to health? (If so, please provide a brief overview of your legal system and explain how such international obligations are incorporated into the system. Also, please list the international treaties and instruments to which your country is a signatory.)				
4.	Does your country have law(s) relating to the organization and/or administration of health care (e.g., general governmental health and public health agencies, including ministries, boards, councils)? [This question generally addresses the same subject matter as Module 2, Questions 1-3.]				
5.	Does your country have law(s) relating to health financing (e.g., taxation, social security, health insurance, cost containment)? [This question generally addresses the same subject matter as Module 2, Questions 4-6.]				
6.	Does your county have law(s) relating to health research (e.g., government support, permits)? [This question differs from but partially addresses the same subject matter as Module 1, Question 24.]				

	MODULE 1: International Digest of Health Legislation				
	Question	Y	N	Explanatory Note	
7.	Does your country have law(s) relating to health				
	education (e.g., information the public, health				
	promotion, access to information)? [This question				
	generally addresses the same subject matter as				
8.	Module 2, Questions 7-10.] Does your country have law(s) relating to quality				
0.	control of health workers (e.g., regulation and				
	licensing, access, specialization, training and				
	education, monitoring)? [This question differs from				
	but partially addresses the same subject matter as				
	Module 1, Question 24.]				
9.	Does your country have law(s) relating to health				
	care facilities, related institutions, and/or services?				
10.	Does your country have law(s) relating to				
1	communicable diseases? [This question generally				
	addresses the same subject matter as Module 3				
	overall.]				
11.	Does your country have law(s) relating specifically				
	to HIV/AIDS, including criminal laws, immigration				
12	laws, and/or family laws?				
12.	Does your country have law(s) relating to organ transplantation and/or human tissues, including				
	blood and blood products?				
13	Does your country have law(s) relating to non-				
15.	communicable diseases?				
14.	Does your country have law(s) relating to oral				
	health (e.g., fluoridation)?				
15.	Does your country have law(s) relating to family				
	health (e.g., family counseling, genetic counseling,				
	maternal health and care programs, prenatal care,				
	prenuptial examinations, sex education)? [This				
	question differs from but generally addresses the				
	same subject matter as Module 1, Question 17.]				
16.	Does your country have law(s) relating to child				
	health (e.g., abuse of children, adolescent health,				
	child labor, daycare facilities, infant care, school				
17	health program)? Does your country have law(s) relating to human				
1/.	reproduction and/or population control?				
18	Does your country have law(s) relating to care of		 		
10.	the elderly (e.g., basic care arrangements, geriatric				
	programs, old-age homes)?				
19.	Does your country have law(s) relating to care of				
	the disabled and/or rehabilitation (e.g., basic care				
	arrangements, mobility and access arrangements,				
	sheltered workshops)?	<u></u>			
20.	Does your country have law(s) relating to mental				
	health?				

MODULE 1: International Digest of Health Legis	lation		
Question	Y	N	Explanatory Note
21. Does your country have law(s) relating to the control of smoking and/or use of other tobacco products? [This question generally addresses the same subject matter as Module 4 overall.]			
22. Does your country have law(s) relating to the control of alcohol use?			
23. Does your country have law(s) relating to the control of drug abuse (e.g., control of narcotics and other illegal substances, addition treatment, criminalization)?			
24. Does your country have law(s) relating to biomedical ethics and/or professional responsibility (e.g., research ethics, confidentiality, advertising, codes of conduct, disciplinary measures, civil and/or criminal liability for wrongdoing)? [This question differs from but partially addresses the same subject matter as Module 1, Questions 6 and 8.]			
25. Does your country have law(s) relating to death and dying (e.g., euthanasia, living wills, determination of death, registration of death)?			
26. Does your country have law(s) relating to post-mortem examinations?			
27. Does your country have law(s) relating to the disposal of the dead?			
28. Does your country have law(s) relating to nutrition (e.g., food fortification, infant foods, malnutrition, nutritional services and education)?			
29. Does your country have law(s) relating to food safety (e.g., adulteration and additives, inspection, irradiation, import and export controls, packaging and advertising, pesticides and veterinary pharmaceutical residues, handling and distribution)?			
30. Does your country have law(s) relating to the safety of consumer products (e.g., toys, kitchen utensils, appliances, ceramics)?			
31. Does your country have law(s) relating to pharmaceuticals and/or related products? [This generally addresses the same subject matter as Module 2, Questions 13-14.]			
32. Does your country have law(s) relating to traditional medicines?			
33. Does your country have country law(s) relating to medical devices?			
34. Does your country have law(s) relating to poisons and/or other hazardous substances?			
35. Does your country have law(s) relating to occupational health and safety?			

MODULE 1: International Digest of Health Legislation				
Question		Y	N	Explanatory Note
to human health (e	have law(s) relating to tection as it pertains specifically .g., sanitary standards for quality, pollution, waste			
	have law(s) relating to radiation			
prevention (e.g., he	have law(s) relating to accident ealth requirements for drivers, ms, road safety, safety in air			
-	have law(s) relating to sports ., doping, safety/hygiene of ports medicine)?			
information (e.g., v disease), including	have law(s) relating to health vital statistics, notification of provisions relating to the role of n obtaining and/or maintaining nd statistics?			

Module 2: Health Systems based on Primary Health Care Values

- The objective of this module is to assess each country's efforts via law to develop a primary health care system in relation to the WHO Western Pacific Regional Strategy for Health Systems Based on the Values of Primary Health Care (Strategy).
- The questions below derive from the Strategy, specifically those issues that historically have been and/or can be regulated by law.
- The Strategy (in English) is available on-line at: http://www.wpro.who.int/NR/rdonlyres/89BE3251-DD0F-4E61-992B-7C54AD83C048/0/RS Health Systems web.pdf . See also Annex 2.

	MODULE 2: Health Systems based on Primary Hea	alth Car	e Values	
	Question	Y	N	Explanatory Note
1.	Does your country have law(s) mandating health authority to develop national health plans, policies, strategies, and/or frameworks?			
2.	Does your country have law(s) mandating health authority to implement and monitor nation health plans, policies, strategies, and/or frameworks?			
3.	Does your country have law(s) mandating health authority to engage in coalition-building with stakeholders outside the health sector?			
4.	Does your country have law(s) relating to the provision of health financing (e.g., taxation, social security, health insurance, cost containment)?			
5.	Does your country have law(s) relating to the provision of minimum health services for your citizens?			
6.	Does your country have law(s) relating to safety-net mechanisms for your citizens to protect them from financial disaster due to health expenditures?			
7.	Does your country have law(s) relating to maintaining numbers of health workers (e.g., production, deployment and retirement, international recruitment)?			
8.	Does your country have law(s) relating to classification among various types of health workers?			
9.	Does your country have law(s) relating to the distribution of health workers?			
10.	Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)?			
11.	Does your country have law(s) relating to the protection of patients as health consumers (e.g. patient bill of rights, including access to services and			

MODULE 2: Health Systems based on Primary Health Care Values				
Question	Y	N	Explanatory Note	
medical technologies, right to receive health interventions at a time and location of their choosing)				
12. Does your country have law(s) relating to monitoring the performance of your health system (e.g., quality control of services)?				
13. Does your country have law(s) relating to the access of essential medicines?				
14. Does your country have law(s) relating to quality control, cost effectiveness, safety, efficacy of medicines and medical technologies?				
15. Does your country have law(s) relating to the access of vaccines?				
16. Does your country have law(s) relating to quality control of vaccines (e.g., cold chain requirements)?				
17. Does your country have law(s) relating to the use of information technology in health care?				

$\frac{Module\ 3:}{International\ Health\ Regulations\ (2005)}$

- The objective of this module is to assess each country's efforts via law towards fulfilling the requirements under the WHO *International Health Regulations* (2005) (IHR).
- The questions below derive from the IHR, specifically those issues that historically have been and/or can be regulated by law.
- The IHR (in English) is available on-line at: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf. See also Annex 3.

Questions	Y	N	Explanator Note
 Does your country have law(s) relating to the designation or establishment of a National IHR Focal Point? (See Article 4) 			
2. Does your country have law(s) relating to the designation of the authorities responsible for public health risks and public health emergencies of international concern? (See Article 4)			
3. Does your country have law(s) relating to the capacities for surveillance and notification of public health risks and public health emergencies of international concern? (See Articles 5-10, Annex 1)			
4. Does your country have law(s) relating to the capacities for public health response to public health risks and public health emergencies of international concern? (See Article 13, Annex 1)			
5. Does your country have law(s) relating to the capacities for public health response at designated points of entry, including airports, ports, and ground crossings? (See Articles 19-22, Annex 1)			
6. Does your country have law(s) relating to health measures for travelers? (See Articles 23, 30-32, 35, 42-43)			
7. Does your country have law(s) relating to certificates of vaccination or other prophylaxis for travelers? (See Article 36)			
8. Does your country have law(s) relating to charges for health measures regarding travelers? (See Article 40)			
9. Does your country have law(s) relating to			

Questions		Y	N	Explanator
				Note
conveyances, goods, p	ggage, cargo, containers,			
human remains? (See				
10. Does your country hav				
	sures regarding baggage,			
	yeyances, goods, postal			
parcels, and/or human				
41)	remains. (See Three			
11. Does your country hav	e law(s) relating to the			
application of health m				
and/or container loadir				
34)	8			
12. Does your country hav	e law(s) relating to the			
	veyance operators with			
respect to health measu	ares? (See Articles 23,			
24, 35, 42-43)				
13. Does your country hav	e law(s) relating to			
health measures for co				
(See Articles 23, 25-26				
14. Does your country hav				
health measures for co				
	3, 27, 28-29, 35, 37-39,			
42-43)				
15. Does your country hav				
health documents for c	onveyances? (See			
Articles 37-39)	1 () 1 ()			
16. Does your country have				
	tance with other States			
Parties and/or WHO w	health emergencies of			
international concern?				
17. Does your country hav				
treatment of personal of				
	l/or WHO with regard to			
public health risks and				
emergencies of interna				
Article 45)				
18. Does your country hav	e law(s) relating to			
	reagents, and materials			
for diagnostic purpose				
	health emergencies of			
international concern?				

Module 4: Framework Convention on Tobacco Control

- The objective of this module is to assess each country's efforts via law towards fulfilling the requirements under the WHO *Framework Convention on Tobacco Control* (FCTC).
- The questions below derive from the FCTC, specifically those issues that historically have been and/or can be regulated by law.
- The FCTC (in English) is available on-line at: http://whqlibdoc.who.int/publications/2003/9241591013.pdf. See also Annex 4.

	MODULE 4: Framework Convention on Tobacco Control					
	Questions	Y	N	Explanatory Note		
1.	Does your country have law(s) relating to national tobacco control strategies, plans, or programs? (See Article 5)					
2.	Does your country have law(s) relating to the pricing and/or taxation of tobacco products? (See Article 6)					
3.	Does your country have law(s) relating to the protection from exposure to tobacco smoke? (See Article 8)					
4.	Does your country have law(s) relating to the regulation of the contents of tobacco products? (See Article 9)					
5.	Does your country have law(s) relating to the regulation of tobacco product disclosure? (See Article 10)					
6.	Does your country have law(s) relating to the packaging and labeling of tobacco products? (See Article 11)					
7.	Does your country have law(s) relating to education, communication, training, and/or public awareness of tobacco issues? (See Article 12)					
8.	Does your country have law(s) relating to tobacco marketing, including advertising, promotion, and sponsorship? (See Article 13)					
9.	Does your country have law(s) relating to tobacco dependence and cessation? (See Article 14)					
10.	Does your country have law(s) relating to illicit trade in tobacco products? (See Article 15)					

MODULE 4: Framework Convention on Tobacco Control				
Questions	Y	N	Explanatory Note	
11. Does your country have law(s) relating to sales to and by minors? (See Article 16)				
12. Does your country have law(s) relating to the provision of support for economically viable alternatives for tobacco workers, growers, and/or individual sellers? (See Article 17)				
13. Does your country have law(s) relating to the protection of the environment and the health of persons in respect of tobacco cultivation and manufacture? (See Article 18)				
14. Does your country have law(s) relating to criminal and/or civil liability, including compensation, with respect to tobacco products? (See Article 19)				
15. Does your country have law(s) relating to research, surveillance, and exchange of information with respect to tobacco consumption? (See Articles 20-22)				

[Annex 2] Reporting Form: Excel Version

Western Pacific Regional Office Tool To Assess Health Law WHO/WPRO has developed a tool to assess health law in countries. The primary purpose of the tool is to determine the comprehensiveness of a country's health law through a series of questions asking whether law(s) have been enacted for specific areas relating to health (e.g., HIV/AIDS). Cell with blue backgound provide a drop down list to choose your entry. Some part of this form have instructions. Yon can read the instructions by clicking on the pink, un Name Name Current Post/Title Current Post/Title **Current Affiliation** Current Affiliation E-mail address E-mail address Telephone Telephone Sections Name Name Current Post/Title Current Post/Title **Current Affiliation Current Affiliation** E-mail address E-mail address Telephone Telephone Sections

World Health Organization

1. Does your country have law(s) relating to national 05 01 See Article 5 tobacco control strategies, plans, or programs? 2. Does your country have law(s) relating to the 05 02 See Article 6 pricing and/or taxation of tobacco products? 3. Does your country have law(s) relating to the 05_03 See Article 8 protection from exposure to tobacco smoke? 4. Does your country have law(s) relating to the 05_04 See Article 9 regulation of the contents of tobacco products? 5. Does your country have law(s) relating to the 05_05 See Article 10 regulation of tobacco product disclosure? 6. Does your country have law(s) relating to the 05_06 See Article 11 packaging and labeling of tobacco products? 7. Does your country have law(s) relating to education. communication, training, and/or public awareness of tobacco issues? o. Dues your country lrave law(s) relating to tobacco marketing, including advertising, promotion, and 05_07 See Article 12 See Article 13 05 08 Does your country have law(s) relating to tobacco 05_09 See Article 14 10. Does your country have law(s) relating to illicit See Article 15 trade in tobacco products? 11. Does your country have law(s) relating to sales to 05 11 See Article 16 and by minors?

[Annex 3] Final Report Template

Report of In-country Analysis for Public Health Law in XXX county

- 1. Background
- 2. Objectives
- 3. Legal System in XXX country
 - A. General Information
 - B. Governance Structure
 - C. Legal System
 - D. The Basic Codes and Other Laws
- 4. Methods
 - A. Total Process of Analysis (including Timeframe, Participants)
 - B. Data Collection Process
 - C. Consultations Process
 - D. Analytical Methods
- 5. Results
 - A. Overview of the Health Laws in XXX country

Table 1. Profiling the Health Laws

- B. Health law coverage and most important gaps in XXX country
 - Table 2. IDHL related Laws
 - Table 3. Health System related Laws
 - Table 4. IHR related Law Laws
 - Table 5. FCTC related Laws
- 6. Conclusion
 - A. Health Law Coverage in XXX country
 - B. Recommendation for improving Health Law in XXX country
- Annex 1. Overview of the Human Resources for Health Laws in XXX country
 - Table 1. Interviewing and Consultation list and Related Areas
 - Table 2. Profiling the Human Resources for Health Laws
- Annex 2. Suitability or Appropriateness of the tool

Difficulties using the tool, How the tool can be improved, How the analysis tool can be used, other comments

글로벌 헬스거버넌스를 위한 국내 공중보건법 및 법체계 모니터링의 중요성에 관한 연구

: 서태평양지역 국가들의 공중보건법을 분석하기 위한 분석도구 프레임웍 개발을 중심으로

세계보건기구 서태평양지역사무처는 2010 년에 회원국의 공중보건법률 모니터링 프로젝트를 시작하였다. 지난 2년동안 국내 보건관련 법률 존재여부 및 수준 확인을 위한 도구를 개발하였고, 도구를 이용하여 일부국가들을 대상으로 파일럿 테스트를 시행하였으며, 현재는 새로운 국가를 대상으로 적용해보려고 준비중이다. 그동안 4 개의 모듈 90 여개의 질문으로 구성된 분석도구에 대해 여러 가지 문제점이 발견되었다. 본 과제의 당위성에 대한 논란이 연구 시작시점부터 현재까지 꾸준히 제기되었으나, 그 활용방안 및 미래의 발전방안에 대한 모델을 제시하지 못해왔다. 따라서 본 논문은 첫째, 글로벌 헬스거버넌스의 도구로써 개별 국가들의 공중보건법 및 법체계를 분석하는 것이 유용하다는 것을 입증하고, 둘째, 공중보건법 분석을 위한 분석도구 프레임웍의 활용방안 높이기 위한 방안을 높이기 위한 방안을 모색하며, 셋째, 글로벌 헬스거버넌스를 위한 국내법률 모니터링의 장기적인 발전방안, 비전,모델을 구현하는 것을 목적으로 한다.

글로벌 헬스거버넌스 및 공중보건법에 대한 문헌리뷰를 실시하였고, 해외주요 학회 참석을 통해 학계현장의 동향을 파악하였으며, 서태평양지역보건의료법률 전문가 회의를 통해 전문가의 의견을 청취하였다. 4 개 국가를대상으로 1 차 파일럿 테스트를 실시함으로써 도구의 적절성 및 활용가능성을검증해보았으며, 캄보디아를 대상으로 현장적용을 위한 2 차 파일럿 테스트를수행하였다. 또한, 공중보건법을 분석도구 프레임웍의 활용방안 및 학술적가치를 높이기 위한 방안모색을 위해, 세계보건기구 내부에 있는 관련전문가들의인터뷰를 통해 분석도구을 소개한 뒤, 분석도구 및 자료의 활용방안에 대한

의견을 청취하였으며, 학계 심포지움에서 두 차례 발표를 진행함으로써 학계의 동향을 파악하였다. 글로벌 헬스거버넌스를 위한 국내법률 모니터링의 장기적인 발전방안, 비전, 모델을 구현하기 위해 그간의 세계보건기구의 보건의료법 관련 활동에 대한 역사를 검토하였으며, 유사한 사례를 검토함으로써 장단점을 비롯한 적용가능성을 찾아내 모델개발에 활용하였고, 전문가 회의를 통해 장기비전을 설정하고자 했다.

연구결과, 글로벌 헬스거버넌스에서 개별 국가의 국제법 준수에 대한 모니터링이 세계보건기구가 이 시점에서 할 수 있는 최대의 공중보건증진 전략 중 하나임을 실증적으로 확인하였다. 새로 개발한 공중보건법 분석을 위한 도구 프레임웍이 적절하였고, 향후 보완방향을 제시함으로써 프레임웍의 효과적인 활용가능성이 모색되었다. 분석를 시행함에 있어 발견된 문제점 및 도전과제로는 정부의 동의절차, 지역전문가의 자격요건 및 질 관리에 대한 개선이 제기되었다. 비교분석을 시행하여 결과를 공개할 경우의 예시를 제시하였고, 결과해석에 대한 여러 가지 주의할 점이 모색되었다. 글로벌 헬스거버넌스를 위한 국내법률 모니터링 체계 모델 구축을 위해 세계보건기구의 역사적 법률 관련 활동 분석결과를 활용하여 세계보건기구 공중보건법 관련 활동의 기본원칙을 개발하였다. 또한, 미래의 비전으로서 1) 분석도구의 개발방향에 있어 1~3 단계의 개념 도입, 2) 분석결과 제시방안, 3) 네트워킹 구축과 정기적인 미팅 개최, 4) 데이터베이스 및 웹사이트 구축, 5) 모델법률 제정 및 국제법의 국내법화 방안을 도출하였다.

본 연구를 통해 글로벌 헬스거버넌스의 도구로써, 개별 국가들의 공중보건법 및 법체계를를 분석 및 모니터링하는 것의 유용성이 입증되었다. 또한 공중보건법 분석 프레임웍의 활용방안 높이기 위한 방안과 학술적 가치에 대해 실증적인 사례를 제시하였으며, 마지막으로 글로벌 헬스거버넌스를 위한 국내법률 모니터링의 장기적인 발전방안, 비전, 모델을 제안하였다.

핵심되는말: 글로벌 헬스거버넌스, 공중보건법, 법체계, 서태평양지역, 세계보건기구