Legal Epidemiology for Accelerating the Implementation of International Health Regulations in the European Region

A Pilot Project in Georgia, Kyrgyzstan, Serbia and Switzerland

Supported by WHO and the Swiss Federal Office of Public Health

http://lawatlas.org/page/who-international-health-regulations-project

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Neuchâtel, 10 May 2019

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Acronyms

CPHLR:	Center for Public Health Law Research
IDS :	Institut de Droit de la Santé/ Institute of Health Law
IHR(2005):	International Health Regulations (2005)
NCDC:	National Centre for Disease Control and Public Health of Georgia
WHO:	World Health Organization

I. Presentation of the project

1. Background

When we think about health systems, we think about healthcare institutions, staff, equipment, medicines, vaccines, financing schemes as well as the determinants of health. As more and more studies show that if we are in good health, it is not only a question of healthcare but a matter of environment in which we are born, live, work and age.

Law can be used to strengthen health systems. Here law is understood as all the binding norms adopted by the legislative power and by the administration when it benefits from a delegation of power from the former. These laws carry a level of authority that allows them to organize a society and frame behaviors. Hence, laws plan for necessary skills of healthcare staff, the conditions for safe, effective and quality pharmaceutical products to put on the market, and the guarantee of the respect of human rights in the practice of public health measures.[1]

There has been a number of scientific studies analyzing the impact of those laws on public health and evidence exist that they have been instrumental, for instance, in the justification of the use and implementation of quarantines[2] or in promoting vaccination coverage rates[3].

The problem is that there is not enough data to systematically analyze the impact of these laws on all public health fields.

Measuring is a common practice in public health and epidemiological surveillance of diseases. For instance in this area, measurement informs action in a variety of areas, such as the identification of health risks or research priorities or to assess the impact of health measures.

In order to ensure regular assessment of the efficiency of laws to promote public health, the law and regulatory field needs to follow the path of public health and ensure law measurement and on-going surveillance.

Legal epidemiology is the scientific study of law as a factor in the cause, distribution, prevention of disease and injury in a population.[4] Using the specific scientific methodology of policy surveillance

[1] BURRIS S., KAWACHI I., & SARAT A. Integrating Law and Social Epidemiology. *Journal of Law, Medicine & Ethics, 30*, 2002. 510-521. See also, BURRIS S., WAGENAAR A.C., SWANSON J., IBRAHIM J.K., WOOD J., & MELLO M.M. (2010). Making the case for laws that improve health: a framework for public health law research. *Milbank Q, 88*(2), 169-210.

[2] KATZ R. Changing the culture of quarantine. Pandemic Preparedness Summit; September 18, 2015; College Station, TX. Scowcroft Paper No. 4.
See also, HODGE J, GOSTIN LO, PARMET WE, NUZO J, PHELAN A. Federal powers to control communicable conditions: call for reforms to assure national preparedness and promote global security. Health Secur. 2017; 15(1):1–4.
See also, KATZ R, VAUGHT A. Controlling tuberculosis in the United States: use of isolation and other measures throughout the country. Disaster Med Public Health Prep. 2017;11(3):337–-342.

[3] RUBINSTEIN REISS D. The law and vaccine resistance. Science. Editorial. 22 February 2019, volume 363, issue 6429, p795. See also, SIGNORELLI, C. IANNAZZO S, ODONE A. The imperative of vaccination put into practice. The Lancet Infectious Diseases. January 2018, volume 18, issue 1. See also, OLSHEN E, MAHON B, WANG S, WOODS E. The Impact of State Policies on Vaccine Coverage by Age 13 in an Insured Population. Journal of Adolescent Health. May 2007, volume 40, issue 5.

developed and used by the Center for Public Health Law Research at Temple University **(CPHLR)** in the United States, this project aims at collecting, analyzing laws of public health significance to observe how European countries implement the International Health Regulations (2005) in their national laws.

2. Objective of the project

The aim of the IHR(2005) is to "*prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade*" (art. 2 IHR(2005)).

The purpose of the project is to conduct a legal epidemiology study to observe the content of national laws implementing IHR(2005) adopted by World Health Assembly in May 2005 and map their content following the scientific policy surveillance. The expected outcome of the project is to accelerate the implementation of the IHR(2005) in the European Region.

The focus of the project is on national level laws (*i.e.,* all the normative acts in the legal system of a country without a limitation to formal laws) that enable the designated countries to conduct preventive, protective and reactive activities in regard to the advent of an event - as "a *means of manifestation of disease or an occurrence that creates a potential for disease*" - that may constitute a public health emergency of international concern.

3. Objective of the pilot phase

This project was initiated through a pilot phase funded by WHO/Euro and the Swiss Federal Office of Public Health. It was conducted between October 2018 and March 2019 in four selected countries: Georgia, Kyrgyzstan, Serbia and Switzerland.

This selection was performed in collaboration with the funders. The countries should fill up the following criteria:

- Be good models from a legal and public health perspective in their region;
- Ensure a diverse and representative sample of countries from different sub-regions of the WHO European Region;
- Have a strong and capable WHO Representative in the country; and
- Include the presence of a sub-regional hub of the WHO Emergencies Programme, with international staff stationed and who could facilitate the subsequent roll-out to other countries.

The pilot phase policy surveillance was conducted through the establishment of a research plan containing 127 questions covering key areas of the IHR(2005): the prevention, preparation, surveillance and alert and response to naturally occurring communicable diseases (see: http://lawatlas.org/page/who-international-health-regulations-project).

[4] BURRIS S, ASHE M, LEVIN D, PENN M, LARKIN M. A Transdisciplinary Approach to Public Health Law: The Emerging Practice of Legal Epidemiology. Annual Review of Public Health, Online Volume 37, March 17, 2016, Forthcoming; Temple University Legal Studies Research Paper No. 2016-01.

4. Presentation of the methodology

The concept of "legal epidemiology" emerged from a long-term collaboration between the Centers for Disease Control and Prevention and CPHLR, and centered on a $22 million, seven-year program of research funding and methodological work established by the Robert Wood Johnson Foundation. Its goal was to support more and better use of law for health by enhancing the frequency and rigor of research to measure the effects of law.[5] Policy surveillance is a practice within the larger discipline of legal epidemiology. Policy surveillance is the systematic, scientific collection and analysis of laws of public health significance and was elaborated as a tool to support evaluation research by creating open-source legal datasets using scientific methods.[6]

The central innovation in the approach is to measure the objective features of legal texts as numerical variables, producing data that can be readily merged with other health datasets and depicted in digital maps, tables and other comprehensible forms.

In accordance with this scientific methodology, the pilot project was conducted following iterative stages:

1. IHR(2005) Background Research: An IHR(2005) literature review of secondary sources to determine what is needed at the national level to implement the IHR(2005);
2. Country-Specific Background Research: An overview of the selected countries' geographic, administrative structure, health status and legal practice;
3. Research Plan: A scientific analytical framework is developed to conduct the legal mapping including scoping and coding;
4. Research and collection of relevant laws required to answer the research plan in each country;
5. The coding phase: Uploading laws to the software MonQcle (a web-based software coding platform developed by Legal Science, LLC), answering the questions listed in the research plan and linking answers to provisions in legal texts followed by quality control procedures;
6. The online publication of the results to http://lawatlas.org/page/who-international-health-regulations-project

The application of these different stages to the pilot project is presented in Section 6 - Steps to implement the methodology.

5. Research team

The essence of the project, and thus the pilot phase, is to be collaborative.

The pilot project was conducted by the researchers from the University of Neuchâtel, Institute of Health law (*Institut de droit de la santé*, **IDS**), Switzerland in collaboration with lawyers from the CPHLR, and with in-country legal and public health researchers. Scientific advice was also provided by WHO experts in the selected countries, in Geneva Headquarters and in the European Office.

[5] BURRIS, Scott. A Transdisciplinary Approach To Public Health Law: The Emerging Practice Of Legal Epidemiology. *Annual Review of Public Health*, volume 37. 2016. http://www.phlr.org/resource/transdisciplinary-approach-public-health-law-emerging-practice-legal-epidemiology

[6] BURRIS, Scott, HITCHCOCK, Laura, IBRAHIM, Jennifer, PENN, Matthew, RAMANATHAN, Tara. Policy Surveillance: A Vital Public Health Practice Comes of Age. J *Health Polit Policy Law* (2016) 41 (6): 1151-1173. https://read.dukeupress.edu/jhppl/article-abstract/41/6/1151/40084/Policy-Surveillance-A-Vital-Public-Health-Practice

The research team from the IDS in Neuchâtel provided overall leadership and coordination of the project. It was responsible for the drafting of the Research Plan, in collaboration with all the research team members. Two lawyers from the IDS also conducted the policy surveillance for Switzerland. The lawyers from the CPHLR have provided expertise and technical assistance on the policy surveillance methodology as well as quality control.

In-country legal experts were identified through the Association of Schools of Public Health in the European Region (ASPHER). Their role was to conduct the legal epidemiology analysis in each covered country, share their expertise and experience about their countries.

The in-country public health experts in each country, except for Serbia, were nominated by the national Ministry of Health and they provided advice on the implementation of the IHR(2005) to the in-country legal expert (Kyrgyzstan) or independently answered the questions in the Research plan and participated in the redundant coding process (Georgia).

The technical assistance as well as the software for the mapping was provided by Legal Science, LLC.

All members of the research team could share hare views, feedbacks and advice on the legal epidemiology process

1. Institute of Health Law (*Institut de droit de la santé*), University of Neuchâtel, Switzerland **(IDS Team)**

Dominique Sprumont, Principal investigator
Géraldine Marks, Team leader, primary researcher, legal expert for Switzerland
Natacha Joset, Primary researcher, legal expert for Switzerland
Vladislava Talanova, Primary researcher
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2. In-country experts in Georgia, Kyrgyzstan and Serbia

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3. Center for Public Health Law Research, University of Temple, United States **(CPHLR team)**

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Andrew Campbell, Senior Program Manager

4. Legal Science, LLC

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5. External advisers

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Alexey M Goryainov, Association of Medical Law of Saint-Petersburg (Russia)

6. Steps to implement the methodology

6.1. Background research

The background research was conducted in two parts: the IHR(2005) background research memorandum and the country-specific background research memoranda.

IHR(2005) BACKGROUND RESEARCH MEMORANDUM

The IHR(2005) memorandum was completed by the IDS research team in October 2018. This memorandum aimed at highlighting the duties of IHR(2005) State parties under the IHR(2005). The analysis was done based on a literature review of the provisions of the IHR(2005) (primary literature sources) and WHO implementation guidelines and documentation (secondary literature sources) between 2005 and 2018.

COUNTRY-SPECIFIC BACKGROUND RESEARCH MEMORANDA

The IDS research team developed four background research memoranda to cover each of the four countries studied in this project. These memoranda were produced between October 1, 2018 and October 22, 2018. The main aim was to report on the geographic, administrative, legal, and public health specificities of the countries in order to have a clear picture of the context in which to conduct legal epidemiology analysis.

Each memo includes the following sections: administrative organization (i.e., federal/unitary States, distribution of competencies between federal/national and sub-national entities), legal organization (i.e., system of law, hierarchy of norms) and healthcare organization of each country as well as their main health concerns (health statistical review). These memoranda also listed a primary sample of laws, decrees, acts, regulations and orders from the countries related to different areas of implementation of IHR(2005). The listed legal documents were preliminarily analyzed in order to delineate their content, decide on the number and nature of possible datasets and the constructs they would respectively contain.

6.2. Delineation of the scope of the analysis - Research plan

In accordance with the policy surveillance methodology, the research team developed a Research Plan that includes the datasets and the constructs and forms the analytical framework for the national legislation. The delineation of the datasets and constructs was based on the IHR(2005) background research memorandum, the country-specific background research memoranda and on several consultations of national and international IHR(2005 experts.

The Research Plan includes four datasets respectively named "Prevention", "Preparation", "Surveillance and Alert" and "Response".

The four datasets are organized in a way that is representative of the aim of the IHR(2005) stated in its Article 2, to "*prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade*."

Due to time constraints in the pilot phase and to ensure quality of the data produced, it was agreed that the research would not cover the entire scope of the IHR(2005). The scope of the research plan of the pilot project covers prevention, preparation, control, and response capacities to the natural spread of communicable diseases on the basis of the following selection criteria:

1. Selected constructs are within the scope of IHR(2005);
2. Selected constructs form a coherent delineation of the public health topics covered in the IHR(2005) and the selection does not run counter the object and purpose of the Regulations;
3. The selection allows for the future extension of the scope of the Research Plan to other coherent topics covered by the IHR(2005);
4. Selected constructs are representative themes for the four countries in the pilot phase (items we can compare because they are relevant for all countries and outcome analysis has an added value for public health research to increase capacity for evidence-based decision making in these countries and beyond);
5. Selected constructs are common to all countries and need to be regulated in national legislation;
6. Constructs are aligned with decision-making needs (prevention-preparation-surveillance-response). The final tool aims at developing capacity for evidence-based decision making in the field of public health (here based on public health research using legal data). Constructs thus have to be aligned with the four countries decision-makers' needs at national level as well as WHO experts.

The successive draft versions of the Research Plan were discussed with IHR experts from the WHO/EURO and WHO HQ. Furthermore, the public health experts in WHO country offices and the national legal and IHR public health experts in the selected countries were also consulted in this process of delineation of the scope of the study.

TOPIC 1: PREVENTION

Preventing the international spread of diseases is the first objective of the IHR(2005) and the focus of the first dataset. The analysis focuses on two aspects of national prevention strategies.

First, on reducing impact of event on public health by optimizing routine immunization coverage in humans (Annex 2, 6, 7 of the IHR(2005)). Immunization is a means to limit contamination and the spread of vaccine-preventable communicable diseases. Therefore, the immunization strategy is observed in peace time as well as during the outbreaks of communicable diseases.

Then, on strengthening multisectoral management of zoonotic events and the human-animal interface (Annex 1 of the IHR(2005)). Some communicable diseases infect animals before possibly mutating to inter-human contagious diseases. Therefore, it is important to observe the legal requirements for the prevention, surveillance and control of animal diseases across sectors.

TOPIC 2: PREPARATION

Protecting against the international spread of diseases requires State parties to the IHR(2005) to prepare for the advent of an outbreak of communicable disease. This dataset covers three strategies:

- Support to emergency planning first, as planning is necessary to limit the sanitary, economic and social consequences of an outbreak of communicable disease (Annex 1 A §2, §6 g and §3 of the IHR(2005)). National laws applicable to the elaboration of emergency plans are displayed.
- Testing the capacities foreseen in plans is also an important part of preparedness (Annex 1§ 2 of the IHR(2005)). Legal measures to encourage assessments of capacities through regular exercises and continuous training of workforce, complements planning measures.
- National legal strategies to manage shortages in pharmaceutical products including vaccines in the advent of an outbreak of communicable diseases (Annex 2 of the IHR(2005)). The focus is here on national laws that regulate the marketing and importation of pharmaceutical products in peacetime and during an outbreak. It also considers how stockpiles are organized.

TOPIC 3: SURVEILLANCE AND ALERT

To control the international spread of a communicable diseases, the IHR(2005) emphasizes on the need for States to build surveillance and alert capacities (Art. 5, 6, Annex 1 and Art. 4, 7, 10 of the IHR(2005)). National laws organizing for the surveillance of communicable diseases in humans are presented here and so does the mechanisms that allow for the communication of the alert to the WHO and other countries. This dataset covers also the legal requirements for epidemiological surveillance and vector controls at the airports (PoE, Art. 19, 20, 22, Annex 1 and 5 of the IHR(2005)).

TOPIC 4: RESPONSE

Responding to the international spread of a communicable disease requires States to have response capacities. The forth dataset displays national law that facilitate response.

The focus is here, first, on national laws that allow each country to mobilize resources to respond to the outbreak and to protect the population (Art. 13, Annex 1 §6 of the IHR(2005)). Public health emergencies require mobilization of health personnel and the availability of health care infrastructures and equipment. “Peace time” organization and routine may be strained and national laws facilitate the organization of surge capacities. Communication channels between all stakeholders are also needed to ensure an efficient use of capacities and are also covered. Furthermore, in the response strategy, the IHR(2005) also emphasizes the need to protect human

rights and thus, national law providing for the limitation of human rights, particularly in the context of compulsory medical examinations, treatment, and quarantine (Art. 31, 32 of the IHR(2005)). Thus, Dataset 4 also observes the protection of human rights in emergency situations.

6.3. Development of the questions

A set of constructs, or measurable features of the law, were created for each dataset. From these constructs, the research team crafted coding questions that would observe, rather than interpret, these features of the law. The IDS research team consulted subject matter experts to review and revise the question sets. The final questions were a collaborative effort on the part of CPHLR lawyers, Swiss IHR public health expert, *One Health* WHO expert at WHO HQ and IHR experts from the WHO/EURO and in-country project researchers.

6.4. Collecting laws

For the aim of this project, the research team decided to include only the national legally binding laws. The international, sub-national and non-binding legal acts were excluded from the project.
The collection of relevant laws was done by in-country experts. The first collection was performed when the datasets and constructs were available. The experts were looking for laws that could be potentially relevant for the project and the selected constructs. The second collection was performed when the questions were available. The experts took their first list of relevant laws and checked if these acts contained the answers to the questions. New necessary laws were added and irrelevant laws were deleted.

To foster the authenticity of the research results, policy surveillance implements a redundant coding process, where two in-country researchers collect and code results independently and then discuss their variations.

In Switzerland, the relevant laws were gathered by two researchers to confirm that all relevant laws were collected. The researchers also consulted the local IHR public health expert to verify if he was aware of other relevant laws within the scope of the project.

In Kyrgyzstan, the WHO office representative adopted a collaborative approach and scheduled several meeting that included national stakeholders and members from the interested national authorities in order to discuss the project as well as to confirm together that all the relevant laws are collected. Therefore, the relevant laws collected by the national legal expert were discussed and confirmed during this meeting.

In Georgia, the collection of relevant laws were performed by the researchers, however, due to the difficulties regarding the accessibility of the legal acts, not all the relevant laws were obtained within the duration of the pilot phase.

Unfortunately, the official nomination of a public health expert by national authorities in Serbia was not possible and the legal expert performed the collection of the relevant laws alone.

6.5. Coding

An in-person coding workshop took place from February 28 to March 2 2019 at the University of Neuchâtel.

Before the workshop, the four datasets were created in the MonQcle software (*i.e.,* the policy tracking software created by Legal Science, LLC and used for this assessment) by the CPHLR, Legal Science, and IDS research teams. Each dataset contained the appropriate coding questions and individual records for each of the countries.

All the in-country experts received the final version of the coding questions in mid-February 2019, two weeks before the coding workshop. This time allowed them to prepare themselves by answering the questions and identify applicable quotes of national laws.

Before the coding workshop, the in-country researchers transmitted to the IDS team all the relevant laws they had collected to answer the questions listed in the Research Plan. National laws were kept in national language. The IDS research team uploaded and formatted these laws to each corresponding country record in MonQcle.

The next chapter describes the coding workshop.

6.6. Coding workshop

During the coding workshop, the in-country researchers were tasked with answering the Research Plan's questions on MonQcle, and to cite the corresponding legal provisions by using the pre-loaded law in the respective dataset.

The redundant coding process initiated during the collection of the laws was also implemented in the coding phase following the same country specificities described in sub-section 6.4 for the collection phase:

- For Switzerland, the lawyers coded their answers independently.
- For Georgia, the lawyer and the public health experts coded their answers independently.
- For Kyrgyzstan, the lawyer and the public health expert came to a consensus on the correct answers and then coded their answers accordingly.
- For Serbia, one lawyer coded the answers without redundant coding.

After initial coding, the CPHLR and Legal Science teams performed an initial quality control check in order to examine the data to identify any outliers, missing entries, citation issues, and errant caution notes.

For the countries where redundant coding took place with two researchers (Georgia and Switzerland), any divergences (or differences in the coded responses) were identified and the researchers invited to resolve them. A divergence rate was calculated where the redundant coding took place. The divergence rate indicates the number of divergences divided by the total number of variables coded between the two countries.

- The divergence rate for Dataset 1: Prevention was 20.9%.
- The divergence rate for Dataset 2: Preparation was 14.1%.
- The divergence rate for Dataset 3: Surveillance and Alert was 16.2%.
- The divergence rate for Dataset 4: Response was 14.3%.

Based on the feedback from the CPHLR and Legal Science teams, the in-country researchers completed or corrected any outliers, missing entries, citation issues, and errant caution notes. Then, the experts in each country worked to resolve divergences, or fix additional coding issues internally through discussion amongst themselves or with CPHLR and Legal Science staff. Any remaining issues after the in-country discussions were discussed among the entire group. The CPHLR and Legal Science staff also identified and discussed larger coding issues that affected the framework as a whole. At the end of the coding workshop, the in-country researchers resolved all divergences and implemented the changes agreed upon during the in-country discussion, as well as during the group discussion.

After the coding workshop and before the publication of the data, a final quality control check was performed to again check for any outliers, missing entries, citation issues, and errant caution notes. All issues were resolved before finalizing the data.

The entire methodology of the project, including the coding scheme decisions made during the coding workshop, can be found in the Research Protocol document.

6.7. Publication of the results - open access tool

The results are freely available on line at the following address:
http://lawatlas.org/page/who-international-health-regulations-project

II. Results

1. The state of the current legal practice in the target countries identified

1.1. Prevention: National Legislation Implementing the IHR(2005)

1.1.1. REDUCING IMPACT OF EVENT ON PUBLIC HEALTH BY OPTIMIZING ROUTINE IMMUNIZATION COVERAGE IN HUMANS (ANNEX 2[7] + ANNEX 6 + ANNEX 7 IHR(2005) + STATEMENT FOLLOWING THE 17TH, 18TH, 19TH IHR EMERGENCY COMMITTEE REGARDING THE INTERNATIONAL SPREAD OF POLIOVIRUS[8])

PREVENTION				
National laws on vaccination				
	Georgia	Kyrgyzstan	Serbia	Switzerland
General law on vaccination	√	√	√	√
Vaccination schedules included in the law	√	√	√	*No*
Authority to establish schedules designated in the law	√	√	√	√
Assessment of efficiency of schedules provided in the law	√	√	√	√
Level of authority performing the efficiency assessment	*National public health authority*	*National public health authority*	*National and sub-national public health authorities*	*National and sub-national public health authorities*
Peace time strategy for vaccination	*Mandatory*	*Mandatory/ Recommended*	*Mandatory/ recommended*	*Recommended*
Advisory group for integration of vaccines in the schedules	√	√	√	√
Declaration of interests necessary for members of the advisory group	*No*	*No*	*No*	√
Specified qualification required for advisory group members	*Professional affiliation*	*Topical expertise/ professional qualification*	*No*	*Topical expertise*
National authority to take census of vaccination rates	√	√	√	*No*
National authority mandated to take measures to increase vaccination rates	√	√	*No*	*No*
Sub-National authority to take census of vaccination rates	√	*No*	√	√

[7] WHO. IHR(2005) Annex 2 - Examples for the Application of the Decision Instrument for the Assessment and Notification of Events that May Constitute a Public Health Emergency of International Concern (non binding)
[8] WHO. Statement of the 19th IHR Emergency Committee Regarding the International Spread of Poliovirus. November 2018.

Sub-national authority mandated to take measures to increase vaccination rates	√	*x*	*No*	√
Regulation of compulsory vaccinations	√	√	√	√
Authority to decide on compulsory vaccinations	*Governement*	*Public health national authority*	*Government/ Public health national authority*	*Government and Sub-national government*
Who can be targeted by a compulsory vaccination decision	*Risk group for a specific disease*	*No*	*Any person/ Risk group for a specific disease/ children/Elderly/ pregnant women/specific professionnals*	*Risk group for a specific diseases/ specific professionnals*
Possible target include: *Any person*	*No*	.	*√*	*No*
Possible target include: *Risk group for a specific disease*	*√*	.	*√*	*√*
Possible target include: R*isk group for a specific disease*	*No*		*√*	*√*
Possible target include: *Specific professionnals*	*No*	.	*No*	*√*
Possible target include: *Elderly*	*No*	*No*	*√*	*No*
Possible target include: *Children*	*No*	*No*	*√*	*No*
Possible target include: *Pregnant women*	*No*	*No*	*√*	*No*
Principles of priorization of vaccine distribution in an outbreak of communicable disease	*No*	*No*	*No*	√

- ⇨ All four countries have a law regulating vaccination. Switzerland is the only country out of the four not to include vaccination schedules in the law. It is an ad hoc document updated every year by the Swiss Federal Office of Public Health. In the three other countries, the immunization calendars are enshrined in sub-laws.

- ⇨ Switzerland is also the only country out of the four to only recommend routine immunization. In other countries, such as Serbia and Kyrgyzstan, the vaccination calendar includes both recommended and mandatory vaccinations while all vaccines in the immunization calendar of Georgia are mandatory.

- ⇨ Compulsory vaccinations for outbreaks of communicable diseases are regulated in all four countries and all designate who can take such decision. However, Kyrgyzstan does not regulate who can be targeted by a compulsory vaccination decision, while Serbia, Georgia and Switzerland designated risk groups and, in the case of Switzerland and Serbia, specific professionals can also be targeted.

- ⇨ There is an advisory committee mandated to advise authorities on the integration of vaccination to the national schedule in all countries. Criteria to select the members of these advisory committees are enshrined in the law in all countries except for Serbia. Members are selected on the basis of their topical expertise in Switzerland and Kyrgyzstan. Professional affiliation is also a criteria in Georgia and Kyrgyzstan. Switzerland is the only country where the members of this advisory committee have to declare any conflicts of interests.

- ⇨ The measurement of vaccination rates is provided at both national and sub-national levels in Georgia and measures can be adopted at both levels to increase these rates.
  In Kyrgyzstan, measurement and promotion of vaccination is a national competence, while in Switzerland, both are cantonal competence, a feature that leads to variation of vaccination coverage among cantons.
  In Serbia, measurement of vaccination rates is provided at national and sub-national levels but no authority is designated in the law to promote these rates.

- ⇨ Switzerland is the only country to regulate the principles of prioritization of vaccine distribution in an outbreak of communicable disease. However, these principles stated in the Epidemic Order (OEp)[9] article 61 are very broad and the Federal Department of Interior (FDI) did not yet produce further criteria in a control list to organize distribution, as it was given the possibility in article 1 OEp.

[9] Ordonnance sur la lutte contre les maladies transmissibles de l'homme (Ordonnance sur les épidémies, OEp) du 29 avril 2015, RS 818.101.1

1.1.2. STRENGTHENING MULTISECTORAL MANAGEMENT OF ZOONOTIC EVENTS AND THE HUMAN-ANIMAL INTERFACE (ANNEX 1 IHR(2005) + WHO GUIDANCE 2018[10])

PREVENTION				
Strengthening the multisectoral management of zoonotic events and the human-animal interface				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Law regulating epidemiological surveillance of animal diseases	√	√	√	√
Surveillance type include: *Reporting of diseases*	√	√	√	√
Surveillance type include: *Specific disease programs*	√	√	√	√
Surveillance type include: *Animal products*	√	√	√	√
Surveillance type include: *Syndromic surveillance*	√	*No*	√	√
Surveillance type include: *Control of importation of animals*	*No*	√	√	√
Entities responsible for the reporting of animal diseases are listed in the law	*√*	*√*	*√*	*√*
It includes : *Veterinarians*	*√*	*√*	*√*	*√*
It includes: *All care givers*	*√*	*√*	*√*	*√*
It includes: *Animal owners*	*√*	*√*	*√*	*√*
It includes: *Staff in slaughterhouses*	*√*	*No*	*√*	*√*
It includes: *All animal keepers*	*√*	*√*	*√*	*√*
It includes: *Laboratory staff*	*√*	*√*	*No*	*√*
It includes: *Industries*	*√*	*No*	*√*	*√*
Reporting from sub-national to national level regulated	√	√	√	√
National authorities supervising the functioning of animal disease surveillance	√	√	√	*No*
What needs to be reported	*Specific disease listed in the law*	*Notification of any animal disease*	*Specific disease listed in the law/Laboratory confirmed diagnostic/Notification of unexpected symptoms*	*Specific disease listed in the law/ Laboratory confirmed diagnostic/ notification of unexpected symptoms*
What level of authority must take first response measures	National and sub-national levels	Sub-national level	National level	Sub-national level

[10] WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018.

Types of measures that can be taken	*No*	*Veterinary examination/ isolation/quanrantine/ Slaugther/ Sequester/ Marketing ban*	*Veterinary examination / isolation/ quarantine/ Slaughter/ Travel ban/ Sequester//*	Veterinary examination / isolation / Quarantine/ Slaughter/ Travel ban/ Sequester/ Marketing ban
Second line intervention	*No*	√	√	√
Conditions for second line to be deployed	*No*	*Reinforce capacities of first responder/ Disease spreads on the territory/ To coordinate sub-national responses*	*Disease spreads of the territory*	*To coordinate sub-national responses/ For specific anaimal diseases*
Training courses to facilitate control of animal diseases regulated	*No*	√	√	√
Who must take the training courses	*No*	*No*	Livestock owners/ hunters	Personnel in slaughterhouses/ researchers conducting animal experimentation in laboratories/ staff in laboratories/ veterinarian/ livestok owners/ hunters
Regulation of exchange of information between animal disease surveillance services and human diseases surveillance services	√	√	√	√
Existence of a coordinating body between animal disease and human disease surveillance	√	√	*No*	√
Composition of the coordinating body regulated	*Public health/ Epidemiology/ Veterinary/ Agriculture/Environment competence*	*No*	*x*	*Public health/Epidemiology/ veterinary/ Agriculture/Environment competence*

⇨ Epidemiological surveillance of animal diseases is regulated in all four countries. Surveillance is organized through the reporting of diseases, disease-specific screening programs and the control of animal products everywhere. Syndromic surveillance is not provided in the law in Kyrgyzstan and the control of the importation of animal is not enshrined in the law of Georgia.

⇨ All countries list in the law the people who have a duty to report animal diseases.
In Kyrgyzstan, any animal disease needs to be reported whereas in the other three countries only the diseases that are on a list need to be reported.
In Kyrgyzstan, personnel in slaughterhouses do not have such a duty stated in the law and it is the same for the auto control operated by industries.

⇨ In Serbia response to an animal outbreak is managed first at the national level, while in Kyrgyzstan and Switzerland the sub-national level intervenes first. In Georgia, it can be both levels.
There is a possibility for second-line intervention in Switzerland, Serbia and Kyrgyzstan. This is to coordinate sub-national responses or for specific animal diseases in Switzerland. In Serbia, this second-line intervenes if the disease spreads on the territory and in Kyrgyzstan if to reinforce the capacity of the first responder.

⇨ The law lists the type of response measures that can be taken in Switzerland, Serbia and Kyrgyzstan. These measures include in all these countries: veterinary examination, isolation, quarantine, slaughter, travel ban, sequester.
In all countries, the reporting from sub-national to national level is regulated. National authorities exist in all countries but in Switzerland to supervise the functioning of animal disease surveillance.

⇨ Training courses to facilitate the control of animal diseases are regulated in all four countries but in Georgia. In Kyrgyzstan, the law does not designate who must take these courses. Hunters and livestock owners are designated in Serbia and Switzerland.
Personnel in slaughterhouses, researchers conducting animal experimentation in laboratories and personnel in laboratories are required to take courses only in Switzerland.

⇨ The exchange of information between human and animal epidemiological surveillance systems is required in all countries but there is no coordinating body in Serbia. The composition of this body is not regulated in Kyrgyzstan.

1.2. Preparation: National legislation implementing the IHR(2005)

1.2.1. SUPPORT TO EMERGENCY PLANNING (ANNEX 1 A §2, §6 G) AND §3 IHR(2005))

PREPARATION				
Support to emergency planning				
	Georgia	Kyrgyzstan	Serbia	Switzerland
General law on response to emergency situation	√	√	√	√
General law applicable to outbreaks of communicable diseases	√	√	√	√
Existence of a specific law on preparation for a communicable disease outbreak	√	√	√	√
Authorities who must adopt preparedness plans	*Government/ National public health authority/ Sub-national authority*	*National public health authority*	*Government/ National public health authority/ Expert commission*	*Government/ National authority for Civil Protection / National public health authority/ Sub-national authority*

Other entities mandated to establish preparedness plan to respond to outbreaks of communicable disease	*No*	*Airports/ Healthcare centres*	*Airports/ Healthcare centres/ Schools/ Essential service institutions/*	*Airports/ Healthcare centres/ All private companies*
Disease- specific preparedness plans required by law	√	√	√	*No*
Declaration of State of Emergency regulated	√	√	√	*No*
Declaration of State of Emergency conditions response to an outbreak of communicable diseases	√	*No*	*No*	.

- ⇨ There is a law that regulates response to emergency situations, and which is applicable to outbreak of communicable diseases, in all four countries. Furthermore, there is a law that regulates preparation for a communicable disease outbreak in all countries.
  Specific authorities such as national public health authorities are mandated to develop preparedness plans in all countries. In Switzerland, the government as well as the national authority for civil protection must also adopt preparedness plans. So does sub-national authorities.

- ⇨ All countries but Switzerland have to cover specific diseases listed in the law in preparedness plans. Switzerland has a national plan for pandemic influenza but it is not a requirement in the law to establish a plan for pandemic influenza or any other disease.

- ⇨ There is a law on the declaration of the State of emergency in all countries but in Switzerland and it is only applicable in Georgia to outbreak of communicable diseases.

1.2.2. ENCOURAGING ASSESSMENTS OF CAPACITIES (ANNEX 1§ 2 IHR(2005)) THROUGH REGULAR EXERCISES AND CONTINUOUS TRAINING OF WORKFORCE (WHO GUIDANCE 2018[11])

PREPARATION				
Encouraging assessments of capacities through regular exercises and continuous training of workforce				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Organisation of simulation exercises regulated	√	√	√	√
Initiater of simulation exercises	*Government/ Specialized department of the Government*	*Specialized department of the Government/ Sub-national level organizations*	*Specialized department of the Government/ Non-Governmental organizations/ Sub-national level organizations/ Healthcare institutions*	*Specialized department of the Government*

[11] WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018.*Op.Cit.* C.7. Human resources. Page 7

Timing of simulation exercises	√	√	√	*No*
Required professional participation	√	√	√	*No*
After action review regulated	No	√	*No*	*No*
After action review initiator	No	*No*	*No*	*No*
Specific training for professionals to respond to outbreaks of communicable diseases	√	√	√	√
Professionals covered	*Medical doctors (GPs)/ Veterinarians/ Hospital personnel/ First emergency responders at sub-national level*	*Hospital personnel/ First emergency responders at national level*	*Hospital personnel*	*Medical doctors (GPs)/ Veterinarians/ First emergency responders at sub-national level*
Timing of trainings regulated	√	√	√	√

⇨ There are provisions in the law to organize simulation exercises at national level in all countries and all countries provide for the authorities that can initiate these exercises. Switzerland does not regulate the frequency of these exercises nor does it provide for the type of professionals that must take part in the exercises. Only Kyrgyzstan regulates the organization of debriefing session after emergency responses or "after-action reviews" but the Kyrgyz law does not state who is in charge for initiating the review.

⇨ The training of professionals to respond to outbreaks of communicable diseases is regulated in all four countries and so do the professionals covered and the timing of the trainings.

1.2.3. MANAGEMENT OF SHORTAGES OF PHARMACEUTICAL PRODUCTS INCLUDING VACCINES (ANNEX 2[12] IHR(2005))

PREPARATION				
Management of shortages of pharmaceutical products including vaccines				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Vaccines that need to be stockpiled	√	√	*No*	√
Specific vaccines stockpiled	*No*	*No*	*x*	*Pandemic influenza vaccine/ Anti-smallpox vaccine*
Principles for priority distribution of vaccines' stockpiles	√	*No*	*No*	√
Medicines that need to be stockpiled	√	√	*No*	√
Specific medicines stockpiled	*Diphteria antitoxin/ Botulinic antitoxin*	*Diphteria antitoxin/ Botulinic antitoxin/ Antirabies antitoxin*	*No*	*Diphteria antitoxin/ Botulinic antitoxi/ Antirabies antitoxin*

[12] WHO. IHR(2005) Annex 2 - Examples for the Application of the Decision Instrument for the Assessment and Notification of Events that May Constitute a Public Health Emergency of International Concern (non binding)

Principles for priority distribution of medicines' stockpiles	*No*	*No*	*No*	√
Marketing of new pharmaceutical products regulated	√	√	√	√
Authorization required	√	√	√	√
Conditions for authorization include: *Quality of the product*	√	√	*No*	√
Conditions for authorization include: *Skills of the producer*	√	*No*	*No*	√
Conditions for authorization include: *Safety of the product*	*No*	√	*No*	√
Conditions for authorization include: *Efficiency of the product*	*No*	√	*No*	√
Conditions for authorization include: *Prior authorization to produce*	*No*	*No*	√	√
Conditions for authorization include: *Prior authorization to import*	*No*	*No*	√	√
Authority granting the authorization	*Ministry of Health*	*Specific national medicine authority*	*Single national therapeutic products authority*	*Single national therapeutic products authority*
Accelerated procedure in times of emergency	√	*No*	√	√
Procedure for pharmaceutical products that have been approved abroad	√	*x*	√	√
WHO oversight in the assessment of quality, safety and performance documentation of pharmaceutical products in a public health emergency	√	*x*	*No*	*No*
Importation of medicine regulated	√	√	√	√
Authorization required	√	√	√	√
Minimal requirements for authorization include: *Professional qualification of the importer*	√	*No*	√	√
Minimal requirements for authorization include: *Equipment of the premises*	√	*No*	*No*	√

Minimal requirements for authorization include: *Good manufacturing practices in the country of origin similar to the country of importation*	√	√	√	√
Minimal requirements for authorization include: *Authorization to produce the medicine*	√	√	√	√
Minimal requirements for authorization include: *vaccine in the country of origin*	√	√	√	√
Minimal requirements for authorization include:*Prior authorization for marketing the medicine*	√	*No*	*No*	√
Minimal requirements for authorization include: *Organization of the business*	*No*	√	*No*	√
Condition for waiving minimal requirements	*Emergency*	*Scientific research/ Emergenc/ Orphan diseases*	*Scientific research/ Emergency/ Orphan Diseases*	*Emergency*
Authorization for marketing required for imported medicine	√	√	√	√
Importation of vaccines regulated like medicines	√	*No*	√	√

- ⇨ Serbia is the only country out of the four that does not regulate the vaccines that need to be stockpiled. The law in Georgia and Kyrgyzstan does not specify which vaccines need to be stockpiled though.

- ⇨ Serbia is also the only country out of the four that does not regulate the medicines that need to be stockpiled. Diphteria antitoxin and botulinic antitoxin are common to the three countries. Antirabies antitoxin is stockpiled in Switzerland and Kyrgyzstan.

- ⇨ There is a law that regulates the marketing of pharmaceutical products in all countries and an authorization is required in all countries. All laws state the conditions for the authorization to be delivered as well as the authority that delivers the authorization. It is the Ministry of Health in Georgia, while in Serbia and Switzerland it is a single national authority for therapeutic products. In Kyrgyzstan, it is a national medicine authority.

- ⇨ There is no accelerated procedure to market a pharmaceutical product in an outbreak of communicable disease in Kyrgyzstan.

- ⇨ The importation of medicines is regulated in all four countries (authorization is necessary). The conditions to market an imported medicine are listed in the laws in all four countries and these requirements can be waived in times of emergency in all four countries. Scientific research and orphan diseases are also conditions to waive these requirements in Serbia and Kyrgyzstan. Only Kyrgyzstan regulated differently the importation of medicines and vaccines.

1.3. Surveillance and Alert: National Legislation Implementing the IHR(2005)

1.3.1. SURVEILLANCE OF COMMUNICABLE DISEASES IN HUMANS (ARTICLES 5 AND 6, ANNEX 1 IHR(2005))

SURVEILLANCE & ALERT				
Surveillance of communicable diseases in humans				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Law regulating surveillance of human communicable diseases	√	√	√	√
Responsible national authority	*Ministry of Health*	*Ministry of Health*	*Ministry of Health*	*Ministry of Health*
Disease notification system	√	√	√	√
Justification for the inclusion of diseases in the list of notifiable diseases	√	*No*	√	√
Who notifies	Doctors/Hospitals/ Laboratories	Doctors/Hospitals/ Laboratories/ Nurses	Doctors/Hospitals/ Laboratories/ Nurses	Doctors/Hospitals/ Laboratories
Agency that receives notifications	*National public health authority/ Sub-national public health authority/ Depends on the nature of the disease*	*Sub-national public health authority*	*Sub-national public health authority*	*National public health authority/ Sub-national public health authority/ Depends on the nature of the disease*
Timing of notification	√	√	√	√
Modalities of notification	*Electronic form/ Phone calls/ Written form/ Telegram/ Depending on the disease*	*Electronic form/ Phone calls/ Written form*	*Electronic form/ Phone calls/ Written form/ Telegram/ Teletext*	*Electronic form/ Phone calls/ Postal letter/ Depending on the disease*
Communication of information on occurrence of diseases from sub-national to national level	√	√	√	√

- ⇨ The surveillance of human communicable diseases is regulated by a national law and supervised by the Ministry of Health in all four countries. These systems all include a notification system. The conditions behind the inclusion of specific diseases in the list of notifiable diseases is regulated in all countries but in Kyrgyzstan. Doctors, hospitals and laboratories are common stakeholders for the notification process and the agency that receives the notification at national level and sub-national levels are designated in all national laws. The timing and modalities (form) of the notification for the different notifiable diseases are also regulated everywhere. Notification modalities depend on the notifiable disease identified in Switzerland and Georgia. Electronic form and phone calls are common means for all countries and Serbia can also transfer the information in any written form, by teletext and telegram.

- ⇨ All countries have official channel for the epidemiological surveillance information to be communicated from sub-national to national level.

1.3.2. CAPACITIES AT POINTS OF ENTRY (POE) - AIRPORTS (ARTICLES 19, 20, 22 + ANNEX 1+ ANNEX 5 OF THE IHR(2005))

SURVEILLANCE & ALERT				
Capacities at Points of Entry (PoE) - Airports				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Law regulating the designation of PoE	√	√	√	√
PoE for the purpose of the IHR(2005) designated in the law	√	*No*	√	√
General border crossing points designated in the law	√	√	√	*No*
Capacities of designated airports PoE regulated	√	√	√	√
Surveillance capacities include: *Law refers to IHR(2005) capacities for PoE*	√	√	√	√
Surveillance capacities explicitly include: *Capacity to communicate adopted public health measures with the National IHR Focal Point*	√	√	√	√
Surveillance capacities explicitly include: *Maintain facilities used by travelers in good sanitary conditions*	*No*	√	*No*	*No*
Surveillance capacities explicitly include: *capacity to supervise decontamination from any vector*	*No*	√	*No*	*No*
Surveillance capacities explicitly include: *capacity to advice conveyance operators in advance for control measures and methods to be employed*	*No*	√	*No*	*No*
Surveillance capacities explicitly include: *capacity to remove and safe dispose any contaminated matter from conveyance*	*No*	√	No	*No*
Surveillance capacities explicitly include: *capacity to conduct medical examination*	*No*	√	√	√
Surveillance capacities include: *capacity to conduct inspections*	*No*	√	√	
Surveillance capacities explicitly include: *have contingency arrangements to deal with an unexpected public health event*	*No*	√	*No*	*No*
Training of personnel to implement surveillance Capacities	*No*	√	*No*	*No*
Response to outbreak of communicable diseases at airports regulated	√	√	√	√

Response capacities include: *Law refers to response capacities in Annex 1B of the IHR(2005)*	√	√	*No*	√
Response capacities include: *Establishing and maintaining a public health emergency contingency plan*	*No*	√	*No*	*No*
Response capacities include: *Assessment and care for affected travelers*	*No*	√	√	No
Response capacities include: *provide appropriate space, separate from other travelers, to interview suspect or affected persons*	*No*	√	*No*	*No*
Response capacities include: *assessment and, if required, quarantine of suspect travelers*	*No*	√	√	*No*
Response capacities include: *desinsect, derat, desinfect, decontaminate*	*No*	√	√	*No*
Response capacities include: *treat baggage, cargo, containers, conveyances, goods or postal parcels*	*No*	√	√	*No*
Response capacities include: *apply entry or exit controls for arriving and departing travelers*	*No*	√	√	*No*
Response capacities include: *equipment, trained and equipped personnel for transfer of travelers who may be infected or contaminated*	*No*	√	*No*	*No*
Training of personnel to implement response Capacities	*No*	√	*No*	*No*
Mandated competent authorities at airports to conduct surveillance	√	√	√	√
Mandated competent authorities at airports to have response capacities	√	√	√	√
Vector surveillance at airports regulated	√	√	*No*	√
Vector control program implemented at a minimum distance of 400 meters from areas of PoE facilities	*No*	*No*	.	*No*

- ⇨ In all four countries, there is a national law regulating the designation of points of entries (PoE). In Kyrgyzstan, general crossing points are designated in the law but not PoE for the purpose of the IHR(2005).

- ⇨ Surveillance and response capacities at airports are regulated in a national law in all countries.

- ⇨ Kyrgyzstan is the only country to have all capacities listed in article 22 of the IHR(2005) explicitly mentioned in national law but all countries directly refer to capacities mentioned in the IHR(2005). Serbia and Switzerland however specifically provide for the necessity to have medical examination capacity. Switzerland requires airports to develop emergency plans.

- ⇨ Kyrgyzstan is the only country to have all capacities listed in Annex 1b of the IHR(2005) explicitly listed in its national law and the law also mentions directly the Annex 1b as in Switzerland, Georgia and Kyrgyzstan.

- ⇨ Training of personnel at airports to implement PoE surveillance and response capacities is only regulated in Kyrgyzstan.

- ⇨ Vector surveillance at airports is provided for in all countries but Serbia. No country provide for the implementation of a vector control program at minimum distance of 400 meters from areas of PoE airports facilities.

1.3.3. ALERT COMMUNICATIONS (ARTICLES 4, 7, 10 AND ANNEX 1 OF THE IHR(2005) + WHO GUIDANCE 2018[13])

SURVEILLANCE & ALERT				
Alert communications				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Process of designation of NFP regulated	√	*No*	√	*No*
NFP entity designated in the law	√	√	√	√
Designated NFP	*Ministry of Health*	*Ministry of Health*	*National reference centre*	*Ministry of Health*
Mandate of NFP described in the law	√	√	√	√
Entities NFP can collect information from are designated in the law	√	√	√	√
Information can be collected from: *central authority responsible for epidemiological surveillance*	√	*No*	√	√
Information can be collect from: *clinics and hospitals*	√	√	√	√
Information can be collected from: *public health services*	√	√	√	√
Information can be collected from: *PoE*	√	*No*	√	√
Entities NFP can provide information to are designated in the law	√	√	√	√
Information can be provided to national authorities	√	√	√	√
Information can be provided to WHO	√	√	√	√
Information can be provided to other international organizations	√	√	√	√
Information can be provided to other countries	√	*No*	√	√

[13] WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018. *Op.Cit*. C.10. Risk communication. Page 17.

Information can be provided to the population	√	√	√	√
Provisions on the communication of personnal data to foreign authorities	*No*	√	√	√

- ⇨ There is a designated National Focal Point in all four countries and the authority is designated in a law that describes its mandate. This entity is within the Ministry of Health in all countries but in Serbia in which the National Focal Point is a national reference centre.

- ⇨ All national law provide for the type of entities that the National Focal Point can collect information from. These entities can be the public health services, clinics and hospitals in all countries. In all countries but Kyrgyzstan, points of entry as well as the central authority responsible for epidemiological surveillance are also mentioned in the law.

- ⇨ The National Focal Point can provide information to national authorities, WHO and International Organizations in all countries. In all countries but Kyrgyzstan, it can also provide information to the population and other countries.
  In all countries but Kyrgyzstan, the National Focal Point can also communicate personal data to foreign authorities.

1.4. Response: National Legislation Implementing the IHR(2005)

1.4.1. EMERGENCY MOBILIZATION OF RESOURCES (SURGE CAPACITY) (ARTICLE 13 + ANNEX 1 §6 + 7[14])

RESPONSE				
Emergency mobilization of resources				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Law requiring mobilization of resources to respond to an outbreak of communicable disease	√	√	√	√
Authority leading the response to an outbreak of communicable disease	√	√	√	√
Secondary authority responding to an outbreak of communicable disease	√	√	√	√
Conditions for the secondary authority to intervene	√	√	√	√
National entity facilitating communication of information among stakeholders	√	√	√	√
Composition of the entity regulated	√	√	√	√
Surge capacity regulated to provide additional human resources to respond to an outbreak	√	√	√	√

[14] WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018.Op.Cit. C8. National Health Emergency Framework. Page 17.

Professions covered listed in the law	√	√	√	*No*
Professions covered include: *first responders*	√	√	√	.
Professions covered include: *essential services*	√	√	*No*	.
Professions covered include: *healthcare professionals*	√	√	*√*	.

⇨ There is a law in all countries that requires mobilization of resources to respond to an outbreak of communicable diseases and there is an authority leading the response to such outbreak. Second-line authorities exist in all countries and the law describes when it should intervene.

⇨ Each country has created an entity that facilitates the communication between all response stakeholders, the composition of the entity is also in the law.

⇨ Surge capacity to provide additional human resources in an outbreak of communicable diseases is regulated by laws in all countries but Switzerland does not list what professions are covered.

1.4.2. COMMUNICATION STRATEGY IN EMERGENCY (RESPONSE TO RUMORS, SOURCES OF RELIABLE INFORMATION, EVIDENCE-BASED COMMUNICATION…)[15]

RESPONSE				
Communication strategy				
	Georgia	Kyrgyzstan	Serbia	Switzerland
Communication to the population in emergency situation regulated	√	√	√	√
Mandated authority responsible for communication to the population in an outbreak of communicable disease	√	√	√	√

⇨ All countries regulate communication to the population in emergency situations and there is a designated authority mandated to communicate to the population during outbreaks of communicable diseases.

1.4.3. RESPECT FOR DIGNITY, HUMAN RIGHTS AND FUNDAMENTAL FREEDOMS OF PERSONS, TRANSPARENCY AND NON-DISCRIMINATION WHEN IMPLEMENTING HEALTH MEASURES, ESPECIALLY DURING HEALTH EMERGENCIES (DATA PROTECTION, PATIENTS' RIGHTS, TRAVELERS' RIGHTS, DUTY TO UNDERGO MEDICAL TREATMENT/VACCINATION…QUARANTINE) (ARTICLES 31 AND 32 IHR(2005))

[15] WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018. Op. Cit. Page 17.See also, WHO. Guide for acceleration of IHR implementation in States Parties. Enhanced Desk Review of National IHR Core Capacities, Action Plan Development, and Stakeholder Mobilization. 2013. Page 27.

RESPONSE

Respect for human rights and fundamental freedoms in the implementation of health measures

	Georgia	Kyrgyzstan	Serbia	Switzerland
National Constitution contains human rights and freedoms	√	√	√	√
Conditions for the limitations of human rights and freedoms are regulated	√	√	√	√
Conditions include : *Legal basis*	√	√	√	√
Conditions include : *Necessity*	√	*No*	*No*	*No*
Conditions include : *Public interest*	√	*No*	*No*	√
Conditions include : *Proportionality*	√	√	*No*	√
Conditions include : *Declaration of State of Emergency*	√	*No*	*No*	*No*
List of measures that can be taken to control the risk of spread of communicable diseases	√	√	√	√
Measures regulated include: *Identification of ill person*	√	√	√	√
Measures regulated include: *Provision of information to the ill person*	√	√	√	√
Measures regulated include: *Medical surveillance*	√	√	√	√
Measures regulated include: *Quarantine and isolation*	√	√	√	√
Measures regulated include: *Medical examination*	√	√	√	√
Measures regulated include: *Medical treatment*	√	√	√	√
Measures regulated include: *Total prohibition to practice a profession*	√	√	*No*	√
Measures regulated include: *Partial prohibition to practice a profession*	*No*	√	*No*	√
Conditions for the measures to be taken are listed in the law	√	√	√	√
Conditions include: *Necessity of the measure to prevent a serious risk for other persons' health*	√	√	√	√
Conditions include: *Information provided to the individual concerned*	√	*No*	*No*	√
Conditions include: *Regular reassessment of the necessity of the measures*	√	*No*	*No*	√
Conditions include: *Proportionality*	*No*	*No*	*No*	√

Duty to undergo a medical examination in an outbreak of communicable disease regulated	√	*No*	√	√
Capacity to refuse medical examination	*No*	.	*Yes*	*Yes, but under certain conditions*
Consequences of refusal include: *compulsory medical examination*	.	.	*√*	*√*
Consequences of refusal include: *denial of entry on the territory*	.	.	*√*	*√*
Consequences of refusal include: *denial of exit on the territory*	.	.	*√*	*√*
Consequences of refusal include: *quarantine*	.	.	*√*	*No*
Consequences of refusal include: *alternative proportionate measures*	.	.	*√*	*√*
Consequences of refusal include: *fines*	.	.	*√*	*√*
Duty for physicians to conduct a medical examination in an outbreak of communicable disease	√	√	√	√
Duty to undergo a medical treatment in an outbreak of communicable disease	√	*No*	√	√
Capacity to refuse medical treatment	*No*	.	*No*	√
Consequences of refusal include: *compulsory treatment*	.	.	*No*	√
Consequences of refusal include: *denial of entry on the territory*	.	.	*√*	*No*
Consequences of refusal include: *denial of exit on the territory*	.	.	*√*	*No*
Consequences of refusal include: *quarantine*	.	.	*√*	*No*
Consequences of refusal include: *alternative proportionate measures*	.	.	*√*	√
Consequences of refusal include: *fines*	.	.	*√*	*No*
Law authorizes the placement of individuals in quarantines	√	√	√	√
Conditions for the implementation of a quarantine include: *respect for human dignity*	*√*	*No*	*No*	*√*
Conditions for the implementation of a quarantine include: *necessity to prevent a serious risk for other persons' health*	*No*	*√*	*√*	*No*
Conditions for the implementation of a quarantine include: *proportionality*	*No*	*No*	*No*	*√*

Conditions for the implementation of a quarantine include: *information to the person concerned*	*No*	*No*	*No*	*√*
Conditions for the implementation of a quarantine include: *reassessment of the utility of the measure*	*No*	*No*	*No*	*√*
Consequences of refusal of quarantine listed in the law	*No*	*No*	*√*	*√*
Consequences of refusal include: *fines*	.	.	*√*	*√*
Consequences of refusal include*: forced quarantine*	.	.	*√*	*√*

- ⇨ All national Constitutions provide for fundamental human rights and freedoms, as well as listing conditions under which these rights can be limited.

- ⇨ A legal basis for limiting a fundamental human right or freedom is required in all countries. Then the other conditions can vary among countries. A public interest is also required in Switzerland and Georgia. Necessity and declaration of a state of emergency are only distinct conditions in Georgia. Respect of the principle of proportionality is required in all countries but Serbia.

- ⇨ The laws in all countries list the types of measures that can be adopted to control the spread of a communicable disease. Identification of ill persons, provision of information to the ill persons, medical surveillance, quarantine and isolation, medical examination and medical treatment are provided for in all countries. Total prohibition to practice a profession is possible in all country but Serbia and partial prohibition is possible in Switzerland and Kyrgyzstan. The conditions for these types of measures to be implemented are listed in the law in all countries. Necessity is a condition everywhere, while proportionality is only a requirement in Switzerland. Regular reassessment of the necessity is a condition is Switzerland and Georgia.

- ⇨ There is a duty to undergo medical examination in all countries except in Kyrgyzstan. In Switzerland this medical examination is an obligation as long as it is noninvasive. In Georgia, this examination cannot be refused, although it can be refused in Serbia. In Switzerland and Serbia fines are applicable and alternative proportionate measures to limit the spread of disease can be taken. Denial of entry of exit is also applicable.

- ⇨ In Switzerland a forced medical noninvasive examination is possible.

- ⇨ A duty exists for doctor to conduct medical examinations during outbreak of communicable diseases in each country.

- ⇨ Switzerland is the only country where medical treatment can be refused. In such situation, alternative proportionate measures to medical treatment would be necessary.

⇨ The laws provide for placing individuals in quarantine in all countries. Georgia and Kyrgyzstan's laws do not provide for consequences of refusal of quarantines. In Serbia and Switzerland forced quarantines are possible.

2. Lessons learnt from the pilot project

Policy surveillance is a flexible methodology that is not subject matter specific, nor confined to a particular legal authority. In other words, policy surveillance can capture any measurable, regulatory legal at any level, from national-level legislation to local hospital ordinances. Although policy surveillance has been conducted at the global level, this pilot project was the first time that policy surveillance was conducted by a multi-national research team. As a result, we learned a number of valuable lessons to consider for expanding the project to include additional countries. The five most important lessons learnt were: (1) transdisciplinary approach is efficient and aided successful completion of the project; (2) scoping is key to success; (3) language barriers present a large challenge but can be overcome; (4) there is more to learn about collecting the law – and some inherent limits; (5) flexible methodology allows for great efficiency.

2.1. Transdisciplinary approach

The transdisciplinary approach is important for any legal epidemiology endeavor, but it is even more important in the international context. For this project, where possible, we paired lawyers with other public health professionals who had different insights into the law. This proved especially important in Georgia, where some laws were unavailable. However, because one of the Georgian team member was a public health expert who was familiar with a particular law due to her work, she was able to spot the fact that the law was missing. In the end, the transdisciplinary approach allowed us to catch a significant hurdle and be able to work around it. It also made the coding more efficient and increased accuracy due to the diverse skill sets of the transdisciplinary team.

2.2. Scoping

Scoping involves selecting the parameters for the project, including the major constructs or variables. In this case, the Research team created a Research Plan based on early scoping efforts. This Research Plan served as the coding questions and due to the significant emphasis on this at the beginning of the project, the framework was clear and captured all the important variables of interest. Clarify of the framework was especially important in the international setting due to the diversity of languages spoken. Because of the clear framework, the coding itself was more efficient.

2.3. Language barriers

While the language barrier is a challenging hurdle, we found that it can be overcome by agreeing on a common language to allow for comparisons (in this case English). Another key element was that most members of the research team spoke two, three or even more languages and were familiar in working in multicultural and multilingual environments. For instance, when it proved difficult to find the right word in English in a given question, we switch to Russian or French to look for an alternative and then move back to English making sure everybody understood and agreed. We also found that keeping the law in the native language for the teams to use while working with the framework

allowed them to complete the work much faster. After answering the questions in their native language, all they needed to do to complete the project was input the answers in English to the MonQcle coding platform.

Use of different languages made supervision by project staff more difficult, and made it impossible for supervisors from project team to directly check the accuracy of coding. These issues can ultimately be addressed by greater capacity within countries and language groups, such that full-teams can be recruited for policy surveillance projects.

Although it was sometimes challenging to overcome the language barriers, it proved also a unique asset to manage the project with great respect for the various cultures and languages involved. It encouraged the research team to listen carefully to each other and to work together to make sure everyone was satisfied with the process and the results.

2.4. Collection of the law

The pilot process also revealed that collecting the law in different countries is time consuming and difficult work. Some countries had issues accessing their laws, and voiced to us the need for ample time to be able to collect all relevant law prior to coding. "Sub-law" or regulation poses a special challenge, since it may require the researcher to consult numerous ministries to get access, and may require the researcher to know the rule exists. Overall, a project model that relies on and supports local public health law capacity is essential to proper legal research.

2.5. Flexibility of the methodology

Lastly, fine-tuning the methods to work in an international context is important for future success in expanding the project. Specifically, we can continue to expand and support local legal capacity, and allow the participants we recruit more time for scoping and collecting the law. We can also continue to refine the quality control processes that we implemented and decide to limit the amount of redundant coding (used for coding quality control) to only what is necessary in a global context. Nonetheless, overall the project was a tremendous success, and the participants now have experience and training to participate in and ultimately lead further projects.

3. Summary of in-country research views and experience

3.1. Georgia: Tamar Dekanosidze, lawyer, Georgian Young Lawyers' Association

I. *" What did I appreciate most about the pilot?*

I appreciated the idea of the project for three main reasons:

a) *the project allows for comprehensive analysis of the most important aspects of the local legislative acts concerning IHR, which includes consulting with and bringing together the analysis of the acts from various fields/sectors.*
b) *the project allows for doing a comparative analysis of the legal situation in several countries, which can provide important benchmarks for my country for example.*

c) *the project examines how the local laws align with IHR and what aspects need to be amended and improved to achieve the full compliance with IHR.*

All the above are good starting points to push forward the process of improving the laws and regulations/sub-laws on the ground.

I found the team of the project very committed, knowledgeable and nice - which is most appreciated.

II. *What was my most important learning?*

In the beginning of the project, I was not aware about the volume of the materials that needed to be researched and analyzed to respond to the questions, as well as the difficulties to get hold of certain legislative acts. Now I know that many of the legal provisions concerning IHR can be found not only in the laws, but also in sub-laws and sometimes in internal documents of the Government institutions. The process also revealed a number of deficiencies and inconsistencies in the Georgian legislation.

The most important learning though, would be reviewing the results of the other countries to see where Georgia ranks in relation to IHR compliance.

III. *What do I think needs to be improved?*

I think the research process needs some methodological improvements and expansion in time to show more comprehensive results:

a) *It's important to allow as much time as possible for the collection of laws and sub-laws that need to be analyzed. Many times these acts are not readily available or are hard to access and obtaining them requires approaching the Government bodies (various Ministries and Legal Entities in Public Law) who issued them.*
b) *IHR is a cross-cutting field (at least in Georgia) and involves the action to be taken by professionals and officials from various fields. Therefore, in the research process it would be important not only to include the professionals from the Ministry of Health, but also of other agencies, who might have the relevant information and sub-laws readily available (e.g. Ministry of Interior, Ministry of Finances, Ministry of Agriculture). The IHR focal point might be in a good position to advise which agencies need to be involved. "*

3.2. Kyrgyzstan: Nadejda Prigoda, lawyer, Kyrgyz-Russian Slavic University

"*I am Nadezhda Prigoda, I am assistant professor at the Kyrgyz-Russian Slavic University.*

First of all, I would like to welcome all of you and express my gratitude for the opportunity to share my opinion and views on the legal epidemiology pilot project.
Special thanks I would like to say to Dominique, Geraldine and Vladislava for the opportunity to participate in the project and to take part in a seminar in Neuchâtel.
As for me the most important stage of the project was its first stage, when I was answering the questions. In this regard I would like to express special thanks to Vladislava Talanova, who has helped me to clarify many issues.

The fact is that the legislation of the Kyrgyz Republic (KR) has some gaps, which became more obvious during the preparation for the seminar. In addition, it is full of contradictions and sometimes its provisions can be interpreted in different ways, which doesn't allow to find clear answers to some questions.

In addition, the problem of the legislation of KR is that many issues are not regulated by laws and governmental resolutions. They are regulated only by orders of the Ministry of Health. According to the legislation of the KR, orders of the Ministry of Health are not included in the list of regulatory legal acts. This means that orders are compulsory only in the field of health care, while the IHR are not only in responsibility of the health sector.

In addition, the status of national focal point for the IHR (2005) in the Kyrgyz Republic is not defined by the law, which causes certain problems.

Besides, in KR there are no officially translated texts of regulatory legal acts in English language, which also causes some difficulties.

The invaluable contribution in my preparation for the workshop in Neuchatel was made by office of WHO in Kyrgyzstan, especially Dr Tasnim Atatrah, who has initiated meetings with key stakeholders on the IHR. These meetings and consultations have allowed to validate the answers to the questions. During these meetings, the necessity to change the legislation of the Kyrgyz Republic in the field of healthcare again became actual and obvious.

As for the seminar, I appreciate that I could not only discover the experiences of other countries that participated in the project, but also the opportunity to discuss and to change the questions and answer options that could be interpreted in different ways. In particular, I mean questions concerning compulsory and enforced vaccination, treatment and hospitalization, the consequences of outbreaks of zoonotic diseases, programs and schedules of vaccination, etc.

Translation of questions into the national language and free access to them will make the project's results more accessible to decision makers in KR.

Since the laws, decrees and orders that were used could be amended, it seems to me that it is extremely important to update the answers in cases of changes in legislation. It will give the possibility to have correct answers for users.

I hope, the project will be continued at the national and international levels. In particular, at the national level we could have evidence-based legislation reforming including the opportunity to adopt the progressive experience and best practices of other countries. As for the international level it would be extended to other countries and in general to implement the IHR (2005)."

4. Conclusions on the validity of the methodology and research plan

The pilot phase of the project tested a process of collaborative policy surveillance in a multi-country setting. Over six months, processes were installed so as to not only reach to objective set for the pilot but also to set the foundations for the easier conduct of the extension phase to other countries in WHO European region, and beyond.

First, a collaborative process between the research team and WHO experts was implemented to establish the Research Plan. Such a process will be reiterated when activities will start to expand the Research Plan to cover the entire scope of the IHR (2005). The pilot phase showed that there was consensus on the validity and potential value of policy surveillance methods. Now that feasibility has been demonstrated, it will be important for the collaboration to develop into and through a shared, practical vision and process for using policy surveillance to document, evaluate and promote IHR compliance in the region.

The legal mapping data captured, in granular detail, the legal building blocks of IHR implementation. The data show considerable progress and commonality across the four pilot countries, but also reveal gaps to be filled. The clear presentation of consistencies and variations and provides national examples of practices that could help other countries to improve their legislation.

The coding workshop at the end of February 2019 in Neuchâtel was also an experience to build on for the future. It was the first time, all country teams could share the issues they had encountered in the process and it has been an opportunity to have solution–oriented discussions. It was a means through which country participants could achieve – and experience – mastery in the policy surveillance and analysis process. For the future development of policy surveillance, concerning IHR and other areas of legal concern for health, there is nothing more important than the development of local capacity and enthusiasm. The trained participants from law and public health should be seen as an important product of the pilot and any future work.

An example of the importance of local knowledge and capacity followed shortly on the completion of the workshop. Under the initiative of Dr. Tasnim Atatrah (WHO Representative, country office in Bishkek), Sanzharbek Temirbekov and Nadejda Prigoda, presented the results of the pilot project at the occasion of the 3rd UN- University of Central Asia's (UCA) Institute of Public Policy and Administration (IPPA) *Development Dialogues* organized in Kyrgyzstan on April 9th, 2019. This event gathered over 60 high-level government representatives, parliamentarians, development partners, researchers, technical experts on health, and civil society representatives, who came together to share inputs on strengthening health emergency preparedness and readiness to advance health security in Kyrgyzstan. For more information about the event, please see: http://kabar.kg/eng/news/development-dialogue-addresses-health-emergency-preparedness-in-kyrgyzstan/ The discussion informed strategic recommendations, which will be included in a policy paper in Kyrgyzstan.

The team at Neuchâtel, Temple University and Legal Science look forward to future discussions about the further development of IHR policy surveillance and its full integration into a region-wide strategy to promote stronger health systems.

III. Extension to other countries

1. Selection of five new countries

The next countries can either be volunteer countries or chosen by WHO on the basis of specific criteria.

2. Extension of coverage of the Research Plan to cover the full scope of the IHR(2005)

2.1. Process

The process of extension of the Research Plan to cover the full scope of the IHR(2005) will follow the same steps as the preparation of the pilot phase Research Plan.

1. The IHR(2005) background memorandum will be further developed to conduct a detailed analysis of the IHR(2005) provisions on surveillance and response to specific hazards[16]. It will be complemented by a literature review of secondary sources to delineate the scope of IHR(2005) member States duties.

   - **Foodborne diseases and food contamination**;
   - **Chemical event and chemical contamination**;
   - **Biological safety**;
   - **Radionuclear event and contamination**

   In addition, the Research Plan will be extended to cover the analysis of national legal frameworks **on points of entry other than airports**.

   Based on our current practice and experience, the number of questions necessary to properly cover all these topics is between 70 to 90.

2. Selected countries (Georgia, Kyrgyzstan, Serbia and Switzerland)'s in-country background memorandum will be further developed by the IDS research team to cover these specific additional themes.

3. Based on the extended IHR(2005) background memorandum and extended background country memorandum, new categorical datasets will be delineated and created.

4. Within each dataset, two or three themes (*constructs*) will be covered. The selection of the constructs will be based on the literature review and discussion with WHO thematic experts.

5. The identification of the constructs will define the field of the questions that are going to be asked to countries to highlight variations in the coverage of their national legal frameworks.

[16] Article 5, 6, 7, 13, Annex 1 and 2 as well as the definitions of "disease", "disinfection" "event", and "public health emergency of international concern" as set forth in Article 1 of the IHR(2005)

6. Questions will be validated by WHO experts and other national, regional and international stakeholders.

2.2. Options for the development of this part of the Research Plan

There are three options for the timing of the extension of the scope of the Research Plan and the number of countries involved:

Option 1: Extension of the pilot project to new countries with the current Research Plan.

Option 2: Extension of the scope of the Research Plan and implementation in the countries included in the pilot project (Georgia, Kyrgyzstan, Serbia, Switzerland).

Option 3: Extension of the scope of the Research Plan and extension to new countries.

The option 1 is a minimal one. During the coding workshop in Neuchâtel and the discussion with the WHO experts, it appeared that it would not be useful to pursue as it will only provide a limited information on the real implementation of the IHR(2005) at the national level. It was therefore decided not to consider it any further.

In Option 2, the scope of the Research Plan would be extended to cover the entire IHR(2005) in the same way as during the pilot phase, on the basis of background memoranda covering the legal framework of Georgia, Kyrgyzstan, Serbia and Switzerland. Then, or partially at the same time, these countries would answer the second set of questions.

In Option 3, the scope of the Research Plan would be extended to cover the entire IHR(2005) while the new participating countries are identified and the country legal and public health experts are found.
The Research team recommends that new countries work on the initial Research Plan (the list of 127 questions) while the new questions are being validated. The countries included in the pilot project could also answer the second set of questions at the same time.

When the Research Plan will have been extended to cover all main aspects of the implementation of the IHR(2005) and that all questions will have been answered for a number of countries (either only the countries included in the pilot project or those countries plus 5 new countries, depending if option 2 or 3 is chosen), the project should move on to include more countries. This last extension should be done in groups of 4-5 countries. For each group it would take 6 months to complete the process. The more countries will be involved, the more it will help training experts in the field who, ultimately, could run the process independently with limited support from the original research team.

2.3. Time

OPTION 2: EXTENSION OF THE RESEARCH PLAN WITHIN THE COUNTRIES THAT WERE INVOLVED IN THE PILOT PROJECT

This option would require 4 months to extend the scope of the Research Plan and then 3 months for the analysis, coding and translation by the countries that were involved in the pilot project.

OPTION 3: EXTENSION OF THE RESEARCH PLAN IN PARALLEL TO THE EXTENSION TO NEW COUNTRIES

For this option, the following elements will have to be foreseen:

This option will also require 4 months at the beginning for the development of the new Research plan. During this period, the new countries (limited to 5) will be selected and the in-country experts will be identified and trained to start the process. This should take 2 months after which they will start answering the first set of questions over a 3 months period, including a 3 days coding workshop. For the second set of questions based on the new Research plan, it should take 2 months, including a 3 days coding workshop to complete for the countries included in the pilot project. As soon as the new countries will have completed step 1 with the existing data sets, they will start completing the step 2 based on the new research plan. It should also take them 2 months including a 4 days coding workshop in which some experts from the countries included in the pilot project will be invited. One additional month will be needed to write country reports and translate the questions in national language. The overall duration of this option will take 8 months.

2.4 – Automatic translation of the questions in the Research Plan in Russian

The software MonQcle can be adapted by Legal Science to add a toggle switch on the dataset page to switch every question and answer response to Russian. It would take approximately 3 weeks to do so and the estimated cost is 18 000 USD.

This would not include any of the text for the plug in itself (i.e. "explore," "profile," country names, etc.) as that would be a major remastering of the plug in and likely be more than 25 000 USD.

This would also not translate the native language already entered into the legal text box and used for citations (i.e. it would translate Georgia law to Russian). Lastly, we would need to receive the proper translations for each question and response.

3. Steps to follow in selected countries

3.1. Inform Ministry of Health and request nomination of an IHR(2005) expert in the National Focal Point (NFP)

If applicable, the first step is to formally inform the Ministry of Health of the project and seek the nomination of a public health/IHR(2005) expert to collaborate in the coding process. The mandate of the expert is to participate in the coding process.

The mandate of the public health expert will be to:

a. Collect the national laws relevant to the implementation of the IHR(2005) in the country and perform an independent analysis by answering the questions listed in the research plan (redundant coder); **or,**
b. Organize meetings with the independent in-country lawyer, recruited to collect the national laws relevant to the implementation of the IHR(2005) in the country and to perform the analysis by answering the questions listed in the research plan. These meetings will aim at promoting systematic discussions on the answers to provide to each question and to develop good collaboration between the lawyer and the public health expert.
c. Participate in the coding workshop either as a redundant coder or as a co-coder with the in-country lawyer.
d. Provide advice, comments, views on the process and methodology when necessary.

The in-country public health/IHR(2005) expert will receive an honorarium in adequacy with his/her mission.

3.2. Identification of one in-country lawyer

An in-country lawyer with expertise in health law or international health law will need to be identified and hired. It will be necessary to determine who will conduct this activity and with whom the contract will be passed.

The mission of the in-country lawyer will be to:

a. Collect laws and sub-laws at national level to answer the list of questions in the research plan, and
b. Prepare for the coding by pre-answering the questions in the research plan. This step is done either independently or in collaboration with the public health/IHR(2005) expert, and
c. Upload the necessary laws to the software MonQcle, and
d. Participate in the coding workshop and code the answers either independently or with the public health/IHR(2005) expert, and
e. Participate in discussion during the coding workshop and provide views on the issues encountered at national level to perform the analysis, and
f. Translate the list of questions in national language, and
g. Develop a short country report in national language, highlighting key findings for the country, and

h. Generally provide advice, comments, views on the process and methodology when necessary.

The in-country lawyer will receive an honorarium in adequacy with his/her mission.

3.3. Collection of laws

The collection of laws and sub-laws will follow these criteria:

a. The laws and sub-laws are applicable on the entire territory (national level), **and**
b. The laws and sub-laws are necessary to answer the questions in the Research Plan.

All laws and sub-laws will have to be systematically collected from a reliable source. This source will have to be described in the background country memorandum.

If multiple sources are used to collect the laws, a hierarchy of the level of a reliability of the sources will have to be provided, if appropriate.

If laws and sub-laws need to be collected through official request to certain departments of the administration or to private entities, sufficient time needs to be allocated to ensure appropriate collection of these documents. Furthermore, detailed information on the process of collection of the laws and sub-laws need to be kept and enshrined in the research protocol.

3.4. Analysis of law and answering the questions

When answering the questions listed in the research plan, questions should not be interpreted. If interpretation is required, it is recommended that the in-country lawyer/public health expert contact the IDS research team to discuss the meaning of the question.

Any interpretation of the question will need to be documented in the Research protocol. Furthermore, country specificities which could be found in other countries may give rise to the addition of answer possibilities in the questionnaire in order to grasp new variations. In this situation, all country researchers will need to be informed of a new answer choice in order to adapt their answers.

The use of a caution note may be an alternative solution to grasp or mention the specific situation of a country.

3.5. Coding workshop

The coding workshop is a face-to-face event where all in-country researchers join in a specific location and meet with the rest of the Project research team.

The purpose of the event is to register all answers to the questions listed in the Research Plan in the software MonQcle and to link each answer to a citation in a law as a justification for the answer.

If the project if extended to five new countries, the workshop will have to be organized during four days to allow sufficient time for the coding, discussions and quality control.

Should the coding process be based on the questionnaire covering the full scope of the IHR(2005), the workshop should last six days.

Coding workshops could be organized every six months.

Furthermore, in-country researchers (at least one) from a previous coding round could be invited at the beginning of the end of the next workshop to share his experience and take part in the discussions of best practices. This process could facilitate the creation of new collaboration partnerships and would be the basis for the creation and maintenance of a Network of participants.

For the purpose of the extension to five new countries, a 6 days coding workshop could be organized three months after the validation of the second set of questions for the Research plan. Thus, allowing the new selected five countries to code all their answers to the entire Research Plan. Depending of funds, the countries included in the pilot project could also join to code their second of answers or possibly, a regional coding workshop could be organized to reduce costs.

3.6. Country reports in national language

Following the coding workshops, the in-country lawyer drafts a short report (common template) that highlights three to four key variations of his/her country legal framework.

The results are presented through the use of maps and explanations of the maps in national language. The aim of the report is to present the project and facilitate follow-up activities at country level to use the date produced.

These reports can be used:

- As a means to identify and highlight best practices;
- As a means to identify priority research questions on the impact of legal measures on health systems' resilience in emergency situations;
- As an opportunity to discuss possible changes/update of the legislation.

3.7. Translation of questions in national language

When necessary, translation in national language of the questions listed in the research plan is performed. This process will allow for the tool to be used more easily at national level by any person that need to access reliable legal information on the implementation of the IHR(2005) at national level. Accessibility is a key aspect of the project.

3.8. Follow-up activities to raise awareness of results and catalyze action

The development and maintenance of a Network of participating countries will allow the continuation of exchanges of views and the sharing of best practices among participants.

The Project Secretariat in the IDS in the University of Neuchâtel would maintain the Network through, ideally a website and a newsletter.

General conclusion

In this pilot project, we have shown that policy surveillance is feasible in the European setting and most likely in other regions of the world. We have also shown that we can train naïve users to successfully do the work, and that the users see the value in capturing and better understanding the state of the law in their countries and in peer countries.

In the coming months, we will be able to use the data to define the current state and key gaps in the law of the four countries in our forthcoming publication(s). Most important, as those data are now available online on a free and open access basis (http://lawatlas.org/page/who-international-health-regulations-project), public health experts can now use this information for their own research. This is also of particular interest for the authorities in each participating country as they benefit from a unique tool that not only allows comparative law study, but also confronting the law with other epidemiological data available in their country. This means that it is possible to better evaluate the impact of the law on the health of the population. Some participating experts in the project have already started and we hope that they will be followed by many.

The open online access to the information is also important as it facilitates the control of its accuracy. Any expert who identifies an error or is aware of additional information can easily inform us so the system can be updated and completed. We hope that the participating countries will continue coding their laws into the data sets allowing the development of a policy surveillance process on the implementation of the IHR(2005).

There are still important key questions and issues that will require further analysis and actions. We found a mixed degree of investment and cooperation in WHO country offices, so a major question is how WHO want to use this work and process – both the process (people) and the output are potentially useful and important to IHR implementation. The same question is true for all countries that are confronted with the challenge of protecting the health of their population through a comprehensive set of legislation that responds to the requirements of the IHR.

The existing general approach to and rationale for policy surveillance uses several mechanisms to translate data into action:

- Transparency (showing the state of the law and the law in relation to peer countries)
- Research (enabling mapping and evaluation research to show state of law and impact)
- Capacity building (helping in-country policymakers and professionals and WHO staff to identify and fill gaps)
- Advocacy (enabling concerted action by stakeholders in country and region, and policy makers, to promote adoption of better research

Any and all of these approaches could be used in an expanded project, but choices as to the strategy and tactics should be made so that the work can be tailored to those strategies and tactics. This is question for WHO and all countries to address. We hope that this pilot project has at least shown possible solutions for achieving in Europe and worldwide better health faster.

Annexes

Annex 1 - List of country researchers

Nom	Prénom	Institution
TALANOVA	Vladislava	IDS, University of Neuchâtel
MARKS	Géraldine	IDS, University of Neuchâtel
JOSET	Natacha	IDS, University of Neuchâtel
Sprumont	Dominique	IDS, University of Neuchâtel
Campbell	Andrew T.	CPHLR, Temple University
Cloud	Lindsay K.	CPHLR, Temple University
Burris	Scott	CPHLR, Temple University
Platt	Elizabeth	Legal Science
Šantrić	Jelena	School of Medicine, University of Belgrade
Tatulashvili	Ana	Public health Emergency Preparedness and Response division at National Centre for Disease Control and Public Health (NCDC) of Georgia
Temirbekov	Sanzharbek	Department of Disease Prevention and State Sanitary Epidemiological Surveillance of the Ministry of Health of the Kyrgyz Republic
Dekanosidze	Tamar	Georgian Young Lawyers' Association
Raeber	Pierre-Alain	Interlifescience
Prigoda	Nadejda	Kyrgyz-Russian Slavic University
GONZALEZ-MARTIN	Fernando	Organisation Mondiale de la Santé
Goryainov	Alexey M.	Association of Medical Law of Saint-Petersburg

Annex 2 - Research Plan

Separate document

Annex 3 - Country reports in national language and translated questions

Separate document