

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

Pilot project in Georgia, Kyrgyzstan, Serbia, and Switzerland

**Prepared by the Institute of Health Law (University of
Neuchâtel, Switzerland) Research Team**

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Legal Epidemiology for Accelerating the Implementation of International Health Regulations in the European Region (Georgia, Kyrgyzstan, Serbia and Switzerland) Pilot Project

I. Date of Protocol: March 15th, 2019

II. Purpose of the Project: The purpose of the project is to conduct a legal epidemiology study to observe the content of national laws implementing the International Health Regulations (2005) in Georgia, Kyrgyzstan, Serbia, and Switzerland and map their content following the scientific policy surveillance methodology according to a specifically designed Research Plan designed by the Project Research Team.

III. Scope: Compile, code, and analyze Kyrgyzstan, Serbia, Georgia, and Switzerland's laws that contribute to the implementation of the International Health Regulations (IHR(2005)) adopted by the World Health Assembly in May 2005.

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 focus of the project is on national laws, as defined in this Protocol, that enable the designated States 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. The study is based on national laws collected by February 1, 2019. However, not all the relevant laws were accessible to the research team on that date for all the selected countries. Further details regarding the limitations as well as other criteria of inclusion and exclusion of the collected laws are available in Section 5.6 of this protocol.

- a. Country Selection:** The selection of the countries was based on the following criteria - the countries should:
- i.** Be good models from a legal and public health perspective in their region;
 - ii.** Ensure a diverse and representative sample of countries from different sub-regions of the WHO European Region;
 - iii.** Have a strong and capable WHO Representative in the country; and
 - iv.** Include the presence of a sub-regional hub of the WHO Emergencies Programme, with international staff stationed there who could facilitate the subsequent rollout to other countries.

In view of these criteria and in accordance with WHO and the SFOPH, Georgia, Kyrgyzstan, Serbia, and Switzerland were identified as priority countries for the pilot.

IV. Project Research Team

- a. **Institute of Health Law (Institut de droit de la santé), University of Neuchâtel, Switzerland (IDS Team)**
 - i. **Dominique Sprumont**, Principal investigator for the project
 - ii. **Pierre-Alain Raeber**, Consultant, IHR public health expert, Interlifescience
 - iii. **Géraldine Marks**, Team leader, primary researcher, legal expert for Switzerland
 - iv. **Natacha Joset**, Primary researcher, legal expert for Switzerland
 - v. **Vladislava Talanova**, Primary researcher

- b. **In-country experts**
 - i. **Jelena Santric**, School of Medicine, University of Belgrade - Legal researcher for Serbia
Nadejda Prigoda, Kyrgyz-Russian Slavic University - Legal researcher for Kyrgyzstan
Tamar Dekanosidze, Georgian Young Lawyers' Association - Legal researcher for Georgia
 - ii. **Ana Kasradze**, Public health Emergency Preparedness and Response division at National Centre for Disease Control and Public Health (NCDC) of Georgia - Public health expert for Georgia
 - iii. **Ana Tatulashvili**, Public health Emergency Preparedness and Response division at National Centre for Disease Control and Public Health (NCDC) of Georgia - Public health expert for Georgia
 - iv. **Sanzharbek Temirbekov**, Department of Disease Prevention and State Sanitary Epidemiological Surveillance of the Ministry of Health of the Kyrgyz Republic - Public health expert for Kyrgyzstan

The public health experts were nominated by the Ministry of Health of each country.

- c. **Center for Public Health Law Research (CPHLR Team)**
 - i. **Scott Burris**, CPHLR Director
 - ii. **Lindsay Cloud**, Policy Surveillance Program Director (within CPHLR)
 - iii. **Andrew T. Campbell**, Senior Program Manager

- d. **Legal Science, LLC**
 - i. **Elizabeth Platt**, VP of Operations, Legal Science, LLC

V. **Data Collection**

- a. **Project dates:** September 2018 - March 2019

- b. **Dates Covered in the Dataset:** National laws in effect as of February 1, 2019. This is a cross-sectional dataset analyzing IHR(2005) in effect at one point in time, February 1, 2019.

- c. **Data Collection Methods:**

i. Phase I: IHR (2005) Background Research

Phase I was completed by the IDS Team in October 2018. The IDS Team produced a memorandum that 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.

ii. Phase II: Country-Specific Background Research

Phase II was completed by the IDS Team under the methodological supervision of the experts from the Policy Surveillance Program (PSP) of the Center for Public Health Law Research at Temple University.

The IDS Team developed four background research memoranda to cover each of the four States studied in this project. The memoranda were produced between October 1, 2018 and October 22, 2018.

A researcher initially produced each memorandum. Then, the drafts were exchanged among researchers to complement the initial research.

The purpose of these memoranda was to report on the geographic, administrative, legal, and public health specificities of the States 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 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 memos also list 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. During this phase, when the national laws were not found in English or French, the researchers used Google Translate to have a general understanding of the provisions.

iii. Phase III: In-Country Experts

Phase III was dedicated to the identification and recruitment of in-country experts. In-country experts were identified through the Association of Schools of Public Health in the European Region (ASPHER). The main role of the in-country experts, as members of the Project Research Team, is to work with the IDS Team to conduct the legal epidemiology analysis in each covered State. The mission of the in-country experts is to:

1. Confirm and complete the background research;
2. Provide relevant and up-to-date laws in national language according to the developed research plan provided to the in-country experts;

3. Prepare for a coding workshop by pre-answering the questions drafted in the research plan;
 4. Code responses for each country (coding workshop) and discuss result; and
 5. Draft the final country summary report
 6. Translate the questions in the research plan in national language.
- iv. **Official IHR(2005) Implementation Guidelines by WHO Used as Secondary Sources for Literature Review in IHR(2005) Background Research:**
1. WHO, Guidance Document for the State Party Self-Assessment Annual Reporting Tool, 2018. WHO/WHE/CPI/2018.17
 2. WHO, IHR Core Capacity Monitoring Framework. Questionnaire for Monitoring Progress in the Implementation of the IHR Core Capacities in States Parties, 2017. WHO/WHE/CPI/2017.41
 3. WHO, Simulation Exercise Manual, 2017. WHO-WHE-CPI-2017.10
 4. WHO, Pandemic Influenza Risk Management, A WHO Guide to Inform and Harmonize National and International pandemic Preparedness and Response, May 2017. WHO/WHE/IHM/GIP/2017.1
 5. WHO, Joint External Evaluation tool and process overview, IHR(2005), 2016.6.18
 6. 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. WHO/HSE/GCR/LYO/2013.1
 7. WHO, Toolkit for implementation in national legislation. Questions and answers, legislative reference and assessment tool and examples of national legislation, 2009. WHO/HSE/IHR/2009.3
 8. WHO, Assessment tool for core capacity requirements at designated airports, ports and ground crossings, 2009. WHO/HSE/IHR/LYO/2009.9
 9. WHO, International Health Regulations (2005). A brief introduction to implementation in national legislation, January 2009. WHO/HSE/IHR/2009.2
 10. WHO, Toolkit for implementation in national legislation. The National IHR Focal Point, January 2009. WHO/HSE/IHR/2009.4
- v. **Databases Used for Literature Review of National Primary Sources:** In order to identify relevant national public health-related norms that meet the objective of the project, the IDS Team used:
1. **Online Material:** Exploring open access legal databases, including GlobaLex, IDRL, FAOLEX, NATLEX, Law Library of Congress, Swiss Institute of Comparative Law, the websites of national ministries (Google Translate was used here as well to read information on websites in national languages).
 - a. **Serbia:**
 - i. Ministry of Health:
<http://www.zdravlje.gov.rs/index.php>

- ii. Drug and Medical Devices Agency:
<https://www.alims.gov.rs/eng/>
- iii. Institute of Public Health of Serbia:
<http://www.batut.org.rs/index.php?lang=2>
- iv. Legal databases:
<https://www.paragraf.rs/propisi.html>
<http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/reg/content>
- b. Switzerland:**
 - i. Descriptive of Functioning of Parliament:
<https://www.parlament.ch/en>
 - ii. Descriptive of Federalism: <https://www.ch.ch/en/>
 - iii. Federal Office for Public Health (FOPH):
<https://www.bag.admin.ch/bag/en/home.html>
 - iv. Federal Office for Agriculture (FOAG):
<https://www.blw.admin.ch/blw/en/home.html>
 - v. Federal Food Safety and Veterinary Office:
<https://www.blv.admin.ch/blv/en/home.html>
 - vi. One Health (in DE, FR, IT):
<https://www.blv.admin.ch/blv/fr/home/das-blv/auftrag/one-health.html>
 - vii. Federal Office for Civil Protection (FOCP):
<https://www.babs.admin.ch/en/home.html>
 - viii. Alertswiss: <https://www.alert.swiss/fr/home.html>
 - ix. Civil protection for Vaud (in FR):
<https://www.vd.ch/themes/securite/protection-de-la-population/>
 - x. Chief Medical officer for Vaud (in FR):
<https://www.vd.ch/toutes-les-autorites/departements/departement-de-la-sante-et-de-laction-sociale-dsas/service-de-la-sante-publique-ssp/office-du-medecin-cantonal/>
- c. Kyrgyzstan:**
 - i. Ministry of Justice: <http://cbd.minjust.gov.kg/ru-ru/npakr/Search>
 - ii. Government of Kyrgyzstan: <http://www.gov.kg/>
 - iii. State Inspectorate for Veterinary and Phytosanitary Safety: <http://gvfi.gov.kg/>
 - iv. Legislationline: <https://www.legislationline.org>
 - v. Ministry of Emergency Situations of the Kyrgyz Republic: <http://en.mes.kg/>
 - vi. The Department of Disease Prevention and State Sanitary and Epidemiological Surveillance
<https://dgsen.kg/>

- d. **Georgia:**
 - i. National Center for Disease Control and Public Health (NCDC): <http://www.ncdc.ge/Default.aspx>
 - ii. Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia: <https://www.moh.gov.ge/en/>
 - iii. Parliament of Georgia: <http://www.parliament.ge/en/>
 - iv. Legislative Herald of Georgia: <https://matsne.gov.ge/en>
2. **Law Collection Databases:**
 - a. **Serbia:**
 - i. Paragraf Lex: <https://www.paragraf.rs/propisi.html>
 - ii. Legal information system of the Republic of Serbia (Службени гласник): <http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/reg/content>
 - b. **Switzerland:**
 - i. Collection of federal and cantonal laws (in DE, FR and IT): <http://www.lexfind.ch>
 - ii. Official classified compilation at the federal level (in DE, FR, IT and partially ENG): <https://www.admin.ch/gov/en/start/federal-law/classified-compilation.html>
 - iii. Official cantonal compilation for canton Zurich (in DE): https://www.zh.ch/internet/de/rechtliche_grundlagen/gesetze.html#a-content
 - iv. Official cantonal compilation for canton Vaud (in FR): http://www.rsv.vd.ch/rsvsite/rsv_site/index.xsp
 - c. **Kyrgyzstan:**
 - i. CIS Legislation: <http://cis-legislation.com/index.fwx>
 - ii. Ministry of Justice: <http://cbd.minjust.gov.kg/ru-ru/npakr/Search>
 - d. **Georgia:**
 - i. Legislative Herald of Georgia: <https://matsne.gov.ge/en>
3. **Official Reports Directly Related to the IHR(2005), Listing Legal Material:**
 - a. WHO, Joint External Evaluation of IHR Core Capacities of the Kyrgyz Republic. Mission report: 29 November - 2 December 2016.
 - b. WHO/Euro. Ministry of Health of the Kyrgyz Republic. Results of the Self- Assessment of Essential Public Health Operations in the Kyrgyz Republic April- September 2016. Bishkek, 2017.
 - c. WHO, Joint External Evaluation of IHR Core Capacities of Swiss Confederation and the Principality of Liechtenstein, Mission report: 30 October - 3 November 2017.

vi. Search Terms for National Literature Review of Secondary Sources:

Internet-based searches were made using keywords, which included the following for each country:

1. **General Terms:** Names of the selected countries combined with “IHR(2005)”; “implementation of IHR”; “WHO”; “Joint External Evaluation”; “outbreaks of diseases”; “health promotion”; “healthcare”; “emergency response”; “civil protection”.
2. **Terms Related to Different Areas of Implementation of IHR(2005):** “health”; “public health”; “communicable diseases”; “infectious diseases”; “food safety”; “zoonosis”; “epidemiological surveillance”; “disease notification”; “animal health”; “veterinary”; “civil protection”; “nuclear safety”; “radiation safety”; “laboratory”; “chemical safety”; “biological safety”; “biosafety”; “nonproliferation”; “National Focal Point”; “point of entry”; “Influenza preparedness plan”.

vii. Inclusion and Exclusion Criteria:

1. **General criteria:**

- a. **Level of the legislation:** Exclusion of international and local level law, i.e., only the national level laws will be included in the coding process. At the national level, all relevant legal acts were included where they were available.
- b. Exclusion of non-binding sources of law.

2. **Specific Criteria:**

a. **Kyrgyzstan**

The analyzed legislation covers the national laws, the resolutions of the Government and the legal acts approved by the resolutions of the Government. These acts are normative legal acts under the national legislation and the hierarchy of norms. Furthermore, the analysis included the orders of the Ministry of Health and the acts approved by these orders. The orders of the Ministry of Health are mandatory only for the health care system (private and public sectors) but they apply at the national level. In December 2018, a meeting took place in Bishkek that was attended by the legal researcher for Kyrgyzstan, public health experts from the Ministry of Health, experts from the Department for Disease Control and Epidemiological Surveillance and representatives of the WHO office in Kyrgyzstan. During this meeting, the experts decided that the Orders of Ministry of Health should be included because they represent a specificity of their legal system and cannot be excluded without losing important information on the regulation of the matter.

b. **Georgia**

The responses to the questions are based on the information at hand at the time of the completion of the study. However,

various legislative acts were not available due to difficult access. Where this occurred, a caution note was provided indicating that a law exists but was unavailable for purposes of this study.

Legislative acts are publicly accessible on the web-page of Legislative Herald of Georgia. However, to gain locate a specific legislative act, a researcher needs to know the exact title of the act or its credentials. Otherwise, the search would need to be conducted within extremely voluminous legislation.

To locate all the relevant legislative acts that comprehensively address the questions of the study, the information was obtained from the following State agencies:

- i. The Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia (Ministry of Health) and its Legal Entities of Public

Law (LEPLs);

- ii. Ministry of Interior and its LEPLs;
- iii. Ministry of Environment Protection and Agriculture of Georgia and its LEPLs;
- iv. Ministry of Finances and its LEPLs.

To locate the relevant sub-laws, the researcher (lawyer) needed to address the above agencies and give them reasonable time for the response (because the agencies do not have the information readily available either). Doing this was not possible because of the time limitations of this pilot project. Even though National Center for Disease Control and Public Health (NCDC) - LEPL of the Ministry of Health - is a National Focal Point of IHR(2005), it does not have the information about all the legislative acts readily available. NCDC also has to address the above Government agencies to obtain this information. In addition, since many of the services (e.g. airports and ports) are privatized, State bodies need more time to obtain information from them.

VI. Development of the Research Plan

a. Development of Datasets and Constructs:

- i. **Procedure of the Development of Datasets and Constructs:** The datasets and the constructs result from the IHR(2005) background research memorandum. 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 (see Section 6.1.2) 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 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);
3. Selected constructs are common to all countries and need to be regulated in national legislation;
4. The datasets and constructs are built in a way to include new constructs (larger scope of analysis and ultimately the entire scope of IHR(2005)) in the research plan in the expansion to new countries (new constructs could be added according to the specific situation of the set of added countries);
5. 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 initial proposal from IDS Team was discussed with:

1. IHR experts from the WHO/EURO and WHO HQ in a Webex call (12.12.2018)
 2. IHR experts from WHO HQ in Geneva (21.12.2018)
 3. IHR expert in WHO/EURO (14.01.2019)
 4. One Health expert from WHO HQ (04.02.2019)
 5. Public health experts in WHO country offices (Skype calls)
 - a. For Serbia (14.12.2018)
 - b. For Georgia (03.12.2018)
 - c. For Kyrgyzstan (10.12.2018)
 6. National legal and IHR public health experts in the chosen countries (Skype calls)
 - a. For Georgia (06.12.2018)
- ii. **Content of the Datasets and Constructs:** The Research plan is divided in four datasets:
1. **Dataset 1:** Prevention;
 2. **Dataset 2:** Preparation;
 3. **Dataset 3:** Surveillance and alert; and
 4. **Dataset 4:** 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”.

Each dataset contains a limited set of themes and sub-themes (constructs) that were selected according to the criteria listed in the above Section 6.1.1.

Dataset 1: Prevention

Preventing the international spread of diseases is the first objective of the IHR(2005) and the focus of Dataset 1 named “Prevention”. 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.

Dataset 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.

Dataset 2 named “Preparation” covers three strategies:

1. 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.
2. 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.
3. 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 peace time and during an outbreak. It also considers how stockpiles are organized.

Dataset 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)). This is the focus of Dataset 3, named “Surveillance and alert.” 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)).

Dataset 4: Response

Responding to the international spread of a communicable disease requires States to have response capacities. Dataset 4 named “Response” 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.

b. Development of the Questions:

- i. Questions were built from the agreed constructs. The proposal from IDS Team was built in collaboration with:
 1. Swiss IHR public health expert;
 2. One Health WHO expert at WHO HQ; and
 3. IHR expert from the WHO/EURO.

The final Research Plan with questions was submitted to the CPHLR and Legal Science teams to control compliance with the methodology and the technical requirements of the software for coding.

VII. Coding

a. Development of Coding Scheme:

- i. Dataset terminology:
 1. Law: All the legislation of a country, it is not limited to formal laws but covers all the normative acts in the legal system.
 2. Vaccination schedule: A set of vaccinations, which may be either recommended or mandatory depending on each country strategy, and that includes the timing of administration of all doses.
 3. National specialized public health authority: An authority that is mandated by the national public health authority (e.g., Ministry of Health), such as the NCDC in Georgia.
 4. Notification of unexpected symptoms: Unexpected signs or events (syndromic surveillance) and includes cattle death, cattle slaughter, and abortion.

5. Second line response: A subsequent response that acts after the first response.
6. Pharmaceutical products: Covers vaccines and drugs.
7. Emergency (situation, response): Situation that poses a risk to life or health of human or animals, regardless of the nature of the event, and that requires prompt action from the States.

b. Coding Methods:

i. General coding rules

1. Researchers coded responses based on objective, measurable aspects of the law. Caution Notes were provided to explain any unique regulations and/or where the law was unclear.
2. The coding was performed in national language. When necessary, the in-country experts added a summary and/or argumentation of the chosen provision(s) in English in the comments (caution notes).
3. PDF texts of legal acts in national language were attached to the record. For Switzerland, the attached PDF laws are in French. For Kyrgyzstan, the chosen national language is Russian.
4. If the answer to a question could be found in a law (hierarchically higher legal act), the sub-law (hierarchically lower legal act) was not quoted. The highest legal act (in the hierarchy of norms) was always quoted.
5. Translation issue: The law was coded in each State's national language. The answers were then inserted in MonQcle in English.
6. Unanswered responses were kept in in the dataset in order to keep the framework consistent for future use.

ii. Specific coding rules

This section includes specific coding rules used when coding the questions and responses throughout each dataset. These rules are not applicable for all the questions, only the questions and answers that need to be clarified for the common understanding are listed.

Dataset 1: Prevention

- **Question 2: Does the law include vaccination schedules?**
 - This question covers vaccination schedules (i.e. lists of vaccinations) and not comprehensive operational programs.
- **Question 3.1: What authority is designated to regulate natural vaccination schedules?**
 - The answer “Ministry of Health” was coded only if explicitly designated in the law.
 - The answer “National specialized public health authority” was coded if the law refers generally to a national public health authority.
- **Question 6.2: What qualifications are specified for advisory group members?**

- “Professional qualifications” was coded when specific qualifications were indicated in the law.
- “Professional affiliation” was coded when being part of a specific institution or organization (including the government) is required by law.
- **Question 9.2: Who can be targeted by a compulsory vaccination decision in an outbreak of communicable diseases?**
 - The answer “Any person” was coded when the entire population can be required to get compulsory vaccination.
- **Question 13: What needs to be reported?**
 - Cattle death, cattle slaughter, and abortion are captured by the “Notification of unexpected symptoms” answer choice.
- **Question 14.2: What types of response measures can be taken?**
 - “Marketing ban” captures instances like measures of prohibition of the production, processing, procurement and sale of products and raw materials of animal origin, as well as veterinary drugs, feed and feed additives that do not meet the veterinary and sanitary requirements.
- **Question 15: Does the law provide for a second line of intervention?**
 - “Second line response” is a subsequent responder that acts only after the first responder.
- **Question 16.1: Who must take these training courses?**
 - Coded the parties who must take the training courses under any circumstance.

Dataset 2: Preparation

- **Question 3.2: What diseases should be covered by preparedness plans?**
 - If there is anything beyond this list, a caution note was added.
 - This question only covers where there is a preparedness plan.
- **Question 5.1: Who is responsible for initiating simulation exercises?**
 - Specialized department of Government includes Ministry of Health.
- **Question 7.1: Which professionals are covered?**
 - Coded only the available answer choices and included others as a caution note.
- **Question 8.1: What vaccines are stockpiled?**
 - Coded only the available answer choices and included others as a caution note.
- **Question 9.1: What medicines are stockpiled?**
 - Coded only the available answer choices and included others as a caution note.

Dataset 3: Surveillance and Alert

- **Question 1.1: What is the national authority responsible for the supervision of surveillance?**

- “Public health separate authority” refers to an agency other than the national public health authority, mandated to conduct certain duties, such as the NCDC in Georgia.

Dataset 4: Response

- **Question 4: Is there a law establishing a national entity facilitating the communication of information between all stakeholders?**
 - This question covers only outbreaks of communicable diseases.
 - **Question 5.1: What professions are covered?**
 - This question covers only professions and not members of an authority.
 - **Question 9: Is the duty to undergo a medical examination in an outbreak of communicable disease regulated?**
 - This question applies to the individual, not to the entire population.
- c. **Coding Process:** A coding workshop took place from February 28th to March 2nd 2019 at the University of Neuchâtel. This section describes all the steps of the coding process before, during and after this workshop.
- i. **Creation of Dataset and Record in MonQcle:** Before the workshop, each of 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 Teams. Each dataset contained the appropriate coding questions and individual records for each of the countries.
 - ii. **Preparation for the Coding Workshop:** All the 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 by answering the questions and identify applicable quotes of national laws.
 - iii. **Uploading of the relevant laws in MonQcle:** All the experts transmitted all the laws relevant for answering the developed questions in national language to the IDS Team before the coding workshop. The IDS Team uploaded and formatted these laws to each corresponding country record in MonQcle.
 - iv. **In-Country Researchers Participating to the Coding Per Country:**
 1. **Serbia:** Jelena Santric – legal expert
 2. **Switzerland:** Géraldine Marks – legal expert (IDS Team), Natacha Joset – legal expert (IDS Team)
 3. **Kyrgyzstan:** Nadejda Prigoda – legal expert, Sanzharbek Temirbekov – public health expert
 4. **Georgia:** Tamar Dekanosidze – legal expert, Ana Tatulashvili – public health expert
 - v. **Initial Coding:** During the coding workshop, the in-country researchers were tasked with answering and citing each applicable coding question by using the pre-loaded law in the respective dataset. The researchers followed the rules described in the sections 7.1 and 7.2.

Some further information about the coding is available in Section 8.2.

vi. Quality Control

1. After initial coding, the CPHLR and Legal Science team exported the data for each country and each dataset and examined it for any missing entries, citations, and caution notes. For the countries with two records, the divergences between the answers of two researchers were identified.
2. In-country discussion: For each dataset, the in-country researchers completed or corrected the missing entries, citations, and citations and resolved the divergences within a country through discussion.
3. The CPHLR and Legal Science team provided the participants with a summary of all divergences or corrections between the countries for each dataset.
4. Group discussion: All the in-country experts together with other members of the research team discussed the identified larger coding issues that affected the framework as a whole.

Further details on quality control procedure are available in Section 8.2 of this protocol.

- vii. Implementation of the Final Changes:** The in-country researchers implemented the changes decided during the in-country discussion as well as during the group discussion in MonQcle.
- viii. Quality Control – Final Check:** After the coding workshop and before the publication of the data, the CPHLR and Legal Science team performed a final quality control check. Further details about this step are available in Section 8.3 of this protocol.

VIII. Quality Control

a. Quality Control – Research:

- i. General Research Quality Control:** For all the countries, the collection of relevant laws was done twice. The first collection was performed when the constructs were available. The experts were looking for laws that could be 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 they could answer the questions with these laws. They added new laws and deleted the irrelevant laws.
- ii. Country-Specific Research Quality Control:**
 1. **Serbia:** The collection of relevant laws was performed only by the local legal expert. No other expert was nominated within the duration of the project.
 2. **Switzerland:** The relevant laws were redundantly researched to confirm that all relevant laws were collected by the researchers. 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.

3. **Kyrgyzstan:** The primary collection of relevant laws was performed by the local legal expert. To confirm that all relevant laws were collected, the legal expert consulted the experts from:
 - a. Ministry of Health;
 - b. Department for Disease Control and Epidemiological Surveillance;
 - c. State Inspectorate for Veterinary and Phytosanitary Security;
 - d. Republican Center of Quarantine and Especially Dangerous Infections of the Ministry of Health;
 - e. Republican Immunoprophylaxis Center as well as the representatives of the WHO office in Kyrgyzstan. Sometimes the relevant laws were not publicly available and the experts from the authorities mentioned above provided the legal expert with the text of these laws that were not publicly available.
4. **Georgia:** The relevant laws were redundantly researched. However, as mentioned in the part 5.6.2, the location and collection of laws in Georgia was difficult due to access issues, and not all the relevant laws were obtained.

b. **Quality Control – Coding:**

i. **Country-Specific Coding Quality Control:**

Note: Redundant coding could only be conducted in Switzerland and Georgia. The redundant coding process is fully independent, redundant coding by two Researchers for each jurisdiction. Redundant coding means that each jurisdiction (a record) is assigned and coded independently by the two Researchers.

1. **Serbia:** Redundant coding was not conducted due to a lack of immediately available resources. For each dataset, the CPHLR and Legal Science team exported the data into a Microsoft Excel document in order to examine the data for any missing entries, citations, and caution notes. The legal expert checked these problems and completed or corrected them.
2. **Switzerland:** Two public health experts redundantly coded each question throughout. The answers of one of the legal expert were discussed with the local IHR public health expert. The CPHLR and Legal Science team exported the data into a Microsoft Excel document in order to identify the divergences and examine the data for any missing entries, citations, and caution notes. The internal divergences within a country were resolved through discussion between two experts. Missing entries, citations and caution notes were corrected.
3. **Kyrgyzstan:** Redundant coding was not conducted due to the particular circumstances of the preparation to the coding workshop. The legal expert answered the questions and presented her answers to other experts from the Ministry of Health, Department for Disease Control and

Epidemiological Surveillance and WHO office at the end of February 2019 in Bishkek, Kyrgyzstan. The public health expert from Kyrgyzstan also took part in this meeting. They discussed the answers and came to a consensus. Both experts therefore had the same answers approved by other authorities. During the coding workshop, they code the answers together and discuss their problems with other experts. The CPHLR and Legal Science team exported the data into a Microsoft Excel document in order to examine the data for any missing entries, citations, and caution notes. The experts checked these problems and completed or corrected them.

4. **Georgia:** Three experts worked on the project, one lawyer and two public health experts. Two public health experts answered the questions together, independently from the lawyer who redundantly coded each question. Two local experts (one lawyer and one public health expert) attended the workshop and coded.

The CPHLR and Legal Science team exported the data into a Microsoft Excel document in order to identify the divergences and examine the data for any missing entries, citations, and caution notes. The internal divergences within a country were resolved through discussion between two experts. Missing entries, citations and caution notes were corrected.

- ii. **Divergence Rates and Resolutions:** Divergence rates were calculated based on the redundant coding conducted by Georgia and Switzerland. This percentage indicates the amount of divergences (of both Georgia and Switzerland combined) divided by the total variables coded between the two countries. This is meant to give an impression of the overall divergence rate within the dataset.
 1. The divergence rate for Dataset 1: Prevention was 20.9%.
 2. The divergence rate for Dataset 2: Preparation was 14.1%.
 3. The divergence rate for Dataset 3: Surveillance and Alert was 16.2%.
 4. The divergence rate for Dataset 4: Response was 14.3%.

After a primary quality control for each country and each dataset, the CPHLR and Legal Science team provided the experts with a summary of all divergences or corrections. All teams met in a larger session to discuss recurring coding issues and propose additional answer choices by dataset. Divergences were resolved through consultation and discussion with the team to reach consensus. The experts then implemented the changes according to the group discussion to obtain the final version of the coding.

- iii. **Quality Control - Final Check:** Prior to publication, the CPHLR team downloaded all coding data into Microsoft Excel to do a final review of coding answers, statutory and regulatory citations, and caution notes. All unnecessary caution notes were deleted and all necessary caution notes were edited for publication. Any responses which were inconsistent with the project's coding rules were updated. Any missing citations were added. Note that unanswered responses were kept in the dataset in order to keep the framework consistent for

future use by additional countries. Thus, some responses were not coded by any team in this round of analysis.

IX. Data Amendments

On September 25th, 2019, three answers for Georgia were amended in **Dataset 4: Response:**

- **Question 9.1.1: Can an individual refuse medical examination?**
 - The answer “Not designated in the law” was added.
- **Question 11.1: Can an individual refuse medical treatment?**
 - The answer was changed to “Yes” and the citation to the Law on Healthcare, articles 9 and 76 was added.
- **Question 11.1.1: What are the consequences of refusal of medical treatment?**
 - The answer “Not designated in the law” was added.