

A legal epidemiology pilot project in Kyrgyzstan, Georgia, Serbia and Switzerland (October 2018-February 2019)

Questions - final version

Research Plan for Mapping Key Features of National Legislation Implementing IHR(2005)

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The purpose of the project is to conduct a legal epidemiology study to observe the content of the body of national laws implementing the International Health Regulations (2005) in Kyrgyzstan, Serbia, Georgia and in Switzerland.

The Institute of Health Law research team in the University of Neuchâtel is working in partnership with the Policy Surveillance Program (PSP) of the Center for Public Health Law Research at Temple University Beasley School of Law, with in-country lawyers as well as national and WHO subject matter experts to set up a robust and appropriate policy surveillance program, tailored to generate the necessary empirical legal data to map national legal setups.

The pilot project consists in **(i)** establishing the necessary policy surveillance Research Plan for Mapping Key Features of National Legislation Implementing IHR(2005), **(ii)** carrying out a comparative mapping of the designated countries national legal frameworks in accordance with the Research Plan, **(iii)** providing complementary reports analyzing findings, **(iv)** documenting each stage of the process through a research protocol and code book to ensure its reproducibility to other countries after the pilot phase.

The Research Plan presented below is the policy surveillance canvas designed by the research team for the purpose of this project.

It has been developed on the basis of:

- 1- A thorough analysis of the provisions of the IHR(2005) as well as on a literature review of secondary sources providing key experts' insights on the duties of its State parties to achieve its goals.
- 2- Background memoranda, produced to provide a clear picture of the administrative, legal and healthcare organization of the four studies countries. They also summarize, on the basis of the analysis of the IHR(2005), a primary sample of laws, decrees, acts, regulations and orders from the countries related to different areas of implementation of IHR(2005). The legal documents summarized were preliminary analyzed in order to delineate their content, decide on the number and nature of possible *datasets* (categories) and the *constructs* (themes and sub-themes in the categories) they would respectively contain
- 3- Consultation with national and WHO subject matter experts.

The purpose of these questions is to highlight interesting variations in coverage of national laws and sub-laws (as defined in the Research Protocol). The resulting data will be coded in order to be mapped.

The Research plan is divided in four *datasets* following the aims of the IHR(2005), and contains a limited set of themes and sub-themes (*constructs*) that were selected, for time constraints in a pilot project, on the basis of their representativeness of the duties of States parties under the IHR(2005) and the studied countries' legal arsenal to manage the risk of spread of communicable diseases.

1- National Legislation Implementing the IHR(2005): Prevention

- **Reducing impact of event on public health by optimizing routine immunization coverage in humans** (Annex 2¹ + Annex 6 + Annex 7 IHR(2005) + Statement following the 17th, 18th, 19th IHR Emergency Committee Regarding the International Spread of Poliovirus²)

Immunization is a means to limit contamination and the spread of vaccine-preventable communicable diseases. National laws and sub-laws can provide for a duty to vaccinate against a pre-determined list of diseases or recommend or provide specific incentives to do so. Furthermore, the distribution of legal competences in this field between national and sub-national administrative regions may lead to variations in vaccination coverage among the entire territory.

a) Existence of legislation establishing immunization programs at national level

1. Is there a law regulating vaccination? (Y/N)		
2. Does the law include vaccination schedules? (Y/N)		
3. Does the law designate an authority to establish vaccination schedules? (Y/N)		
	<p>3.1 What authority is designated to regulate national vaccination schedules?</p> <p>(Check-all-that apply)</p> <ul style="list-style-type: none"> • Expert committee • Ministry of Health • National specialized public health authority 	
4. Does the law provide for the assessment of the efficiency of national vaccination schedules?		

¹ 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)

² WHO. Statement of the 19th IHR Emergency Committee Regarding the International Spread of Poliovirus. November 2018.

(Y/N)		
	<p>4.1 Who is designated to perform the efficiency assessment?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • National public health authority • Sub-national public health authority • Not designated in the law 	
<p>5. What is the peace time national strategy for vaccination?</p> <p><i>(check-all-that-apply):</i></p> <ul style="list-style-type: none"> • Mandatory vaccinations • Recommended vaccinations • None 		

b) Existence of a legal mandate for an Advisory group to advise authorities on the selection of vaccinations for the national program

(Y/N)		
	<p>6.1 Should the members of the advisory group declare conflicting interests?</p> <p>(Y/N)</p>	
	<p>6.2 What qualifications are specified for advisory group members?</p> <p><i>(check all that apply)</i></p> <ul style="list-style-type: none"> • Topical expertise • Professional qualifications • Professional affiliation • Not designated in the law 	

c) Measurement of vaccination rates

7. Is there a national authority mandated to take census of vaccination rates? (Y/N)		
	7.1 Is the national authority required to take measures to increase vaccination rates? (Y/N)	
8. Is there a sub-national authority mandated to take census of vaccination rates on sub-national parts of the territory? (Y/N)		
	8.1 Is the sub-national authority required to take measures to increase vaccination rates? (Y/N)	

d) Conditions for emergency compulsory vaccinations

9. Are compulsory vaccinations regulated for outbreaks of communicable diseases? (Y/N)		
	<p>9.1 Who decides on compulsory vaccinations in an outbreak of communicable diseases?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Government • Sub-national government • Public health national authority • Public Health sub-national authority • Not designated in the law 	

	<p>9.2 Who can be targeted by a compulsory vaccination decision in an outbreak of communicable diseases?</p> <p>(Check-all-that-apply):</p> <ul style="list-style-type: none"> • Any person • Risk groups for a specific disease • Children • Elderly • Pregnant women • Specific professionals • Not identified in the law 	
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e) Prioritization of vaccine distribution to the general population in times of emergency epidemic

<p>10. Does the law regulate the principles of prioritization of vaccine distribution in an outbreak of communicable disease?</p> <p>(Y/N)</p>	
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f) **Strengthening multisectoral management of zoonotic events and the human-animal interface (Annex 1 IHR(2005) + WHO Guidance 2018³)**

Some communicable diseases infect animals before possibly mutating to inter-human contagious diseases. Laws providing for the prevention, surveillance and control of animal diseases (epizootic) across sectors (public health, animal health, agriculture and environment) will be analyzed and compared to identify variations among the four countries.

a. Existence of regulation of epidemiological surveillance of animal diseases (epizootic)

³ WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018.

<p>11. Is there a law regulating epidemiological surveillance of animal diseases (epizootic)?</p> <p>(Y/N)</p>			
	<p>11.1 What types of surveillance are provided?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Reporting of diseases • Disease-specific screening programs • Animal products • Control of importation of animals • Syndromic surveillance 		
<p>12. Is the reporting of an animal disease occurrence required?</p> <p>(Y/N)</p>			
	<p>12.1 Who is responsible for reporting the occurrence of an animal disease?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Veterinarians • All animal caregivers • Animal owners • Personnel in 		

	<ul style="list-style-type: none"> slaughterhouses All animal keepers Laboratory staff Industries (autocontrol) Not designated in the law 		
	<p>12.2 Is the reporting process from sub-national level to national level regulated?</p> <p>(Y/N)</p>		
	<p>12.3 Are there national authorities responsible for supervising the functioning of animal disease surveillance?</p> <p>(Y/N)</p>		
<p>13. What needs to be reported?</p> <ul style="list-style-type: none"> Specific diseases listed in the law Notification of any animal diseases Notification of unexpected symptoms Laboratory confirmed diagnosis 			

b) Response to animal diseases (epizootic)

<p>14. Does the law establish who must respond first to the detection of an animal disease?</p> <p>(Y/N)</p>			
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	<p>14.1 Who is responsible for taking first response measures?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • National level first response measures • Sub-national level first response measures 		
	<p>14.2 What types of response measures can be taken?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Veterinary examination • Isolation • Quarantine • Slaughter • Travel ban • Sequester • Marketing ban • Not designated in the law 		
<p>15. Does the law provide for a second line of intervention?</p> <p>(Y/N)</p>			
	<p>15.1 What are the conditions for this second line response to be deployed?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • To reinforce capacities of first responders 		

	<ul style="list-style-type: none"> • If the disease spreads on the territory • To coordinate sub-national responses • For specific animal diseases 		
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c) Mandatory trainings to facilitate the control of animal diseases

16. Are training courses facilitating control of animal diseases required by law? (Y/N)			
	<p>16.1 Who must take these training courses?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Personnel in slaughterhouses • Researcher conducting animal experimentation in laboratories • Personnel in laboratories • Veterinarians • Livestock owners • Hunters • Not designated in the law 		

d) Existence of regulation for the management of diseases at the human-animal interface

<p>17. Is the exchange of information between animal disease surveillance services and human diseases surveillance services regulated?</p> <p>(Y/N)</p>			
<p>18. Is there a coordinating body established between animal and human disease surveillance?</p> <p>(Y/N)</p>			
	<p>18.1 What is the composition of the coordinating body?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Public health competence • Epidemiologist competence • Veterinary competence • Agriculture competence • Environment competence • Not designated in the law 		

2- National Legislation Implementing the IHR(2005): Preparation

- **Support to emergency planning (Annex 1 A §2, §6 g) and §3 IHR(2005))**

Planning consists in foreseeing and describing the logical sequence of tasks to accomplish in an emergency setting and the means necessary to reach intermediary and final objectives within a certain timeframe. Planning is necessary to limit the sanitary, economic and social consequences of an outbreak of infectious disease. National emergency plans may be all-hazard plans or/and specific contingency plans for different types of emergencies. Some countries have enshrined their plan in legislations, be it a general law on emergency situations and/or specific legal norms for specific risks or State of emergency laws.

- a) Existence of regulation of emergency preparedness applicable to outbreak of communicable diseases

1. Is there a law that regulates response to emergency situations? (Y/N)	
	1.1 Is the law applicable to outbreaks of communicable diseases? (Y/N)

- b) Existence of a legal mandate to adopt measures to prepare for the advent of a communicable disease outbreak

2. Is there a specific law on preparation for a communicable disease outbreak? (Y/N)		
3. Are specific authorities mandated to establish preparedness plans to		

<p>respond to communicable disease outbreaks? (Y/N)</p>		
	<p>3.1 What are these authorities? <i>(Check-all-that apply)</i></p> <ul style="list-style-type: none"> • Government • National Authority for Civil Protection • National public health authority • Sub-national authority • Expert commission 	
	<p>3.2 What diseases should be covered by preparedness plans? <i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Plague • Anthrax • Pandemic Influenza • Tuberculosis • Cholera • Yellow fever • Brucellosis • Sap • Melioidosis • Epidemic typhus • Monkeypox • Rift valley fever • Viral hemorrhagic fevers • Marburg • Ebola • Lassa • Junin • Machupo • Meningococcal 	

	<ul style="list-style-type: none"> infection • Smallpox • Poliomyelitis • Diphtheria • Measles • Botulism • SARS • Seasonal influenza • Zika • CCHF • Not designated in the law 	
	<p>3.3 What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Airports • Healthcare centers • Schools • Essential service institutions • All private companies • Migrant centers • Not designated in the law 	-

c) Use of state of emergency declaration of state of emergency regime to respond to outbreaks of communicable disease

4. Is there a law regulating the declaration of a state of emergency? (Y/N)		
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	<p>4.1 Is the declaration of state of emergency a condition to respond to an outbreak of communicable disease?</p> <p>(Y/N)</p>	
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- **Encouraging assessments of capacities (annex 1§ 2 IHR(2005)) through regular exercises and continuous training of workforce (WHO Guidance 2018⁴)**

Testing the capacities foreseen in plans is an important part of preparedness. National laws can define who is responsible for initiating simulation exercises at the national level as well as the frequency and scope of such exercises. To ensure the quality of certain services, national laws can also provide for the necessary degrees/skills to obtain to be authorized to practice. They can also delineate duties for continuous training for the exercise of certain activities.

- a) Existence of regulations for testing emergency planning resources (simulation exercises)

<p>5. Are there provisions on the organization of simulation exercises to test the preparedness plans at the national level?</p> <p>(Y/N)</p>	<p>5.1 Who is responsible for initiating simulation exercises?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Government • Specialized department of the Government • Specialized expert committee • Private companies • Non-governmental organizations • Sub-national level organizations • Health care institutions • Not designated in the 	
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⁴ WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018. *Op.Cit.* C.7. Human resources. Page 7

	law	
	5.2 Is the timing of simulation exercises regulated? (Y/N)	
	5.3 Are professionals required to participate in simulation exercises? (Y/N)	

b) Existence of regulation for "after-action reviews"

6. Does the law regulate debriefings following emergency responses? (Y/N)	6.1 Who is in charge of initiating the review? <i>(Check-all-that-apply)</i> <ul style="list-style-type: none"> • National public health authority • Government • Specialized department of the Government • Specialized expert committee • Private companies • Not designated in the law 	
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c) Existence of training requirements for professionals involved in response

7. Is the training of professionals to respond to outbreaks of communicable diseases regulated? (Y/N)	7.1 Which professionals are	
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	<p>covered?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Medical doctors (GPs) • Veterinarians • Hospital personnel • First emergency responders at sub-national level • Not designated in the law 	
	<p>7.2 Is the timing of the training regulated?</p> <p><i>(Y/N)</i></p>	

- **Management of shortages of pharmaceutical products including vaccines (Annex 2⁵ IHR(2005)).**

Infectious diseases outbreaks can generate/highlight a shortage in pharmaceutical products. Here, legislation has the capacity to organize the stockpiling of specific drugs, particularly antibiotics and to determine how this can be financed. Legislation can also identify criteria for prioritizing their distribution. Finally, legislation can also define the conditions under which new drugs can be marketed internally, particularly in times of emergency if off label use can be authorized.

- a) Existence of a list of therapeutic products (medicines/vaccines) that must be stockpiled

<p>8. Does the law regulate vaccines that need to be stockpiled?</p> <p><i>(Y/N)</i></p>		
	<p>8.1 What vaccines are stockpiled?</p> <p><i>(Check-all-that apply)</i></p> <ul style="list-style-type: none"> • Pandemic Influenza vaccine • Anti-smallpox vaccine 	

⁵ 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)

	<ul style="list-style-type: none"> • Not designated in the law 	
	<p>8.2 Are there provisions on the principles regulating priority distribution of vaccine stockpiles?</p> <p>(Y/N)</p>	
9. Does the law regulate the medicines that need to be stockpiled? (Y/N)		
	<p>9.1 What medicines are stockpiled?</p> <p><i>(Check-all-that apply)</i></p> <ul style="list-style-type: none"> • Diphtheria antitoxin • Botulinic antitoxin • Antirabies antitoxin • Not designated in the law 	
	<p>9.2 Are there provisions on the principles regulating priority distribution of medicines stockpiles?</p> <p>(Y/N)</p>	

b) Conditions for marketing new drugs during emergencies

10. Is there a law that regulates the marketing of new pharmaceutical products? (Y/N)		
	<p>10.1 Must the new product be authorized before marketing?</p> <p>(Y/N)</p>	
		<p>10.1.1 What are the conditions to obtain the authorization for marketing?</p>

		<p><i>(Check-all-that apply)</i></p> <ul style="list-style-type: none"> • Quality of the product • Safety of the product • Efficiency of the product • Prior delivery of an authorization to produce • Prior delivery of an authorization to import • Skills of the producer • Favourable risk-benefit balance • Not designated in the law
		<p>10.1.2 What authority grants the authorization?</p> <p><i>(Check-all-that apply)</i></p> <ul style="list-style-type: none"> • Ministry of Health • Separate public health national authority • Specific national vaccines authority • Specific national medicine authority • Single national therapeutic products authority • Expert committee • Not designated in the law
	<p>10.2 Are there provisions on an accelerated procedure in times of emergency?</p> <p>(Y/N)</p>	
		<p>10.2.1 Is there a specific procedure to be used in an outbreak of communicable disease to market pharmaceutical products that</p>

		have been approved abroad? (Y/N)
		10.2.2 Does the law grant WHO oversight in the assessment of quality, safety and performance documentation of the pharmaceutical product in the case of a public health emergency? (Y/N)

c) Conditions for importation

11. Is the importation of medicines regulated? (Y/N)	11.1 Must an authorization be obtained to import medicines? (Y/N)	11.1.1 What are the minimal requirements must an importer meet to obtain authorization? <i>(Check-all-that-apply)</i> <ul style="list-style-type: none"> • Professional qualification of the importer • Organization of the business • Equipment in the premises • Good manufacturing practices in the country of origin similar to the country of importation • Authorization to produce the medicine/vaccine in
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		<ul style="list-style-type: none"> the country of origin Prior authorization for marketing the medicine/vaccine in the country of origin Not designated in the law
		<p>11.1.2 Under what circumstances can these requirements be waived?</p> <ul style="list-style-type: none"> Scientific research Emergency Orphan diseases Not designated in the law
	<p>11.2 Must an authorization for marketing of an imported medicine be obtained before marketing?</p> <p>(Y/N)</p>	
<p>12. Is the importation of vaccines regulated like medicines?</p> <p>(Y/N)</p>		

3- National Legislation Implementing the IHR(2005): Surveillance and Alert

- Surveillance of communicable diseases in humans (articles 5 and 6, Annex 1 IHR(2005))

Epidemiological surveillance of infectious diseases requires the establishment of an epidemiological surveillance system likely to monitor the health situation of a specific population on a delineated territory at all times to be able to detect abnormalities. Legislation can define who is participating in this activity, lists of notifiable diseases, the notification process, the type of information provided, as well as the conditions for sentinel and syndromic surveillance. Legislation can also establish specific trainings for relevant professionals to ensure consistency when notifying. Legislation is also a means to guarantee the confidentiality of patients in this process.

- Existence of a system for detection and surveillance of communicable diseases
- Central authority for epidemiological surveillance
- Channels for communication of information from sub-national to national level

- d) Notifiable diseases
- e) Origin or source of notifications
- f) Ways of notifying
- g) Update list of notifiable diseases

1. Is there a law regulating the surveillance of human communicable diseases? (Y/N)			
	<p>1.1 What is the national authority responsible for the supervision of surveillance?</p> <p><i>(Categories mutually exclusive)</i></p> <ul style="list-style-type: none"> • Ministry of Health • Public health separate authority 		
2. Is there a disease notification system? (Y/N)			
	<p>2.1 Does the law regulate the general conditions behind the inclusion of specific diseases in the list of notifiable diseases?</p> <p>(Y/N)</p>		
	<p>2.2 Who is responsible for notification?</p> <p><i>(Check-all-that -apply)</i></p> <ul style="list-style-type: none"> • Doctors • Nurses • Hospitals • Laboratories 		

	<ul style="list-style-type: none"> • Not designated in the law 		
	<p>2.3 What agency normally receives the initial report?</p> <p>(Check-all-that-apply)</p> <ul style="list-style-type: none"> • National public health authority • Sub-national public health authority • It depends on the nature of the disease • Not designated in the law 		
	<p>2.4 Is the timing of notification regulated?</p> <p>(Y/N)</p>		
	<p>2.5 What are the modalities of notification?</p> <p>(Check-all-that-apply)</p> <ul style="list-style-type: none"> • Electronic Forms • Phone calls • Postal letter • Written form • Telegram • Teletext • Depending on the disease • Not designated in the law 		
3. Does the law regulate communication of information on the occurrence of diseases			

from sub-national to the national level? (Y/N)			
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- **Capacities at Points of Entry (PoE) - Airports** (articles 19, 20, 22 + Annex 1+ Annex 5 of the IHR(2005))

a) Existence of regulation of the process of designation of PoE

4. Is there a law regulating the designation of points of entry (PoE)? (Y/N)		
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b) Are PoE designated by a law?

5. Are PoE for the purpose of the IHR(2005) designated in a law? (Y/N)	
6. Are general border crossing points designated in a law? (Y/N)	

c) Existence of regulation of epidemiological surveillance at designated airports

7. Are designated airport PoE capacities regulated? (Y/N)		
	7.1 What airports surveillance capacities are required?	

	<p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Monitor source of contamination in all goods and containers • Maintain facilities used by travelers in good sanitary conditions • Capacity to supervise decontamination from any vector • Capacity to advise conveyance operators in advance for control measures and methods to be employed • Capacity to remove and safe dispose any contaminated matter from conveyance • Capacity to conduct medical examinations • Capacity to conduct inspections • Have contingency arrangements to deal with an unexpected public health event • Capacity to communicate adopted public health measures with the National IHR Focal Point • Law refers to IHR(2005) capacities for PoE • Not designated in the law 	
	<p>7.2 Is training of personnel to implement PoE capacities regulated?</p> <p>(Y/N)</p>	

d) Existence of regulation for response to communicable diseases outbreaks at airports

<p>8. Is the response to outbreaks of communicable diseases at airports regulated?</p> <p>(Y/N)</p>		
	<p>8.1 What airports response capacities are required?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Establishing and maintaining a public health emergency contingency plan • Assessment of and care for affected travelers • Provide appropriate space, separate from other travelers, to interview suspect or affected persons • Assessment and, if required, quarantine of suspect travelers • Disinsect, derat, disinfect, decontaminate • Treat baggage, cargo, containers, conveyances, goods or postal parcels • Apply entry or exit controls for arriving and departing travelers • Equipment, trained and equipped personnel for transfer of travelers who may be infected or contaminated • Law refers to response capacities listed in Annex 1B of the IHR(2005) • Not designated in the law 	
	<p>8.2 Is training related to responding to emergency outbreaks of communicable diseases regulated?</p> <p>(Y/N)</p>	

- e) Existence of competent authority with a legal mandate to conduct surveillance and response activities at airports

9. Does the law mandate competent authorities at designated airports to operate surveillance? (Y/N)		
10. Does the law mandate competent authorities at designated airports to have response capacities? (Y/N)		

- f) Existence of regulation for vector surveillance at airports (Annex 5).

11. Is there a law regulating vector surveillance at airports? (Y/N)		
	11.1 Is a vector control program implemented to a minimum distance of 400 meters from areas of PoE airports facilities? (Y/N)	

- **Alert communications** (articles 4, 7, 10 and Annex 1 of the IHR(2005) + WHO Guidance 2018⁶)

Identifying an outbreak of an infectious disease is one step, communicating the alert is the following stage. Alerting consists in providing basic information to the right institutions that have

⁶ WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018. *Op.Cit.* C.10. Risk communication. Page 17.

been legally mandated to release appropriate information at the right time (when necessary) to a specific audience.

Here legislation can designate responsible entities, particularly IHR National Focal Points (NFPs) and provide them with a legal mandate to allow them to appropriately conduct their activities in accordance with the provisions of the IHR(2005). Legislation can also define how the NFP can collect information from different sectors and the conditions under which it can share this information nationally and internationally.

a) Mandatory designation of a IHR National Focal Point (NFP)

12. Is there a law regulating the process of designation of an IHR National Focal Point? (Y/N)	
13. Is there a law designating an entity as an IHR National Focal Point? (Y/N)	
	<p>13.1 What entity is designated an IHR National Focal Point? (<i>Categories mutually exclusive</i>)</p> <ul style="list-style-type: none"> • Ministry of Health • Other Ministry • National reference center • Public health academic institution

- b) Existence of regulations regarding the mandate of the NFP*
- c) Existence of regulation for information-exchange at the national level for the NFP to collect/gather appropriate information*
- d) Mandatory NFP communication of information*

14. Does the law describe the mandate of the National Focal Point? (Y/N)	
15. Which entities can the	

<p>National Focal Point collect information from?</p> <p>(Check-all-that-apply)</p> <ul style="list-style-type: none"> • The central authority responsible for epidemiological surveillance • The points of entry (PoE) • The public health services • The clinics and hospitals • Not designated in the law 	
<p>16. Which entities can the National Focal Point provide information to?</p> <p>(Check-all-that-apply)</p> <ul style="list-style-type: none"> • National authorities • WHO • Other international organizations • Other countries • The population • Not designated in the law 	
<p>17. Are there provisions on the communication of personal data to foreign authorities?</p> <p>(Y/N)</p>	

4- National Legislation Implementing the IHR(2005): Response

- **Emergency mobilization of resources (surge capacity) (article 13 + Annex 1 §6 +⁷)**

Public health emergencies require mobilisation of health personnel, the availability of health care infrastructures and equipment. “Peace time” organization and routine may be strained and require the implementation of specific emergency plans to cope with the additional volume of work

⁷ WHO. Guidance Document for the State Party Self Assessment Annual Reporting Tool. 2018. *Op.Cit.* C8. National Health Emergency Framework. Page 17.

required. Here legislation can facilitate the planning of surge capacities (e.g. medical students or retired professionals are used to replace regular health personnel that may fall ill. Legislation can also provide for guaranteeing essential services to develop and implement contingency plans to prioritize services.

a) Existence of regulations on mobilization requirements

1. Is there a law requiring mobilization of resources to respond to an outbreak of communicable disease? (Y/N)	
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b) Designation of a legally mandated lead authority for response

2. Does the law designate an authority to lead the response to an outbreak of communicable disease? (Y/N)	
3. Does the law designate a secondary authority responsible for responding to an outbreak of communicable disease? (Y/N)	
	3.1 Does the law describe when the secondary authority should intervene in the response to an outbreak of communicable disease? (Y/N)
4. Is there a law establishing a national entity facilitating the communication of information between all stakeholders? (Y/N)	
	4.1 Is the composition of the national entity regulated? (Y/N)

c) Additional human resource capacity set out in legislation

5. Is surge capacity regulated to provide additional human resources in an outbreak of communicable disease? (Y/N)	
	<p>5.1 What professions are covered? (Check-all-that-apply)</p> <ul style="list-style-type: none"> • Healthcare • First responders • Essential services • Not designated in the law

- **Communication strategy in emergency (response to rumors, sources of reliable information, evidence-based communication...)⁸**

- a) Existence of regulation for emergency communications
- b) Designation of an official unit for emergency communications (applicability to communicable disease outbreaks)
- c) Description of mandatory training received for spokesperson
- d) Description of official channels of communication for scientific-based decision-making

6. Is there a law that regulates communications to the population in emergency situations? (Y/N)	
	<p>6.1 Is there a designated authority mandated to lead the communication to the public in case of an outbreak of communicable disease? (Y/N)</p>

- **Respect for dignity, human rights and fundamental freedoms of persons, transparency and non-discrimination when implementing health measures, especially during health**

⁸ 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.

emergencies (data protection, patients' rights, travelers' rights, duty to undergo medical treatment/vaccination...quarantine) (articles 31 and 32 IHR(2005))

Emergency situations, particularly when unforeseen, can generate limitations to individual and collective rights. Public health emergencies are no exception to this rule and excessive measures may be implemented to allegedly restore public order, resulting in infringements to human rights. The threshold between legitimate limitations of human rights and clear violation will be determined by law, including applicable international human rights law. For example, the use of quarantine, compulsory medical examinations and/or treatment or vaccination can be provided for in legislation, as is the case with patients' rights.

a) Human rights and fundamental freedoms of persons

7. Does the national Constitution contain fundamental human rights and freedoms? (Y/N)		
	7.1 Are the conditions for the limitations of fundamental rights and freedoms specified? (Y/N)	
		<p>7.1.1 What are the conditions to limit fundamental rights and freedoms?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Legal basis • Necessity • Public interest • Proportionality • Declaration of state of emergency

b) Measures taken towards individuals

8. Does the law list the type of measures that can be taken to control the risk of spread of	
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communicable diseases? (Y/N)	
	<p>8.1 What types of measures are regulated?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Identification of an ill person • Provision of information ill person • Medical surveillance • Quarantine and isolation • Medical examination • Medical treatment • Total prohibition to practice profession • Partial prohibition to practice profession
	<p>8.2 Under what conditions can the measures be executed?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Necessity of the measure to prevent a serious risk for other persons' health • Proportionality • Information provided to the individual concerned • Regular reassessment of necessity of measures • Not designated in the law

c) Duty to undergo medical examination

9. Is the duty to undergo a medical examination in an outbreak of communicable disease regulated? (Y/N)		
	9.1 Can an individual refuse	

	<p>medical examination?</p> <p><i>(Mutually exclusive)</i></p> <ul style="list-style-type: none"> • Yes • Yes, but under certain conditions • No • Not designated in the law 	
		<p>9.1.1 What are the consequences of refusal of medical examination?</p> <p><i>(Check-all-that apply)</i></p> <ul style="list-style-type: none"> • Compulsory medical examination • Forced medical examination • Denial of entry on the territory • Denial of exit of the territory • Quarantine • Alternative proportionate measures to limit the risk of spread of disease can be taken • Fines • Not designated in the law • None
<p>10. Is there a duty in the law for physicians to conduct a medical examination in an outbreak of communicable disease?</p> <p>(Y/N)</p>		

d) Duty to undergo medical treatment

<p>11. Is there a law regulating the duty to undergo a medical treatment in an outbreak of communicable disease?</p> <p>(Y/N)</p>		
	<p>11.1 Can an individual refuse medical treatment?</p>	

	<p>(Mutually exclusive)</p> <ul style="list-style-type: none"> • Yes • No • Yes, but under certain conditions • Not designated in the law 	
		<p>11.1.1 What are the consequences of refusal of medical treatment?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Compulsory treatment • Forced treatment • Denial of entry on the territory • Denial of exit of the territory • Isolation • Quarantine • Alternative proportionate measures to limit the risk of spread of disease can be taken • Fines • Not designated in the law

e) Conditions for quarantines

<p>12. Does the law provide for placing individuals in quarantines? (Y/N)</p>	
	<p>12.1 Under what conditions can a quarantine be implemented?</p> <p><i>(Check-all-that-apply)</i></p> <ul style="list-style-type: none"> • Necessity to prevent a serious risk for other persons' health • Proportionality • Information to person concerned • Respect of human dignity • Reassessment of utility of measure

	<ul style="list-style-type: none">• Not designated in the law
	<p>12.1.1 What are the consequences of refusal of quarantine?</p> <p><i>(Check-all-that apply)</i></p> <ul style="list-style-type: none">• Compulsory quarantine• Forced quarantine• Denial of entry on the territory• Denial of exit of the territory• Alternative proportionate measures to limit the risk of spread of disease can be taken• Fines• Not designated in the law