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INTRODUCTION

The COVID-19 pandemic revealed serious deficiencies in legal preparedness for public health emergencies. These deficiencies exist at both international and domestic levels, and they span both the content and implementation of existing instruments. Inadequate legal frameworks have contributed to the COVID-19 pandemic becoming a protracted global health emergency. Nevertheless, there is reason for optimism. The COVID-19 pandemic has boosted recognition of the importance of legal preparedness for emergencies, which was previously neglected in the health sphere. It has also helped to identify key areas for improvement, notably by highlighting gaps in the content of, and compliance with, the International Health Regulations (2005). The current negotiations on a new, wide-ranging international pandemic instrument are an opportunity to strengthen international legal preparedness for public health emergencies, drawing on the important lessons from the COVID-19 pandemic. However, international efforts to strengthen legal preparedness will also need to be replicated at the domestic level, with technical and financial support from the international community when needed, if they are to translate into practical action.

Definitions

Laws and legal frameworks: This chapter considers the role of law in public health emergencies. It uses the terms 'law' and 'legal framework' interchangeably to refer to any type of legal instrument, whether domestic or international. The chapter also discusses non-legal instruments, namely policies and contingency plans, which form an integral part of the governance framework for public health emergencies.

Legal facilities are special legal rights that are provided to a specific organization (or a category of organizations) to enable it (or them) to conduct operations efficiently and effectively. Legal facilities may come in the form of positive rights (i.e. to do a particular thing), access to simplified and expedited regulatory processes, or exemptions from ordinary laws (IFRC, 2021).

6.1 WHAT WE SAW PUBLIC HEALTH EMERGENCY LAWS WERE DRAFTED IN HASTE

As discussed in the preceding chapters, the COVID-19 pandemic revealed serious and widespread deficiencies in our efforts to prevent health risks and prepare for **public health emergencies (PHEs)**.

In many countries, particularly in the first few months of the pandemic, the response was chaotic and disorganized. As discussed in Chapter 1 section 1.1.1, different government actors struggled to coordinate their actions and develop effective and accessible communication strategies, and health systems and workers found themselves overwhelmed by unexpectedly high numbers of cases requiring hospitalization, global shortages of essential supplies including oxygen and personal protective equipment, insufficient staffing, and inadequate emergency protocols.

One of the root causes of the chaos was gaps in the content and implementation of laws and policies, at both the international and domestic levels. Legal frameworks have the potential to create an enabling environment for effective and timely prevention, preparedness for, response to, and recovery from PHEs. International law can create reciprocal obligations for states to cooperate and coordinate with one another in the management of health risks and PHEs. Meanwhile, national and subnational laws can establish the architecture for comprehensive and effective domestic systems for managing health risks and PHEs. They can also mitigate many of the key challenges discussed in this report, from ensuring that effective prevention and preparedness takes place (Chapter 1) to facilitating the participation of local actors and communities (Chapter 2) and protecting vulnerable groups from disproportionate health and socioeconomic impacts (Chapter 4). However, this potential was not realized, contributing to states' lack of capacity to face the COVID-19 pandemic.

When the COVID-19 pandemic began, states had to develop new laws at lightning speed, often without adequate time for robust debate or consultation with experts and stakeholders. While some degree of emergency law-making may be inevitable in the face of a major emergency, the weaknesses and gaps in existing laws necessitated a huge volume of emergency law-making. Partly due to their rapid development, these new laws also had gaps and unintended consequences, undermining the effectiveness of the response. As will be seen in this chapter, to avoid repeating these mistakes in future outbreaks, epidemics or pandemics we need to invest in **legal preparedness** for PHEs.

6.2 WHAT WE LEARNED THERE WAS A LACK OF LEGAL PREPAREDNESS BOTH INTERNATIONALLY AND DOMESTICALLY

In mid-2021, two major reports were released examining the functioning of international and domestic legal frameworks during the COVID-19 pandemic. The reports documented multiple failings.

Firstly, the International Health Regulations (IHR) Review Committee, established by the Director-General of the World Health Organization (WHO), published a report on the functioning of the IHR during the COVID-19 response (WHO, 2021).

Secondly, IFRC published a report entitled *Law and Public Health Emergency Preparedness and Response: Lessons from the COVID-19 Pandemic* (IFRC, 2021). The following sections of this chapter draw on these two reports to identify, in turn, the major weaknesses and gaps in domestic and international legal and policy frameworks relating to PHEs.

6.2.1 Weaknesses and gaps in domestic laws and policies

Both the IHR Review Committee COVID-19 report and the IFRC law and PHE report found that many states' domestic legal frameworks for PHEs were outdated or not fit for purpose when the COVID-19 pandemic struck (IFRC, 2021; WHO, 2021). Some states had laws dating back to the early 1900s or even the late 1800s (IFRC, 2021). The IFRC law and PHE report, which is based on research in a sample set of 32 states, identified the following common weaknesses and gaps in domestic laws and policies relating to PHEs.

- Need for greater integration: In most cases, PHEs are managed through a mix of both general disaster
 laws and specific PHE laws (IFRC, 2021). Integration between these different types of laws is needed to
 avoid conflicts, duplications or gaps in the practical arrangements they create (for example leadership,
 roles and responsibilities, and coordination mechanisms) (IFRC, 2021). As discussed in Chapter 1,
 integration is also key to creating a multi-hazard system that can manage increasing, compounding and
 overlapping risks.
- **Lists of prescribed diseases:** Some states have laws targeting a list of prescribed diseases including, in some cases, diseases that are no longer prevalent (for example smallpox) (IFRC, 2021). If a law applies only to a list of prescribed diseases it cannot be used to address novel or emerging health risks such as COVID-19.

- Lack of provisions on prevention and recovery: While domestic laws and/or policies generally do address PHE preparedness and response, the prevention and recovery phases are noticeably absent from many states' laws and policies (IFRC, 2021). This is a major omission because as discussed in Chapter 1 many health risks, including zoonotic spillover from animals, can be prevented.
- **Need for more detailed preparedness provisions:** While laws and/or policies do generally make some provision for PHE preparedness, there is scope for clearer and more detailed provisions, including creating enforceable preparedness duties (for example contingency planning, training) for key actors (IFRC, 2021). As discussed in Chapter 1, boosting preparedness is critical because prevention has its limits; despite our best efforts, it is inevitable that some disease outbreaks will occur.
- **Absence of an all-of-society and all-of-government approach:** Domestic legal and policy frameworks rarely explicitly provide for the participation of non-governmental actors in PHE preparedness and response through, for example, the allocation of formal roles and responsibilities or inclusion in coordination mechanisms. This is a major gap given that as discussed in Chapter 2 local actors and communities need to be at the centre of epidemic and pandemic prevention, preparedness and response.

In addition to these general weaknesses and gaps, some of the practical challenges that arose during the pandemic had, as their root cause, a lack of exceptions to 'situation normal' laws. In some countries, public financial management and procurement laws inhibited fast-tracking the procurement of drugs and medical products (WHO, 2021). Efforts to optimize the use of the health workforce were hindered by professional licensing laws that did not allow practitioners to move between different subnational jurisdictions, or for retired practitioners and final-year students to practise (WHO, 2021).

In some cases, the laws that were rapidly introduced to respond to the COVID-19 pandemic had gaps and unintended consequences, ultimately undermining the effectiveness of the response. For example, lockdowns, border closures and export restrictions were not always subject to clear exemptions for humanitarian actors (though exemptions were generally provided for other frontliners, such as medical personnel). This impeded humanitarian actors' ability to assist those most in need, both from the COVID-19 pandemic and from the many other disasters and crises that continued to occur (IFRC, 2021). These types of restrictions also had negative impacts on vulnerable groups, including restricting access to health and social care for older people, causing migrants to become stranded without livelihoods and creating barriers to people fleeing domestic violence (IFRC, 2021).

Finally, The *Lancet* Commission on lessons for the future from the COVID-19 pandemic identified a widespread failure to formulate policies that addressed the unequal impacts of the pandemic (<u>Sachs et al, 2022</u>). Indeed, as discussed in Chapter 4, the COVID-19 pandemic had its most severe impacts on vulnerable groups that were already left behind, who suffered disproportionate health and socioeconomic impacts. On this point, the IFRC law and PHE report found that legal and policy measures introduced to protect and assist vulnerable groups during the COVID-19 pandemic were more prevalent in states with more resources and had to be introduced by rapidly making new laws and policies, rather than relying on existing provisions (<u>IFRC</u>, 2021).

6.2.2 Weaknesses and gaps in international law

When the COVID-19 pandemic struck, there were also major weaknesses and gaps in the international legal framework relating to PHEs. The most important international instrument relating to PHEs is the International Health Regulations (IHR) (2005) (IHR, 2005). This international treaty is legally binding on 196 states, including the 194 Member States of the World Health Organization (WHO). The IHR's central aim is to prevent, protect against, control and provide a public health response to the international spread of disease (IHR, 2005). Unfortunately, gaps in both the content and implementation of the IHR undermined the management of the COVID-19 pandemic.

The IHR requires states parties to implement 'core capacities' (IHR, 2005 art 13(1), Annex 1A) for surveillance and response to public health events which, if they had been fully implemented, should have strengthened their preparedness for a pandemic. However, there have been widespread deficiencies in states' implementation of the core capacities, notwithstanding the fact that the final date for full implementation of the core capacities was June 2012 (WHO, 2011; WHO, 2015; WHO, 2016; WHO, 2021; Bartolini, 2021). Self-reported data reveals ongoing inadequacies: in 2021, the average implementation rate for the 13 core capacities was 65% (e-SPAR, no date). Partly underlying the deficiencies in IHR implementation is the fact that the IHR lacks enforcement mechanisms: it 'has no teeth' (WHO, 2021).

The IHR Review Committee COVID-19 report found the "vast majority" of countries had low or moderate levels of national preparedness and identified critical gaps in governance, subnational capacity, and essential public health functions like testing, contact tracing and treatment (WHO, 2021). The Committee concluded that lack of compliance of states parties with certain obligations under the IHR, particularly on preparedness, contributed to the COVID-19 pandemic becoming a protracted global health emergency (WHO, 2021). The Committee also expressed concerns regarding the information-sharing obligations under the IHR, stating that renewed commitment is needed with respect to the notification provisions under the IHR, including provision of sufficient information by states parties to the WHO (WHO, 2021).

In addition to these weaknesses in implementation of the IHR there are gaps in the content of the treaty itself. As the IHR Review Committee COVID-19 report found, the IHR does not cover several of the elements necessary for the comprehensive global management of health risks and PHEs (WHO, 2021). Key gaps in the IHR include:

- Prevention and management of zoonotic risks as part of a One Health approach.
- All-of-government and all-of-society coordinated national health emergency planning and preparedness.
- Benefit sharing for countries in need (for example access to antivirals, vaccines and other medical countermeasures).
- · Sharing of pathogens, specimens and genome sequencing information (WHO, 2021).

Meanwhile, the IFRC law and PHE report identified another important gap in the IHR. The core capacities do not reference the need for domestic authorities to develop an early warning system to provide clear and actionable early warnings of health risks to the general population (IFRC, 2021). This is a significant omission given the importance of early warnings in preventing or impeding the spread of infectious diseases. Thus, even if all states parties fully implemented the IHR, this would not be enough to ensure the effective global management of health risks and PHEs.





6.3 WHAT WE NEED TO DO CONTINUOUSLY IMPROVE LEGAL PREPAREDNESS

International and domestic law has the potential to provide the foundation for preventing, preparing for, responding to and recovering from PHEs far more effectively and quickly. To realise this potential, it is necessary to invest in **legal preparedness** for PHEs. Legal preparedness refers to having in place well-designed, well-understood and well-implemented laws, policies and plans for PHEs. Importantly, legal preparedness is not just an outcome, but equally an ongoing process that entails regularly reviewing and updating laws and ensuring they are fully implemented (IFRC, 2022).

At the domestic level, legal preparedness means developing laws, policies and plans that provide the architecture for a comprehensive system for managing health risks and PHEs. To this end, domestic laws need to, amongst other things, assign clear roles and responsibilities, create coordination mechanisms, establish state of disaster/emergency mechanisms, and allocate financial resources. Additionally, they should contain legal provisions to mitigate the common legal problems that arise during PHEs. In many cases, this entails developing targeted exceptions to 'situation normal' laws, to fast-track the availability of the necessary relief personnel, goods and equipment.

Achieving domestic legal preparedness is a continual process involving regularly reviewing and updating laws, policies and plans relating to PHEs. Governments need to review and update these instruments periodically (for example once every five years) to ensure that they do not become outdated (IFRC, 2022). This should also take place after a significant PHE occurs to enable the identification and implementation of lessons learned (IFRC, 2022). A good example of this is the legal reforms introduced by the Republic of Korea following the Middle East respiratory syndrome (MERS) outbreak of 2015, which resulted in the country having a high level of legal preparedness to face COVID-19 (see Box 6.1). Furthermore, as laws can only be as effective as their implementation, governments also need to ensure their full implementation through developing operational procedures, training actors (especially concerning their roles and responsibilities), and dissemination and awareness raising for the public (IFRC, 2022).

IFRC has developed an assessment tool to guide the review of existing laws, policies and plans relating to PHEs. Called the Guidance on Law and Public Health Emergency Preparedness and Response (PHE Guidance) (IFRC, 2022), it is designed to assist domestic decision makers to identify critical legal and policy issues, and to evaluate how well those issues are currently addressed by existing laws and policies. The Guidance comprises nine key questions. For each question, there is a rationale, a set of targeted subquestions, and a list of possible laws and policies to consider. When a country completes a review using the PHE Guidance and other relevant guidance documents, it can identify weaknesses and gaps that need to be addressed, either by amending or developing new laws and policies (WHO, 2009a; WHO, 2009b; WHO, 2009c).

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At the international level, legal preparedness requires two broad categories of obligations. The international community must ensure that legal instruments create both types of obligation. First, it is necessary to have international legal obligations concerning how states manage health risks and PHEs in their own territories, both to ensure minimum good practice and to avoid the spread of health risks to other states. This includes, for example, obligations to address the risks of emergence and transmission of zoonotic diseases and to provide early warning of new health risks to the public, and principles, such as equity, that should guide domestic laws. Second, international legal obligations are needed to facilitate cooperation and coordination between states in the management of health risks and PHEs. This includes sharing and facilitating access to information, pathogen samples, genome sequencing data, diagnostics, therapeutics and technology. Such obligations need to be well implemented; based on experience with the IHR, this may require strengthening compliance through mandatory external or peer-review evaluation mechanisms (WHO, 2021; IFRC, 2021).

Fortunately, two endeavours to improve the international legal framework are currently underway. Firstly, a new international legal instrument governing pandemics is being negotiated under the auspices of the Intergovernmental Negotiating Body, which was established by the World Health Assembly in December 2021 (WHA, 2021). Secondly, in parallel, a Working Group on Amendments to the International Health Regulations (2005) has been mandated by the World Health Assembly to consider targeted amendments to the IHR (WHA, 2022). These processes will culminate in 2024, when both the Working Group and the Intergovernmental Negotiating Body report to the 77th World Health Assembly with, respectively, a proposed package of targeted amendments to the IHR and a draft pandemic instrument (WHA, 2021; WHA, 2022).

Through these parallel processes, the international community has an opportunity to strengthen international legal preparedness for PHEs, drawing on the important lessons from the COVID-19 pandemic. In addition to addressing the gaps identified by the IHR Review Committee COVID-19 report, it will be critical that any new pandemic instrument:

- First, addresses equity in its broadest sense, not only in terms of access to medical countermeasures
 (for example therapeutics and diagnostics) but also in terms of access to health countermeasures, a
 broader term that also encapsulates information and primary healthcare (among other things). Equally,
 addressing equity in its broadest sense means recognizing the social determinants of health and the
 need for related legal and policy measures during PHEs, as well as protections for access to basic health
 services, regardless of legal status.
- Second, addresses basic principles guiding domestic legal and policy frameworks, which could include, inter alia, the need for whole-of-society and whole-of-government frameworks, the need for legal facilities and protections for frontline responders, or an obligation related to early warning and early action within countries.
- Finally, recognizes the importance of community engagement and the role of local actors and communities in the management of health risks and PHEs, and specifies what that might entail, bearing in mind the variety of domestic legal contexts.

BOX 6.1 / CASE STUDY

LEGAL PREPAREDNESS PAID DIVIDENDS WHEN COVID-19 HIT THE REPUBLIC OF KOREA

When the first case of COVID-19 was detected in the Republic of Korea on 20 January 2020, the country was well prepared — including legally prepared.

The Republic of Korea's main law regulating pandemic prevention, preparedness and response is the Infectious Disease Control and Prevention Act. It was passed in 2010 to implement the International Health Regulations (2005) and provided the legal basis for the response to the 2015 Middle East respiratory syndrome (MERS) outbreak. Unfortunately, the infectious disease response system did not function effectively early in the MERS outbreak, which grew to be the largest outside the Middle East with 186 confirmed cases and 38 deaths (Moon, 2021; WHO, no date; Yang et al, 2021).

Afterwards, the National Assembly swiftly updated the Act to implement lessons learned (MHW RoK, 2015). The changes to the Act underpinned comprehensive reforms to strengthen the country's system for preventing and responding to disease outbreaks (Moon, 2021). Some of the key changes were:

- Establishing an information system to systematically collect and analyse infectious disease-related information.
- Allowing the Minister of Health and Welfare to quickly designate a new infectious disease; previously this took three months, slowing down containment measures.
- Providing quarantine officers and epidemiological investigators with powers to take on-the-spot measures to stop an infectious disease spreading (for example evacuating residents).
- Permitting the government to collect information from patients and medical institutions and share that information widely, including with the public.
- Stipulating a minimum number of epidemiological investigators to be assigned to the central, city and province levels (MHW RoK, 2015).

By 2017, the country had made large improvements. A WHO Joint External Evaluation found that its impressive preparedness derived from its recent experience with the MERS outbreak in 2015, and that it now had comprehensive laws, policies, plans and manuals in force (WHO, 2017).

The Republic of Korea's efforts paid dividends when COVID-19 emerged. The country succeeded in controlling case numbers in February and March 2020, without stringent lockdown measures (Yang et al, 2021). The 2015 reforms were a key enabling factor. The revised Act permitted the Minister of Health and Welfare to rapidly designate COVID-19 as a new infectious disease. It also ensured there was an existing network of 134 epidemiological investigators at central, city and province levels. These investigators sprang into action, accurately tracking the spread of the virus. The revised Act also enabled the government to collect information from patients and medical institutions and share it with the public; this was not possible for legal reasons during the MERS outbreak (Moon, 2021).

KEY RECOMMENDATIONS

The international community must boost international legal preparedness for PHEs. This requires adopting a new international pandemic instrument and updating the IHR to underpin the effective and equitable global management of health risks and PHEs. Any new pandemic instrument should address equity in its broadest sense, promoting equitable access to health countermeasures both between and within states. Any new pandemic instrument should also emphasize the importance of community engagement and the role of local actors and communities in the management of health risks and PHEs. Finally, it should set the basic principles guiding domestic legal and policy frameworks.

National and subnational governments must strengthen domestic legal preparedness for PHEs.

They can do so by reviewing their laws, policies and plans and updating them to address the weaknesses and gaps identified. The IFRC's Disaster Law team stands ready to work with governments to review and update existing instruments to ensure they are fit for purpose. Specifically, in many countries domestic legal and policy frameworks relating to PHEs need to be updated to:

- Enhance integration with general disaster laws and policies to avoid conflicts, duplications or gaps in the practical arrangements they create (for example leadership, roles and responsibilities, and coordination mechanisms).
- Be broad enough to address novel and emerging health risks rather than applying only to a list of prescribed diseases.
- Address all aspects of managing PHEs from prevention through to preparedness, response and recovery.
- Include clearer and more detailed provisions on preparedness, including legally requiring key actors to
 perform key preparedness actions and providing them with the support they need to do it (for example
 contingency planning).
- Facilitate the participation of all actors and stakeholders (especially local actors and communities) through the allocation of formal roles and responsibilities, inclusion in coordination mechanisms and consultation.
- Provide legal facilities to all recognized frontline responders, including authorized local actors such as National Societies, to facilitate their movement and that of the goods they need, and give them priority consideration for access to pandemic response products to protect them.
- Introduce legal provisions to mitigate the common legal problems that arise during PHEs, including targeted exceptions to 'situation normal' laws that impede the availability of relief or medical personnel, goods and equipment.
- Include early warning, early action obligations towards their own populations.
- Include legal protections to guarantee equal access to essential health countermeasures, including pandemic response products, for the most vulnerable groups and communities, regardless of legal status and on the basis of need.

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