International Law and Pandemics

A PRIMER

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A PRIMER

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Introduction

“International pandemic law”, as such, does not exist. Instead, multiple fields of international law bear upon the management of infectious disease outbreaks. These range from international health regulations and human rights to intellectual property and bio-security law. The purpose of this primer is to provide a concise overview of each branch of relevant international law, as well as the international institutions that are involved in implementing that law. Aimed at policymakers, practitioners, journalists, students, and scholars – both lawyers and non-lawyers – it is a “one stop” source for non-specialists who seek to inform themselves about the basics of each field, as it relates to pandemics. For those who wish to dig deeper, each chapter contains footnotes and suggestions for further reading.

A simple definition of a pandemic is “an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people.” While some elements of that definition are contested – for example whether the outbreak must cross a border — it is useful for the purposes of this primer. The international element, in particular, is important because it triggers application of the International Health Regulations (IHR) — the centerpiece of the global health law regime. The IHR define a “public health emergency of international concern” as:

...an extraordinary event which is determined...

(i) to constitute a public health risk to other states through the international spread of disease and

(ii) to potentially require a coordinated international response.2

This is not to say that the application of all international law depends on cross-border transmission. Human rights and humanitarian law, for example, may apply to certain purely internal phenomena. But the transnational dimension is what brings some bodies of law into play that otherwise would not be — trade law, for example.

It is not unusual for multiple bodies of law to apply to one issue area: the environment, cyber-security and migration are other examples. This patchwork of law need not be a problem as long as the different parts operate in harmony. However, it does not always work that way. When there are conflicts, contradictions, or even the inevitable ambiguities in the law, there is no overriding principle or compulsory mechanism to resolve them. In a global health emergency, the uncertainty and possibility of delayed action can cost lives.

Moreover, fragmentation of the legal regime has an institutional dimension. The World Health Organization is the principal global health organization, but it operates alongside the World Bank, UNICEF, the World Trade Organization, regional organizations, international and regional courts with overlapping and yet independent jurisdictions, various public-private partnerships such as GAVI (the Vaccine Alliance), and many
governmental and non-governmental actors. Many of these institutions seek to coordinate their actions, but in a health emergency, a rational division of labor among a multiplicity of actors is hard to achieve.

This primer does not seek to bring coherence or unity to the law, but does illuminate how the different bodies of law relate to each other. The International Health Regulations, for example, must be implemented in a manner that is consistent with human rights law. The law of state responsibility sets out general rules for holding countries accountable for violations, but these are to be read in light of specific rules for particular regimes. Many of the chapters in this primer cross-reference each other to highlight those connections.

COVID-19 is the latest – but not the first – pandemic to prompt calls for international legal and institutional reform. Concerns about equitable global access to vaccines has led to appeals for suspension or reform of intellectual property law. Questions have been raised about whether the IHR are fit for purpose and whether human rights law imposes a duty to cooperate in addressing outbreaks. A group of states have led the charge for a new ‘pandemic treaty’, negotiation of which has now been endorsed by the World Health Assembly. To begin in November 2021, these negotiations would consider everything from early detection of outbreaks through better surveillance, to better response through the equitable distribution of vaccines. It would also look at ways to strengthen the international institutional framework, perhaps by empowering the WHO.

Negotiating a new treaty is one way of changing the law. There are other ways. Even the World Health Assembly is open to the possibility that negotiations there may produce an “agreement or other international instrument”, as opposed to a treaty. The law also develops through practice. This is obviously true for customary law. It is also true for treaty law, given, for example, the role of practice in treaty interpretation. Practical experience in trying to implement the law may reveal flaws or gaps, leading to adaptation. Or imprecise principles and other forms of “soft law” may be given content through practice and the discursive interaction associated with it. Thus, this primer looks not only at the corpus of rules, principles and norms that apply to pandemics, but also the fault-lines of debate in their implementation.

The primer contains ten chapters covering seven areas of law and a half-dozen institutions. All the chapters were researched, drafted, and edited by students, overseen by Fletcher faculty. The students and faculty involved are listed in the opening pages of this primer. While individuals took the lead on particular chapters, we see this as a collective effort and hence collective authorship.

Chapter one is about the International Health Regulations. Binding on the 196 member states of the World Health Organization, the IHR were revised in 2005 following the SARS pandemic. They are designed “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.” Among their 66 articles, plus several Annexes
and Appendices, the IHR impose two main obligations on states. The most immediate is to notify the WHO of an “extraordinary event” that could constitute a Public Health Emergency of International Concern, and to share information with the WHO about that event (Articles 6 and 7). A more long-term obligation is for states to build “core capacity” in their health systems to detect infectious disease outbreaks and to respond effectively (Articles 5 and 13). The IHR also empower the WHO to make non-binding recommendations. States have fallen short in implementing their obligations and have not always followed the recommendations. Post-COVID 19, there have been calls for reform of the IHR – a subject of lively debate. Moreover, adoption of a new pandemic treaty could obviate the need for revision of the IHR.

Chapters two and three are about the responsibility of states for violations of international pandemic law. Chapter two reviews customary law, reflected in the Articles on the Responsibility of States for Internationally Wrongful Acts (ARSIWA), on the threshold conditions for, and legal consequences of, a breach. It considers issues of standing and attribution (including, e.g., in what circumstances a state may be held responsible for acts committed by non-state actors). It also outlines the legal consequences of a breach, including requirements of cessation of wrongful conduct, restitution, compensation, and the various forms of satisfaction. Chapter three is about what ARSIWA terms “circumstances precluding wrongfulness.” These are defenses (justifications or excuses) that a state may plead against what would otherwise be well-founded claims of its responsibility for an illegal act. The defenses include force majeure, necessity, distress, consent, self-defense, and countermeasures. The chapter identifies the first three as those most relevant to infectious disease outbreaks. However, none provides a blanket authorization to engage in what would otherwise be illegal acts during a pandemic. In each case, the viability of the defense will depend on the particular circumstances of the impugned conduct and its relationship to the pandemic within which it occurs.

Chapters four and five cover international human rights law. The first focuses on the right to life and the right to health, as embodied in the Universal Declaration of Human Rights, the WHO Constitution, and various global and regional treaties. Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) stipulates “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and calls specifically for “the prevention, treatment and control of epidemic, endemic, occupational and other diseases.” Like other economic and social rights, the right to health is meant to be realized “progressively.” The Committee charged with overseeing the ICESCR has offered authoritative guidance on the elements of the right, but there is still room for interpretation about precisely what it requires. Chapter five is mainly about permissible restrictions on certain human rights, such as freedom of movement and freedom of assembly, in a public health emergency, as well as the more dramatic step of formal derogation from human rights treaty obligations. It also examines such soft law instruments as the Siracusa Principles, which provide additional guidance on the requirements that rights limitations (quarantines for example) be necessary and proportionate.
Chapter six covers trade and intellectual property. The chapter focuses on the body of trade law administered by the World Trade Organization, which creates exceptions to free trade obligations in order to protect public health and public welfare. It thus addresses the question of whether states may restrict exports of medicines or medical equipment. These exceptions must be implemented in a manner that does not arbitrarily or unjustifiably discriminate against other WTO Member States or constitute a “disguised” restriction on international trade. The WTO also administers The Agreement on Trade-Related Aspects of Intellectual Property Rights. “Flexibilities” are built into the agreement, but the scope of these flexibilities, and the relationship between obligations to protect intellectual property and the right to health, are uncertain. In 2021, India and South Africa pushed for a waiver of intellectual property protections for COVID-related medical technologies, including the vaccines.

International humanitarian and criminal law are covered in Chapter seven. Humanitarian law applies in armed conflicts, whether international or non-international (with slightly different rules for each). Various provisions of the Geneva Conventions and their Additional Protocols are relevant to pandemics, including the prohibition against attacking medical personnel or facilities, the obligation to care for the sick, and the heightened obligations of states to populations living under their belligerent occupation. A difficult question concerns the obligation on states not to withhold consent to humanitarian relief “arbitrarily.” What “arbitrarily” means in the context of a pandemic in a conflict-affected state is unsettled. International criminal law is a narrow category of egregious human rights abuses for which individuals can be held accountable. Although these crimes are not necessarily more likely to occur in a pandemic, certain features of pandemics may facilitate certain forms of international criminality. The intentional infliction of mass-killing through the spread of disease or the deprivation of access to medicine could constitute the crime against humanity of extermination. The residual crime-against-humanity category—“other inhumane acts”—could cover various other ways of intentionally causing great suffering or serious injury to health, such as through a deliberate policy of withholding vital public health information in a pandemic. In an armed conflict, certain war crimes could also apply, including willfully impeding the delivery of objects indispensable to civilian survival, such as essential medical supplies.

Chapter eight addresses a cluster of treaties that can be called “biological security law”. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity seeks to ensure the safe transfer, handling, and use of living modified organisms created through modern biotechnology. The Biological Weapons Convention (BWC) is not about naturally occurring disease but rather the weaponization of biological agents. However, it belongs in this pandemic law primer because almost every biological agent that can be used for weapons also has legitimate health or agricultural purposes (the so-called dual use challenge). Article X of the BWC affirms that States Parties have the right to participate in the exchange of “equipment, materials, and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes,” and aims to regulate these activities without hampering economic or technological development. This chapter also addresses debates about the “securitization” of health. Calling a
pandemic a security threat can draw attention and resources to it, but may also distort the response by treating it as a short-term emergency rather than long-term capacity-building enterprise.

Chapters one through eight refer to many of the international institutions that play a role in implementing pandemic law. Chapters nine and ten offer a more focused look at the most important of those institutions. Chapter nine provides detail about the mandate, role and practices of the World Health Organization and World Bank. Picking up on the “securitization of health” theme, it also considers the role of the UN Security Council (SC). The SC has on three occasions declared pandemics to be a threat to international peace and security, although its record of action in addressing the pandemics is mixed. Chapter ten is about public-private partnerships, or what may be called global public policy networks. These are trisectoral alliances among governments, intergovernmental organizations, and non-governmental actors – both for profit and not-for profit. The GAVI Alliance is widely seen as a successful example. The chapter also describes the Coalition for Epidemic Preparedness Innovation (CEPI), COVAX (the mechanism established to ensure equitable distribution of the COVID vaccines), and the Global Health Security Agenda. This chapter is a fitting conclusion to the primer because these networks may be important components of the future of global health governance.

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1 International Epidemiology Association dictionary.
2 IHR, Article 1, Definitions.
3 World Health Organization, “Special Session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response”. A74/A/CONF./7 (25 May 2021).
International Health Regulations

Introduction

The World Health Assembly is empowered by Article 21(a) and Article 22 of the World Health Organization (WHO) Constitution to adopt regulations “... designed to prevent the international spread of disease.” After such regulations are adopted, they become binding on all WHO Members, unless the members specifically opt out within a specified time period. The WHO’s revised International Health Regulations (IHR), which came into force in 2007, is the most important international legal framework governing infectious disease control.

The IHR is a multinational agreement, legally binding on 196 States Parties, including 194 WHO Member States, along with two non-member states: the Holy See and Liechtenstein. The IHR defines countries’ rights and obligations in handling public health emergencies that have the potential to cross borders. The regulations are meant to prevent, protect against, control, and provide a public health response to the international spread of diseases in ways that are proportionate and limited to public health risks, without unduly interfering with international traffic and trade.

History of the International Health Regulations

The International Sanitary Conference, held in 1851, marked the beginning of international health cooperation. The conference’s main objective was to standardize maritime quarantine regulations of different European nations for combating cholera. It ultimately led to a binding agreement in 1892, the International Sanitary Convention (ISC). Between 1851 and 1903, four conventions were adopted and eventually consolidated into a single International Sanitary Convention in 1903. By 1926, the ISC covered cholera, plague, yellow fever, typhus, and smallpox.

Meanwhile, there were coordinated political efforts to establish a permanent international health agency, which resulted in the Rome Agreement of 1907, along with the establishment of the Office International d’Hygiène Publique in Paris. When the Constitution of the WHO came into force in 1948, the WHO inherited the functions of its predecessors, becoming the focal international health agency. WHO Member States replaced the ISC with the International Sanitary Regulations in 1951 and later revised them to International Health Regulations in 1969.

Revisions to the International Health Regulations

The emergence of new infectious agents and proliferation of endemic diseases in the 1980s and 1990s led the World Health Assembly to call for revision of the IHR in 1995. In the subsequent ten years, the IHR underwent a series of minor revisions. The 2003 SARS
outbreak exposed the inability of the international community to deal with emerging infectious diseases, which prompted a major rethinking of the IHR. One of the major identified weaknesses was that the IHR applied to only cholera, plague, and yellow fever. Since SARS was not covered, China severely delayed its alert to the WHO. The 2005 revision addressed this and other deficiencies, such as states employing excessive measures that negatively affected global trade and travel.5

The 2005 IHR marked a dramatic change from previous versions. There was a shift from the passive approach of relying on a list of diseases to a dynamic and open-ended approach, where diseases are more broadly defined.6 Accordingly, under the expanded scope, the IHR now covers diseases “irrespective of origin or source,” including events that may be biological, chemical, and radio-nuclear in origin, and regardless of whether the infectious disease or its source is known or unknown. Compliance under the revised IHR is premised on the good faith and cooperation of States Parties, instead of imposing rigid measures on them. Also seeking assistance and international cooperation from States Parties and the WHO in building national public health capacities is encouraged.7 The WHO further assumes a central role in surveillance, risk assessment, and fashioning effective and proportional responses to public health crises.8
The Roles, Responsibilities, and Obligations of States Parties

The revised 2005 IHR imposes two key obligations on States Parties: to notify the WHO of an outbreak that may spread across borders, and to build the capacity to detect and respond to such an outbreak.

Information Sharing Obligations

Under Article 6, States Parties have an obligation to notify the WHO of events which may constitute a public health emergency of international concern (PHEIC), as per their assessment using the decision instrument in Annex 2.

Part II of the IHR imposes capacity-building requirements on States Parties, which are related to information sharing—such as surveillance. States Parties are expected to establish national IHR Focal Points (NFPs) for routine information sharing, coordination during health crises, and facilitation of communication between states and the WHO. After receiving and assessing notifications from State Parties, the WHO can request more information from NFPs. Additionally, the WHO can seek more information from non-state sources, which helps it to expand beyond singular reliance on States Parties. The parties to the IHR also have an ongoing obligation to inform and respond to requests regarding verification of information concerning such events.

Developing National Core Capacities

The IHR requires countries to develop core capacities, as delineated in Annex 1, for detecting, assessing, notifying, and reporting public health risks and PHEICs. The IHR also obliges states to build capacities for prompt and effective response, and to control and contain diseases at points of entry. The WHO Secretariat has developed the IHR State Party Self-Assessment Annual Reporting (SPAR) tool as a means to assess the implementation of these regulations. Although core capacity requirements are legally binding in the absence of reservations made by a State, the WHO granted extensions to States for meeting the requirements. Those extensions ended in 2016 but many States Parties are still not in full compliance. According to the SPAR tool, Europe scored 75 percent across all criteria, with the Americas scoring 71 percent. Yet despite having made substantial progress in building core capacity, many developed States fell short in their response to COVID-19.
The Roles, Responsibilities, and Obligations of the WHO

Declaration of a Public Health Emergency of International Concern

For a public health event to be classified as a PHEIC, it must have significance and impact for global public health. Since the IHR came into force in 2007, six PHEIC have been declared due to: the H1N1 pandemic influenza in 2009; polio in 2014; Ebola in West Africa in 2014; Ebola in the Democratic Republic of the Congo in 2019; the Zika virus and its possible association with microcephaly and Guillain-Barré syndrome in 2016; and COVID-19 in January 2020. Interestingly, in 2014, at the time of the Ebola epidemic, West Africa officially notified the WHO within three months of its first case. However, the WHO delayed in categorizing it as a PHEIC.

A PHEIC is defined as an extraordinary event, which is determined “(i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response” (emphasis added).

According to Article 12, only the Director-General has the power to determine whether an event is a PHEIC after considering the information provided by States Parties, an expert group called the Emergency Committee, and the Annex 2 decision instrument. The Director-General is required to review scientific principles and then assess the risk to health, spread of disease, and possible interference with international trade and traffic. The WHO also has the authority to independently gather surveillance data on potential PHEICs. A PHEIC automatically expires after three months, unless extended or terminated early. Once a PHEIC is declared, the Director-General, in consultation with the EC, makes temporary recommendations on health measures States Parties should implement. The EC process has been criticized for lack of transparency, considering it does not share its deliberations and reasons for coming to a particular decision.

Recommendations under the IHR

The IHR provides two types of recommendations in furthering its purpose and scope: temporary recommendations and standing recommendations. Temporary recommendations, which are time-limited and risk-specific, are released by the WHO to inform states about the most appropriate way to respond to a PHEIC. For routine and periodic application of health measures for specific, ongoing public health risks, the WHO may also issue standing recommendations. The criteria for issuing temporary or standing recommendations and specific examples of these recommendations are also provided in the IHR. The Director-General offers the recommendations for the purpose of providing public health guidance and to counteract unnecessary restrictions on travel and trade. Because such recommendations are non-binding, the weight they carry depends on the expertise and normative authority that resides in the WHO.
The WHO Secretariat also produces guidance documents and practical tools that are aimed at supporting the States Parties in fulfilling relevant obligations under the IHR. The guidance document for the use of Annex 2 of the IHR is mainly directed towards NFPs and other entities responsible for assessing the need to notify the WHO of public health events under the IHR. While the use of Annex 2 itself is legally binding, the procedures described in the guidance documents that are designed to support members in using Annex 2 are not binding.

**Intersection between IHR and Other Areas of Law**

**The IHR and Human Rights law**

The IHR specifically states that implementation measures must respect the dignity, human rights, and fundamental freedoms of persons and travelers, and must be applied in a non-discriminatory manner. The United Nations Charter and the WHO Constitution guide implementation of the IHR. States Parties are also obligated to take into consideration the gender and sociocultural concerns of travelers when implementing health measures.

Under the IHR, imposition of additional national health measures by States Parties (beyond those recommended by the WHO) must be based on a scientific risk assessment and must not be more restrictive of international traffic and not more invasive to individuals than existing options for achieving the desired level of protection. These principles also apply when the WHO Director-General is issuing, modifying, or terminating recommendations. Principles of informed consent and the right to privacy are also included in the IHR, requiring States Parties to obtain prior express informed consent of travelers before applying health measures, and to ensure individual privacy and confidentiality when processing personally identifiable information. Human rights and related legal frameworks are discussed in more detail in chapters four and five.

**The IHR and Trade Law**

Under the World Trade Organization (WTO), the relevant legal regime for health-related trade restrictions is the Agreement on Sanitary and Phytosanitary Measures. It allows for the imposition of measures on States Parties of varying intensity, ranging from tariffs to complete import bans. The WTO usually shows deference to other organizations on matters relating to scientific evidence. Since, to date, the WHO has never recommended any trade restrictions for combating a public health risk under Article 18(2) of the IHR, any conflict between the two organizations remains a theoretical possibility. More information on trade law can be found in chapter six.
Compliance with the IHR

State Compliance with IHR Obligations

Balancing states’ sovereign rights with their shared commitment to prevent the international spread of diseases forms the essence of the IHR. While there are no enforcement mechanisms or formal penalties for failing to meet reporting obligations, non-compliance can lead to several consequences, such as a tarnished international image, increased mortality rate, economic and social disruption, and public outrage. A recent case of possible non-compliance is China’s delay in notifying the WHO about the COVID-19 outbreak—a breach of the obligation under Article 6 of the IHR to notify the WHO of an outbreak that could spread across borders within 24 hours. In 2019, Tanzania also withheld information regarding the suspected re-emergence of Ebola cases.

Dispute Settlement Mechanisms

The dispute settlement mechanisms available under the IHR are provided in Article 56. They include negotiation, mediation, and conciliation. Disputes may also be referred to the Director-General of the WHO or settled by arbitration with the consent of all parties to the dispute. To date, the dispute settlement provisions have never been invoked. There are several possible reasons for this, including the absence of a defined timeline when opting to resolve disputes peacefully and the reluctance by States Parties to submit disputes to third-party adjudication. In any event, an arbitration conducted under the IHR must be in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes Between Two States. These rules have an additional consent requirement which could potentially deter states from utilizing arbitration.

Future of the IHR

A comprehensive review of the IHR and the behavior of States Parties in the notification process for PHEICs indicates that the IHR lacks adequate accountability mechanisms for compliance, enforcement, oversight, and transparency. After the COVID-19 outbreak in 2020, the 73rd World Health Assembly convened a review committee under the IHR to assess the functioning of the IHR during the COVID-19 response as well as the implementation of relevant recommendations from previous IHR reviews. The Committee’s findings focus on roles and responsibilities of the WHO Secretariat and States Parties, the lack of a stand-alone mechanism for monitoring and evaluating the general compliance by States Parties (beyond core capacities compliance), and the rigid binary nature of declaring a PHEIC. In order to have a robust mechanism for the next pandemic, there is consensus amongst States Parties and experts that several provisions of the IHR need to be amended. The committee further suggested a universal peer review mechanism to enhance the legal credibility of these regulations. The committee’s final report, presented in May 2021, comprises all findings, recommendations, and next steps – including the recommendation to adopt a “pandemic treaty”, negotiations on which are to begin in November 2021.
Further Reading

   - In this FAQ, the WHO summarizes salient features of the IHR.

   - This article focuses on new developments brought about by the 2005 IHR.

   - This article analyzes the manner in which the criteria to declare a PHEIC were interpreted in respect to COVID-19.

   - This article analyzes the strengths and weaknesses of the international health regulations.

   - This paper analyzes the legal architecture of the ‘core capacity building’ obligation of States.

   - This article critically analyses the performance of the IHR since 2005 and suggests detailed reforms.

   - This article analyses the implementation of the 2005 IHR, its limitations exposed by COVID-19, and suggests critical reforms in the global health law.

   - This article examines the role played by the emergency committee and criticisms surrounding its functioning.
   • This two-part article lays out the obligations of States under the IHR and compliance measures available to the WHO in the context of COVID-19.

   • This paper evaluates the IHR under other regimes of international law, such as human rights, trade law, peace and security law, and the law of development finance.

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5. World Health Assembly, Severe Acute Respiratory Syndrome (SARS), WHA56.29 (May 28, 2003); World Health Assembly, Revision of the International Health Regulations, WHA56.28 (May 28, 2003).
6. See IHR, art. 1.
7. IHR, art. 44.
12. IHR, art. 1.
14. IHR, arts. 17, 18.
17. IHR, arts. 31, 32, 42.
18. IHR, arts. 43.1, 43.2.
19. IHR, art. 17.
20. IHR, arts. 23.2, 31.2, 45.
CHAPTER TWO

State Responsibility: Attribution and Existence of a Breach

Introduction

The action or inaction of States in response to a pandemic may implicate international legal obligations.\(^1\) For example, States may have failed to comply with reporting requirements under international health law. Likewise, measures such as travel restrictions and quarantine specifications may implicate international human rights law principles such as freedom of movement. Similarly, trade practices and foreign investment may be stymied, causing investors to invoke fair and equitable treatment for investors, requirements that arise under international investment law.

While there have been numerous pandemics throughout history, this remains a novel topic and a seldom discussed issue in the law of State responsibility. This chapter is an introduction to State responsibility in relation to pandemics. It specifically addresses State responsibility pertaining to acts or omissions that constitute breaches of international law which, either directly or indirectly, are relevant to pandemics.

What Law Governs?

State responsibility is the principal form of responsibility in international law, as international legal obligations are more commonly imposed on States.\(^2\) Therefore, understanding this body of law is fundamental to understanding the chapters that follow.

State responsibility is governed by rules of customary international law.\(^3\) The customary international law rules on State responsibility are secondary rules, meaning they do not describe the substantive content of international obligations or elements of the underlying wrongful conduct. They only describe the conditions in which a State can be considered responsible for wrongful conduct and face subsequent legal consequences.

The rules of customary international law on State responsibility are default rules; they apply in a residual manner in the absence of the application of more specific rules. For example, there are rules of law governing specific subject matter in relation to pandemics, such as the International Health Regulations (IHR), which contain specific rules of State responsibility. Certain treaty regimes may have their own principles of State responsibility as well. Where there are conflicting rules between the specific subject matter and the customary international law rules on State responsibility, the “special rules of international law” will supersede, constituting a *lex specialis*.\(^4\) The customary international law rules of State responsibility will apply absent an applicable specific rule.
The customary international law rules on State responsibility are largely reflected in the International Law Commission’s Articles on Responsibility of States for Internationally Wrongful Acts. The Articles on Responsibility of States for Internationally Wrongful Acts [hereinafter “ILC Articles on Responsibility”] were adopted by the International Law Commission of the United Nations in 2001. The ILC Articles on Responsibility are mainly considered a codification of customary international law on State responsibility. The ILC Articles on Responsibility have been cited by the International Court of Justice.

**State Obligations**

States have obligations arising from a variety of sources, such as treaty law and customary international law. States are responsible for breaches of their obligations. Obligations may be classified as negative or positive. Positive obligations are those that require action from the State. For example, States have an obligation to report disease transmission to the World Health Organization under the IHR (see chapter two). Other examples of positive obligations include measures to protect the health of citizens or enforce sanctions. Negative obligations are those that require the State to not take action. For example, States have a duty to not infringe on the privacy of individuals or limit an individual’s freedom of movement.

There are circumstances that preclude responsibility for breaches of both positive and negative obligations, particularly during an emergency. These will be discussed in chapter four.

**Standing for Pandemic Related Interests**

‘Standing’ is the entitlement of a party (such as a State) to invoke the responsibility of a wrongdoing State. “Standing (locus standi) is defined as ‘the requirement that a State seeking to enforce the law establishes a sufficient link between itself and the legal rule that forms the subject matter of the enforcement action.’ That sufficient link is the existence of an interest in the matter.” The interest must be a legal interest.

In a pandemic context, it may be challenging for States to establish a sufficient link between its pandemic-related injury and another State’s international obligation and breach of the obligation due to numerous causation and factual issues. However, States may be able to demonstrate standing through *erga omnes* obligations (owed to the community of States) or *erga omnes partes* obligations (owed to a group of states), as evidenced in Article 33 of the ILC Articles on Responsibility. *Erga omnes* obligations are considered obligations owed to all States because of a universal interest in preventing the breach of particularly fundamental rights. As a result, any State may invoke an obligation to allege a breach of the fundamental right, and then obtain standing to bring a claim.

**Internationally Wrongful Acts by a State**

A State’s conduct constitutes an internationally wrongful act when its action or inaction is attributable to the State and constitutes a breach of the State’s obligations.
Actions and Omissions

A State’s conduct can consist of either actions or omissions. An action may include taking affirmative steps to restrict citizens’ freedom of movement. An omission is a failure to act or inaction by the State in a circumstance where the State was obligated to act. For example, “In the United States Diplomatic and Consular Staff in Tehran case, the Court concluded that the responsibility of the Islamic Republic of Iran was entailed by the ‘inaction’ of its authorities ‘to take appropriate steps’, in circumstances where such steps were evidently called for.” Both actions and omissions can constitute conduct that results in a breach of international obligations.

Attribution

Actions or omissions must be attributable to the State in question in order to constitute an internationally wrongful act.

Conduct of the organs of a State (Art. 4) such as governmental agencies, legislature, or judiciary, will be considered conduct of the State. The conduct of organs of the State will be pertinent for establishing an internationally wrongful act in the context of a pandemic as State executive and legislative action will likely lead the pandemic responses. The conduct of persons with governmental authority will constitute conduct of the State as well (Art. 5). Persons with governmental authority could include private companies who have been empowered by law to carry out a public function on behalf of the government. The conduct of individuals who are empowered to exercise governmental authority is relevant during a pandemic as States may authorize non-governmental organizations or companies, and therefore their agents, to carry out the State pandemic response. Conduct directed by a State, if the person or group of persons is acting under the “instructions of, or under the direction or control of” the State, is attributable to the State (Art. 8).

Breach

In order to establish an internationally wrongful act, the conduct (either action or omission) of the State must constitute a breach of an international obligation. ILC Articles on Responsibility, Art. 12, states, “[t]here is a breach of an international obligation by a State when an act of that State is not in conformity with what is required of it by that obligation, regardless of its origin or character.” The State must be bound by the obligation at the time of the alleged breach (Art. 13). The breach occurs at the time
when the act that is not in accordance with international obligations is undertaken. The breach continues during the entirety of the time that the State is not in conformity with its obligation (Art. 14).

**Causation**

To establish an internationally wrongful act, there must be a causal link between the injury and breach. The injury must be “caused by the internationally wrongful act” (Art. 31). Moreover, the injury must result from the wrongful act, “rather than any and all consequences flowing from an internationally wrongful act” (Art. 31). In a pandemic, the causal link for a breach of international obligations may be difficult to establish due to scientific uncertainty and the inherent complexity of having numerous parties involved.

**Legal Consequences of Breaches**

There are legal consequences for internationally wrongful acts committed by a State (Art. 28). First, the State responsible for the internationally wrongful act must cease that conduct and offer assurances of non-repetition (Art. 30). Second, States found responsible for committing an internationally wrongful act must make full reparation for any injury caused (Art. 31). There are circumstances that preclude wrongfulness by a State, such as distress, necessity, and force majeure. These circumstances will be discussed in detail in chapter four.

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**Article 30**

*Cessation and non-repetition*

The State responsible for the internationally wrongful act is under an obligation:
- (a) to cease that act, if it is continuing;
- (b) to offer appropriate assurances and guarantees of non-repetition, if circumstances so require.

**Article 31**

*Reparation*

1. The responsible State is under an obligation to make full reparation for the injury caused by the internationally wrongful act. 2. Injury includes any damage, whether material or moral, caused by the internationally wrongful act of a State.

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*a. Reparation*

There are three forms of reparation available to injured States. Reparation should be assessed in the order of restitution, compensation, and satisfaction.

Restitution is the requirement to “re-establish the situation which existed before the wrongful act was committed,” as long as it is not materially impossible nor involves a disproportionate burden (Art. 35). If a State found responsible for an internationally
wrongful act cannot re-establish the situation which existed prior to the breach, as is likely for events related to a pandemic, then the responsible State will be obligated to provide compensation as reparation.

Compensation “shall cover any financially assessable damage including loss of profits insofar as it is established” (Art. 36). If the injured State cannot be made whole by restitution or compensation, then the responsible State must look to satisfaction as a form of reparation.

Satisfaction may consist of “an acknowledgement of the breach, an expression of regret, a formal apology or another appropriate modality,” as long as satisfaction is proportional to the injury and is not humiliating to the responsible State (Art. 37).

The “contribution to the injury by willful or negligent action or omission of the injured State” will be taken into account in assessing the reparation due to the injured State by the responsible State (Art. 39).

b. Countermeasures

An injured State may take unilateral measures in response to the breach of its rights by the wrongdoing State. These are called countermeasures. An injured State may only take countermeasures “in order to induce that State to comply with its obligations” (Art. 49). Countermeasures may only be taken during the period of non-performance of the wrongdoing State, and the countermeasures should be conducted in a manner to encourage or permit the resumption of the wrongdoing State’s performance of obligations in question (Art. 49). If in conducting a countermeasure, the injured State’s conduct results in a breach of an international obligation (constituting an internationally wrongful act), the wrongfulness is precluded (Art. 22) as long as the countermeasure is enacted with requisite proportionality (Art. 51) and in accordance with procedural requirements (Art. 52).

c. Additional Consequences of Breaches of Peremptory Norms

There are particular consequences for breaches of peremptory norms. A peremptory norm (jus cogens) refers to a generally accepted principle of international law to which no derogation is permitted by a State. If a jus cogens norm is violated, “States shall cooperate to bring to an end through lawful means any serious breach . . . No State shall recognize as lawful a situation created by a serious breach within the meaning of article 40, nor render aid or assistance in maintaining that situation” (Art. 41). If aspects of the pandemic, such as the immense loss of life, are established to be a “gross or systematic” failure of “an obligation arising under a peremptory norm,” then there will be an obligation on other States to cooperate to end the breach.

Conclusion

Understanding the law of State responsibility in the context of pandemics is key to evaluating the legal obligations owed by States and for determining how States may be
held responsible for wrongful conduct. Following chapters in this primer will discuss the primary legal obligations found in international humanitarian law, human rights law, and trade law.

**Further Reading**

   - This article provides a review of the final changes to the text of the ILC Articles on Responsibility with commentaries, adopted in 2001.

   - This backgrounder provides a brief discussion of three areas of international law affected by SARS (i.e., WHO’s International Health Regulations, Civil and Political Rights, and Principles of State Responsibility) and the efforts to contain the spread of disease.

   - This article addresses the question of whether countries have obligations arising under public international law to prevent and contain disease and to help other countries during pandemics. The authors look to other realms of international law, such as human rights law and wartime norms, to examine the existence of obligations, cooperation and enforcement.

   - This resource is the text of the Draft Articles on Responsibility of States for Internationally Wrongful Acts, adopted by the ILC, alongside commentaries, which provide insight into the development of the text and guidance on interpretation of each article.

   - This article investigates the possibility of state responsibility for transnational pandemics, focused primarily on COVID-19. Analysis is focused on assessing whether
rules laid out in international health regulations and the WHO Constitution are binding and whether it is feasible to initiate legal procedures before the International Court of Justice for violations in this realm.

   - This commentary focuses on the issues with existing frameworks of responsibility for epidemic and pandemic diseases. Additionally, it begins to consider how responsibility might be reimagined in relation to epidemic and pandemic diseases.

   - This resolution provides an acknowledgement by the General Assembly of the ILC draft articles on responsibility of States for internationally wrongful acts and the recommendation that it should consider the possibility of convening a conference to examine the articles with a view to development of a convention.

   - This article explores why there is an absence of State practice in pursuing State responsibility for handling of pandemics, and the impact on the framework of relevant international law.

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1. There is a distinction between State responsibility for conduct carried out in response to a pandemic, and State responsibility for a pandemic. “[N]o claim is known to have been made for State responsibility over the “Spanish flu”, HIV/AIDS, Ebola, SARS, H1N1, H1N9, or MERS crises before the onset of the Covid-19 pandemic.” Yee, Sienho. “To Deal with a New Coronavirus Pandemic: Making Sense of the Lack of Any State Practice in Pursuing State Responsibility for Alleged Malfeasances in a Pandemic—Lex Specialis or Lex Generalis at Work?” *Chinese Journal of International Law* 19, no. 2 (June 2020): 237–252 [DOI: https://doi.org/10.1093/chinesejil/jmaa022].


3. Customary international law is established through a pattern and practice of States, motivated by a sense of legal obligation (opinio juris).


5. The International Law Commission (ILC) is a body of the United Nations, tasked with the codification and progressive development of international law. The ILC is comprised of legal experts, scholars, and former judges.

6. The ILC Articles on Responsibility can be found in the Annex of UN General Assembly resolution 56/83 of 12 December 2001.

7. There are a few Articles in the ILC Articles on Responsibility that are not considered customary international law and are considered progressive development.


10. See Case Concerning Barcelona Traction, Light, and Power Co., Ltd (Belgium v. Spain), Judgment, 1970 ICJ 1 (February 5, 1970); Advisory Opinion Concerning Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, 2004 ICJ GL No. 131 (July 9, 2004) (holding that all States have an interest in maintaining erga omnes obligations); Questions relating to the Obligation to Prosecute or Extradite (Belgium v. Senegal), Judgment, 2012 ICJ GL No. 144 (July 20, 2012) (holding that Belgium’s interest in protecting erga omnes parties obligations under the Convention Against Torture constituted standing).
12 ILC Articles on Responsibility, art. 2.
13 ILC Draft Articles on Responsibility with commentary, 35 (Art. 2).
14 ILC Articles on Responsibility, art. 5.
15 ILC Articles on Responsibility, art. 12.
16 ILC Articles on Responsibility, art. 31.
17 ILC Draft Articles on Responsibility, with commentary 92 (Art. 31).
18 ILC Articles on Responsibility, arts. 20-25 (Chapter V).
19 ILC Articles on Responsibility, art. 35.
20 ILC Articles on Responsibility, art. 36.
21 ILC Articles on Responsibility, art. 37.
22 ILC Articles on Responsibility, art. 39.
23 ILC Articles on Responsibility, art. 49.
24 ILC Articles on Responsibility, art. 41.
CHAPTER THREE

State Responsibility: Circumstances Precluding Wrongfulness

Introduction

Chapter two of this primer provides an overview of the law of state responsibility – the situations in which a State will be held responsible for an internationally wrongful act. This chapter covers circumstances precluding wrongfulness (CPW), that is the exceptions to what would otherwise be considered breaches of international law. It synthesizes relevant public international law and legal analysis on the application of CPW in a pandemic, covering: force majeure, necessity, distress, consent, self-defense, and countermeasures.¹

Force Majeure

For an event to be defined as “force majeure” it must be (1) an unforeseen event or irresistible force that is (2) out of the State’s control, in a context in which (3) there is no action the State could take to carry out its obligation under the event. It must also be the case that (4) the State neither caused, nor played any part in the creation of the event. Additionally, the State (5) may not have assumed the risk of said event.² In sum, the State must not have any element of “free choice.”¹

At a high level, many pandemics would appear likely to satisfy all five criteria. Take, for example, the ongoing SARS-CoV-2 pandemic (colloquially COVID-19). Given the novel and infectious nature of the disease, it seems that the event would be considered beyond the State’s control and that it would likely render the discharge of some international obligations materially impossible. However, a closer examination suggests that the defense is more complicated. Each of the five factors is considered below, within the context of a pandemic.

1. Occurrence of an irresistible force or of an unforeseen event: The ILC defines a force as irresistible if there was a “constraint which the State was unable to avoid or oppose by its own means.” In order for an event to be considered unforeseen, the event “must have been neither foreseen nor of an easily foreseeable kind.”⁴

The question is whether a first clear diagnosis would preclude a State from claiming that what followed was unforeseeable. If so, the viability of invoking force majeure would seem to hinge instead on whether what followed was irresistible. That would depend on the mitigation measures available in the pandemic in question.

2. Beyond State Control: Whether a pandemic is beyond a State’s control would depend again on mitigation measures and the information available at the time.
3. **Materially Impossible:** The ILC suggests that both natural and physical events may satisfy the material impossibility criterion. Nevertheless, a State must have involuntarily committed the wrongful act in question. A mere increase in the difficulty of compliance would not be sufficient.

For example, if one State’s aircraft must divert into another State’s territory to avoid an insurrection, such an event would make discharge of the obligation not to do so “materially impossible.” Should a pandemic, like an insurrection, be considered beyond a State’s control? Some scholars have suggested that whether a pandemic could meet this “very high standard” will depend on the obligation.  

4. **Non-contribution:** The State must not have “caused or induced the situation in question.” It is unclear whether varying State responses to a pandemic could then be used to demonstrate that its spread was not beyond a State’s control. If so, States that, for example, preferred looser quarantine policies could be barred from invoking the CPW as a defense against responsibility for the resulting effects of the pandemic.

5. **Assumption of Risk:** If a State has unequivocally assumed a particular risk (whether explicitly or by its conduct), then it is prohibited from “claim[ing] force majeure to avoid responsibility” for any breach arising from the realization of that risk. Such an assumption of risk must have been directed to whomever the obligation was owed. The applicability of this exception to the effects of a pandemic would depend on the circumstances of the obligation and the relevant interactions between the interested States.

**Necessity**

A State may invoke necessity if (1) the act safeguards against a “grave and imminent peril” that threatens an essential interest and (2) “does not seriously impair an essential interest of the State or States towards which the obligation exists, or of the international community as a whole.”  

Also, (3) the act must be the only way for the State to safeguard an essential interest, and (4) the State must not have contributed to the situation. There are also temporal considerations, whereby a State’s invocation of necessity is only available as a defense at the time of the event.

(1) For an act to be of grave and imminent peril, the act must constitute a risk “that an essential interest will be gravely harmed.” While the risk must be present immediately, the ‘harm’ can be a past, ongoing, or future event. The risk and harm of a pandemic could satisfy this element. Courts have previously determined that the continued functioning of a State’s public service and “the well-being of a State’s population” qualify as essential interests.

(2) and (3) The act must be the only way for the State to safeguard an essential interest and must not seriously impair the essential interest of another State or of the international community. Whether there is a threat to another State’s essential interest would need to be evaluated on a case-by-case basis, and would depend on the obligation at stake. Whether the action taken was the only way to avoid the State’s safeguard of its essential interest will depend on the range of responses available to it.
(4) In evaluating whether a State is precluded from invoking necessity by its own contribution, the State must have made a “sufficiently substantial” contribution to the situation.13 Whether a State’s actions preceding a pandemic would qualify as “sufficiently substantial” is subject to interpretation based on the obligation in question.

In any event, imposition of such policies, however temporary, should be subject to scrutiny and not given the blanket reprieve of necessity.14

Distress

Article 24 of the ILC Articles on Responsibility of States for Internationally Wrongful Acts addresses distress, explaining, “the wrongfulness of an act of a State not in conformity with an international obligation of that State is precluded if the author of the act in question has no other reasonable way, in a situation of distress, of saving the author’s life or the lives of other persons entrusted to the author’s care.”15

In order to prove distress (1) a State must verify there is a threat to life, (2) a special relationship between the State and persons in question must be established, (3) there must be no other reasonable way for a State to deal with the threat, (4) it must be proven that the State itself did not contribute to the situation, and (5) measures taken by the State must be deemed proportionate.16

1. Threat to life: It can reasonably be assumed that pandemics are such a threat. International organizations, such as the WHO, explicitly declare whether a pandemic constitutes a threat to life.17 Yet, when there is real and imminent danger that is non-life-threatening, distress cannot be invoked.18

2. Special relationship: A special relationship would ordinarily be closer than that between a State and its citizens, however it might be established on that scale if the central government is the only authority with the ability to put in place containment, mitigation, or quarantine measures.19

3. No other reasonable way for a State to deal with the threat: The WHO recommendations may be considered as evidence of the State’s rationale and decision-making process at the time of action. When assessing actions during a pandemic, it is imperative to avoid hindsight bias.

4. Non-contribution: This may be scrutinized in the same way as force majeure, with the distinction that priority should be given to necessary life-saving measures.

5. Proportionate measures: Proportionality means a State’s acts are a “rational and reasonable exercise of means towards achieving a permissible goal, without unduly encroaching on protected rights of either the individual or another State.”20 The scope and threat of a pandemic are such that many related actions would likely be considered proportionate.

Additionally, if the act in question is likely to cause a comparable or greater danger than the one that is meant to be avoided, distress cannot be invoked.21
Consent

It is unlikely that pandemics themselves would directly implicate consent. For consent to be implicated, the State must have “valid consent” by another State that justifies the asking State’s act under the specific terms. Importantly, consent must be given in advance or during the event. Consent would ordinarily be narrow and would not allow violation of the international obligation, writ large.\(^{22}\)

Self-defense

Article 21 of the Articles on Responsibility of States for Internationally Wrongful Acts references self-defense as follows: “The wrongfulness of an act of a State is precluded if the act constitutes a lawful measure of self-defense taken in conformity with the Charter of the United Nations.”\(^{23}\) As a general principle, admitting self-defense as an exception to the prohibition against the use of force is undisputed.\(^{24}\)

Pandemics are unlikely to implicate self-defense. Implication is only possible if a pandemic, or its spread, is attributed to another State in a way that would amount to an armed attack. In this case, the act of self-defense must be necessary and proportionate in the pursuit of legitimate military objectives.

Countermeasures

A countermeasure is a unilateral act adopted by one State (State A) in response to a subjective qualification of another State’s (State B) prior act being illegal. State A’s response would be considered illegal if not for the prior wrongful act committed by State B.\(^{25}\) It should be noted that sanctions, which an organization may be allowed to adopt, are lawful measures and cannot be considered countermeasures.\(^{26}\) The lawful means in which a State may execute countermeasures is discussed in further detail in the chapter two on State Responsibility.

Conclusion

Pandemics are not only a worst-case scenario in the realm of infectious diseases, but they also pose nuanced challenges for international law. Force majeure, necessity, and distress are likely to be implicated during a pandemic, although each CPW and its application to any particular act would need to be assessed on its own merits in each pandemic. Consent and self-defense are unlikely to be implicated directly by a pandemic, although either could occur during a pandemic.

The subsequent chapters will address human rights law, trade law, humanitarian law, and the role of international institutions during pandemics. While the circumstances precluding wrongfulness are only relevant at the State level, many of the other chapters will also cover protection of individuals.
Further Reading

   - This piece assesses how the circumstances precluding wrongfulness cope with situations in which multiple States or International Organizations try to rely on the circumstances in order to exonerate themselves for prima facie wrongful conduct.


   - Paddeu’s two-part blog post looks at the relevance of the circumstances precluding wrongfulness in the context of the COVID-19 pandemic.

   - Paparinskis evaluates the impact of COVID-19 on international law, offering his own insights as well as a critical assessment of other international legal scholars, including Paddeu.

   - Though the title references only private international law, the piece offers worthy insight into the history of force majeure in international law and its relevant application to the COVID-19 pandemic. This is a useful primer for understanding force majeure’s applicability to pandemics more broadly.


2 The situation of force majeure is due, either alone or in combination with other factors, to the conduct of the State invoking it; or the State has assumed the risk of that situation occurring.

3 ILC, Draft articles on the responsibility of International Organizations, with commentaries, Yearbook of the International Law Commission, 2011, vol. II, Part Two, 68. [hereinafter “ILC Draft Articles on Responsibility of IOs”]. The Draft Articles on Responsibility of IOs are not applicable to states, but many of the principles are similar and so the commentary to those Articles is illuminating.


5 ILC Draft Articles on Responsibility of IOs, 72-73.


7 ILC Draft Articles on Responsibility, with commentaries, 78.

8 ILC Draft Articles on Responsibility, with commentaries, 80.


10 Paddeu, “Part II.”
11 Paddeu, “Part II.”
12 ILC Draft Articles on Responsibility of IOs, 74.
13 ILC Draft Articles on Responsibility, with commentaries, 84.
14 ILC Draft Articles on Responsibility, with commentaries, 84.
15 ILC Articles on Responsibility”, art. 24.
16 Paddeu, “Part II.”
19 Oxford Public International Law, “Distress.”
21 ILC Draft Articles on Responsibility of IOs, 73-74.
22 ILC Draft Articles on Responsibility, with commentaries, 72-74.
23 ILC Articles on Responsibility, art. 21.
24 ILC Draft Articles on Responsibility, with commentaries, 74.
25 ILC Draft Articles on Responsibility, with commentaries, 75-76.
26 ILC Draft Articles on Responsibility of IOs, 72.
CHAPTER FOUR

Human Rights: Right to Life, Right to Health, and Associated Rights

Introduction
State pandemic responses implicate some of the most fundamental legal protections under international human rights law, such as the non-derogable right to life and the right to health, free from discrimination. Public health crises and the ways in which States respond also inherently involve other economic, social, and political rights. International human rights law imposes on States the obligation to protect these rights, while international and regional human rights conventions and treaties bestow the rights on individuals themselves. Not only do states have a negative obligation to prevent any violation of these fundamental rights, but they also have a positive obligation to protect them. This chapter explores States’ obligations to protect human rights, including the rights to life and health, when the international community is confronted by global pandemics like COVID-19.

State Obligations under International Human Rights Law
States have both positive and negative obligations that arise from treaties and customary international law. Positive obligations require proactive measures by a State, while negative obligations require a State not to take certain actions. States are obliged to actively protect and not to infringe upon the right to life and the right to health, though more specific State obligations differ in scope depending on the treaty from which the obligation arises.

Under the International Covenant on Civil and Political Rights (ICCPR), for example, States have a responsibility “to respect and to ensure...the rights recognized” in the Covenant. To comply with the ICCPR, therefore, States are expected to immediately apply the positive obligation to respect and recognize the enumerated civil and political rights. The Human Rights Committee holds States to a “due diligence” standard for the positive obligation to ensure rights. Under the International Covenant on Economic, Social, and Cultural Rights (ICESCR), States are required to take steps to their greatest ability to achieve “progressive realization” of the right to health, meaning that “States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12.” While States progressively work toward realization of these rights, the Convention also requires immediate action to eliminate discrimination and meet minimum core measures. Therefore, States have at minimum a negative obligation not to impede peoples’ right to health. Although the Committee on Economic, Social and Cultural Rights (CESCR) provides guidance on how to measure a State’s fulfilment of the “best efforts” standard, the ICESCR is inherently more flexible than the ICCPR, given the somewhat subjective nature of this threshold.
State obligations to protect the right to health and right to life manifest in a variety of ways during a pandemic. For instance, according to CESCR General Comment No. 14, during a pandemic States must establish urgent medical care systems and mobilize health care resources. At a minimum, States have a negative obligation not to prevent individuals’ access to health care. States also have a positive obligation to protect the right to life of detained or incarcerated individuals and provide them with necessary medical care – an obligation that many would argue has been neglected by a number of States.

In certain circumstances there can be exceptions to both positive and negative obligations. For instance, a State’s positive obligation to protect the right to health might also require the State to restrict peoples’ movement. The analysis of when and whether such restrictions are lawful will be discussed in chapter five.

The Right to Life

The right to life is arguably the most fundamental principle of international human rights law. The Universal Declaration of Human Rights (UDHR), though non-binding, states that “everyone has the right to life, liberty, and security of person.” The ICCPR outlines in Article 6 that “every human being has the inherent right to life,” protected by law, and free from arbitrary deprivation. Regional treaties — including the American Convention on Human Rights, the European Convention on Human Rights, and the African Charter on Human and Peoples’ Rights — also recognize the fundamental right to life.

The right to life is non-derogable, according to the ICCPR, meaning it cannot be suspended under any circumstance. States have a positive obligation to protect peoples’ right to life, and a duty not to violate it. The Human Rights Committee states in General Comment No. 36, that the right to life should be “narrowly interpreted,” and calls on States to take positive measures to protect the right to life, including against “life-threatening diseases.” According to legal scholars, General Comment No. 36 articulates a “due diligence obligation” for States, that “could be read as including protecting individuals from threats to life posed by others carrying an infectious and deadly disease, such as COVID-19.”
**The Right to Health**

The right to health and access to care is laid out in several international conventions and declarations. “Health is a fundamental human right indispensable for the exercise of other human rights,” opens CESCR General Comment No. 14, elaborating that, “the right to health includes certain components which are legally enforceable.” According to the CESCR, States Parties are held to three levels of obligations: to respect, protect, and fulfill, with “a strong presumption that retrogressive measures taken in relation to the right to health are not permissible.” Additionally, General Comment No. 14 more broadly lays out four fundamental elements of the right to health: availability, accessibility, acceptability, and quality of health care and facilities.

The World Health Organization (WHO) Constitution declares that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.” The ICESCR stipulates in Article 12 that States must “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” With 196 Parties to the WHO Constitution and 170 States Parties to the ICESCR, these are widely accepted international norms. Article 25 of the UDHR also specifies that “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family.” Regional human rights instruments including the American Declaration of the Rights and Duties of Man, the African Charter on Human and Peoples’ Rights, and case law surrounding the European Convention on Human Rights all contribute to the concept of individual rights to physical health under international law.

Additional rights and obligations are outlined specifically in regard to pandemics. Article 12 of the ICESCR requires that States Parties take necessary positive steps towards the “prevention, treatment, and control of epidemic, endemic, occupational, and other diseases.” The CESCR’s General Comment No. 14 further qualifies these obligations, requiring of States “the creation of a system of urgent medical care in cases of accidents, epidemics and similar health hazards.” While the CESCR attempts to give guidance, it can be difficult to establish how to judge whether States have put forward their “best effort” to protect these rights. The inherently flexible nature of the ICESCR means that there is uncertainty about how to assess whether a State Party is meeting its best-efforts standard. Especially when facing a novel virus, analyzing whether a State has met this threshold is highly context dependent and fact sensitive.
Protection Against Discrimination

A number of international and regional treaties also provide for the right to physical and mental health without discrimination. The Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), the Convention on the Rights of the Child (CRC), the International Convention on the Elimination of All Forms of Racial Discrimination (CERD), and the Convention on the Rights of Persons with Disabilities (CRPD), among others, obligate States Parties to ensure access to healthcare services without discrimination.

States Parties to these treaties are obligated to ensure that responses to diseases like COVID-19 are equitable and non-discriminatory. UN human rights experts have also specified that “everyone has the right to life-saving interventions” for COVID-19, without exception or discrimination. In April of 2020, the CESCR called on States Parties to uphold their positive obligations to protect their citizens’ right to health, and “make all efforts to mobilize the necessary resources to combat COVID-19 in the most equitable manner.”

Jurisprudence

International human rights bodies have refined the scope of these rights in their jurisprudence. States’ obligations to protect the right to life and the right to health have been the subject of human rights cases, particularly regarding access to health care.

The Human Rights Committee wrote in Toussaint v. Canada that excluding undocumented immigrants from the Canadian federal healthcare program constituted a violation of the right to life. In Cyprus v. Turkey, the European Court of Human Rights (ECtHR) wrote that “an issue may arise under Article 2 of the Convention [for the Protection of Human Rights and Fundamental Freedoms] where it is shown that the authorities of a Contracting State put an individual’s life at risk through the denial of health care which they have undertaken to make available to the population generally,” and found that a State is in fact obligated to take “appropriate steps to safeguard the lives of those within its jurisdiction.” In Stoyanovi v. Bulgaria, the ECtHR interpreted the same Convention’s right to life provision as a positive obligation requiring the State to take preventative measures.

In its advisory opinion on the Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territories, the International Court of Justice (ICJ) found that human rights obligations extend to areas where a State exercises jurisdiction, even if beyond its territory. The opinion also recognized that at minimum, the right to health establishes negative duties for States, and therefore Israel’s erection of a barrier in the West Bank restricting access to health services violated Article 12 of the ICESCR. While not binding, the opinion reinforces the fact that States have both positive and negative obligations surrounding the rights to health and life.

These court opinions could have implications for States’ obligations to provide preventative care for its entire population, including those who are imprisoned, in immigrant detention facilities, and within any area where a State exercises jurisdiction.
Conclusion

UN bodies began issuing statements and guidance in the early days of the COVID-19 pandemic to ensure State compliance with treaty obligations. The UN Office of the High Commissioner for Human Rights (OHCHR) has released pandemic-related guidance on topics ranging from access to health care and housing, to considerations for different populations of people, to privacy concerns, and beyond. “Respect for human rights across the spectrum, including economic, social, cultural, and civil and political rights, will be fundamental to the success of the public health response and recovery from the pandemic,” writes the OHCHR. The OHCHR has also published a toolkit of treaty law assessments and jurisprudence to strengthen UN and State-based responses to COVID-19.

In the course of one year, independent human rights experts who advise the Human Rights Council, called special procedures (SPs), released 144 press releases, 14 guidance documents and reference tools, and 16 official reports calling for equal access to treatments and vaccines globally, and identifying concerns and potential violations. At the time of writing, SPs had also issued 372 letters “related to concerns directly connected to COVID-19 or the measure adopted in the context of the pandemic.” Since March of 2020, human rights treaty bodies have “urged global leaders to ensure that human rights are respected in government measures to tackle the public health threat posed by the COVID-19 pandemic,” issuing human-rights-specific pandemic response recommendations to States. On the extent to which States can limit or derogate from their human rights obligations in a public health emergency, see chapter six of this primer.

International understandings of the ways in which human rights law is implicated in pandemic responses will continue to evolve in the post-COVID-19 era. For instance, human rights bodies will persist in seeking to develop clarification on a State’s obligations to provide accurate information to its citizens, and to provide adequate care and protection to individuals outside of its borders or foreign nationals within its territories. A broad interpretation of State obligations to prevent the spread of disease could also include an obligation not to share disinformation about the virus, or even for States to refrain from economic sanctions that could weaken another State’s ability to care for its population. As vaccinations and other life-saving measures continue to be distributed globally, questions of non-discrimination, equity, and adequate protection of the right to life and right to health will also need to be addressed.

Further Reading

   - This UN policy brief on human rights and COVID-19 was released in April 2020, at the beginning of the global pandemic, and underscores why human rights are so important to pandemic response. Additionally, it reports on the effects of COVID-19 on human rights and protections around the world.
   • The Committee on Economic, Social and Cultural Rights released this statement in April of 2020, reiterating State obligations to protect economic, social, and cultural rights during the pandemic, and offering recommendations to ensure fulfillment and protection of the obligations and rights provided in the Covenant.

   • The Office of the High Commissioner released this COVID-19 guidance on the various ways in which economic, social, cultural, civil, and political human rights are fundamental to public health care and access, and post-pandemic recovery. The guidelines cover privacy, information, housing, the rights and vulnerabilities of specific populations, access to health care, and a variety of other relevant topics.

   • This OHCHR webpage consolidates COVID-19 recommendations, statements, and press releases from different human rights treaty bodies.

   • This toolkit, published by OHCHR, examines treaty law and jurisprudence, and translates them into operable UN and State responses to pandemics.


13 UDHR, art. 25.


15 ICESCR, art. 12.

16 CESCR, General Comment No. 14, art. 12, para. 16.


21 European Court of Human Rights, Cyprus v. Turkey, [GC], no. 25781/94, May 10, 2001, https://hudoc.echr.coe.int/eng#/%(itemid)%22(%%2001-59454%22)).


24 ICJ Wall Advisory Opinion, para. 134.


26 OHCHR Guidance.


CHAPTER FIVE

Human Rights: Permissible Restrictions in Public Health Emergencies

Introduction

The World Health Organization’s declaration of a global pandemic on 11 March 2020 generated a range of reactions by State authorities around the world in attempts to prevent the spread of COVID-19. To combat the public health emergency, some countries implemented preventive measures by declaring a state of emergency (e.g., Estonia, France, Hungary, Georgia, Latvia, Moldova, Romania, and Armenia), while others adopted policies without any such declaration (e.g., United Kingdom, Austria, Ireland, Slovenia, and Turkey). The restrictions placed on the exercise of human rights led international organizations to review these actions and produce advisory documents with recommendations directed at the protection of international human rights.

The objective of this chapter is to describe the international law that applies to the introduction and management of emergency regimes to overcome health crises, such as pandemics, in a manner that respects human rights.

Permissibility of Restricting Rights

Human rights are universal. States have duties to protect and promote human rights in all circumstances, including an obligation to prevent third parties from interfering directly or indirectly with the enjoyment of rights. As a general matter, crises should be handled through normally applicable powers and procedures, in full compliance with human rights law. Hence, full respect for human rights without restriction is the norm. States are also obliged to enact positive measures to ensure the enjoyment of human rights.

Nevertheless, human rights are not absolute. Under several international and regional human rights instruments, including the International Covenant on Civil and Political Rights (ICCPR), states can restrict certain rights through limitations and derogations. The Siracusa Principles provide guidance on the conditions in which restrictions are permissible. Elaborating on the ICCPR, which states that restrictions must be necessary and provided for by law, the non-binding Siracusa principles add the following elements: they must support a legitimate goal, be proportionate, temporary, and subject to review against abusive applications.
Restriction of Human Rights in Regular Situations (Not Rising to a State of Emergency)

In non-emergency situations, human rights restrictions are permitted in individual cases and for public purposes, such as the protection of national security, public order, and public health. The list of grounds for these restrictions in the ICCPR is exhaustive. Moreover, the restriction should not affect the substance of the rights infringed.\(^2\)

Public health is a legitimate ground for limiting the exercise of some rights, such as freedom of movement, freedom of expression, and freedom of peaceful assembly, regardless of whether an emergency exists.\(^3\) According to the Siracusa Principles, if measures “aimed at preventing disease or injury or providing care for the sick and injured” require the restriction of those freedoms, they are permissible.\(^4\) However, the restrictions must be: in accordance with the law; in the interest of a legitimate objective of general interest; necessary in a democratic society; the least intrusive measure available to reach the same objective; and, based on evidence. Limitations cannot be applied in an arbitrary or discriminatory manner.

Restriction of Human Rights in Emergency Situations

Limitation clauses can be invoked to restrict certain human rights during states of emergency that meet specific internationally defined thresholds. In such circumstances, a state may also derogate from certain obligations.\(^5\) Because derogation entails a more general restriction of human rights, it is permissible only in the event of an exceptional public danger when the limitation clauses are not sufficient to cope with the emergency.
Derogating allows states to deviate from obligations and in some cases completely suspend rights, whereas limitation clauses impose restrictions on enjoyment of certain rights.

The conditions for the exercise of derogations during states of emergency are provided for in various legal instruments, including the ICCPR, the European Convention on Human Rights (ECHR), and the American Convention on Human Rights (ACHR). Other human rights treaties either do not include such a provision (e.g., the African Charter on Human and Peoples’ Rights) or do not mention the applicability of the treaty in emergency situations (e.g., the Convention on the Rights of the Child).

Generally, any derogation is limited to the exigencies of the situation and should be implemented only to the extent necessary to achieve the goal. This requirement concerns the duration, territorial area, procedural commitments, and material scope of the state of emergency.⁶

**What Is a State of Emergency?**

An emergency is a situation producing an actual or potential threat to the organized life of the population of the state, whether wholly or partly.⁷ A global pandemic can constitute a state of emergency. Any measures a government takes should aim to restore the state of normalcy by eliminating the cause of the emergency. The exercise of this state power is constrained by substantive and procedural requirements.

**Substantive Criteria**

Under the ICCPR, derogations are permitted in times of exceptional public emergencies, when the very existence of the nation is called into question. Exceptional public emergencies may include armed conflict, natural disasters, a terrorist threat, or a pandemic.⁸ Evidence of the gravity of the situation must be provided by State authorities when declaring a state of emergency. The crisis or danger must be actual or imminent; restrictions cannot be imposed as a precaution based only on fear of potential danger.

According to the Siracusa Principles, two conditions must be met to establish that the existence of a nation is threatened: (1) the threat must affect the entire population of the state and either the whole or part of its territory; and (2) the situation must threaten “the physical integrity of the population, the political independence or the territorial integrity of the State, or the existence or basic functioning of institutions indispensable to ensure and to protect the rights recognized” in the ICCPR.⁹

Additionally, measures undertaken to the “extent strictly required by the situation” must be necessary and essential to address the threat.¹⁰ The Human Rights Committee (HRC) possesses the competence to make an independent determination of whether a specific measure is “strictly required.” Any derogation from human rights shall not be inconsistent with the State’s other obligations under international law, namely international humanitarian law (see chapter eight of this primer).
**Procedural Criteria**

The mere existence of an exceptional situation does not automatically render derogation from human rights obligations permissible. Human rights treaties require states that declare a state of emergency to immediately notify other parties to the treaties (or in the case of the European Convention on Human Rights, the Secretary-General). The requirement to notify serves to inform the people affected, other Member States, and the international community about the derogation. The communication should include the provisions from which the state has derogated and the expected duration. The reporting obligation limits states’ ability to modify the scope of their derogation. A follow-up notification should be provided upon termination of the derogation.\(^\text{11}\)

**State Discretion and Duties**

Although the WHO declared COVID-19 outbreak to be a pandemic, State authorities have the discretion to decide whether to declare an emergency given the circumstances in their own countries. If they do so, they are required to provide a justification for the decision.\(^\text{12}\) International human rights law requires that the proclamation of an emergency regime should be provided for by domestic law, and measures must be both necessary and proportionate to the aim pursued. Legal provisions governing the introduction and administration of a state of emergency should be clear.\(^\text{13}\)

Further, States have a duty to independently determine the necessity of derogation to address the emergency situation.\(^\text{14}\) The principle of proportionality requires that this duty be carried out on a continuous basis; the situation should be reviewed periodically to determine whether a “threat to the life of the nation” and the need for derogation still exist.\(^\text{15}\) The exercise of these powers is subject to international oversight to ensure measures are enacted only for the purpose of safeguarding the public, within the bounds of international law. Such oversight is necessary as grave human rights violations tend to occur under the pretext of states of emergency.

**Non-derogable Rights**

Certain human rights can never be limited or derogated from by States, even in a state of emergency. Peremptory norms of general international law (jus cogens) are excluded from any derogation by the Vienna Convention on the Law of Treaties (Article 53). The ICCPR enumerates a list of non-derogable rights in Article 4(2), including the right to life and prohibitions on torture and slavery. The HRC has added non-discrimination and other rights to that list.\(^\text{16}\) The absolute character of such rights means that it is impermissible to restrict them.

**Derogating from Civil and Political Rights**

During a declared public health emergency, states may impose measures to prevent the spread of disease (e.g., self-confinement, wearing masks, and vaccination). In doing so, it is necessary for States to ensure the restrictions imposed are proportionate, contribute
to the legitimate aims of disease prevention and protection of public health, and do not infringe non-derogable rights. State authorities “may not derogate from their duty to treat all persons ... with humanity and respect for their human dignity and must pay special attention to the adequacy of health conditions and health services.”

**Right to Life and Physical/Bodily Integrity**

The right to life is recognized as a non-derogable right that should not be narrowly interpreted. Its protection is a precondition for the enjoyment of all other rights. The ICCPR prohibits subjection of a person to medical or scientific experimentation without free consent, even in the event of a pandemic. Public health concerns do not justify testing a drug on any person who has not given consent.

In the past, the European Court of Human Rights (ECtHR) held that compulsory vaccination, as an involuntary medical intervention, represents an interference with the right to respect for private life. However, in April 2021, the ECtHR ruled that compulsory vaccinations may be necessary in democratic societies and do not contravene European human rights law.

**Freedom of Movement and Deprivation of Liberty (Quarantine)**

Restrictions on freedom of movement must be provided by law, necessary in a democratic society for the protection of public health and must be consistent with all other rights enshrined in the ICCPR. When possible, States have a duty to attempt to balance between requiring strict physical distancing and the right to move freely. Although movement may be restricted within and between countries during a state of emergency, the right of persons to enter to their own country is protected.

Confinement is a public health measure that might be implemented to manage a public health crisis. Confinement is justified only if there is no less intrusive and restrictive measure available to achieve the same goal. The principle of proportionality requires that confinement be voluntary whenever possible.

Involuntary confinement constitutes a deprivation of liberty. In a such case, the minimum rights for persons deprived of liberty would apply. Imposing involuntary confinement to prevent the spread of an infectious disease could be considered legitimate if public health interests are carefully balanced against the interest of an individual and the applicable measure respects the principle of necessity. Involuntary confinement would be considered arbitrary if it is discriminatory or completely disproportionate to the legitimate aim to be achieved.

**Freedom of Expression and Right to Public Information**

Freedom of expression, including free media, and access to information, are basic elements of a democratic society, allowing individuals to freely form their opinions and to manage their respective actions. Throughout the COVID-19 pandemic, many governments sought to restrict the right of access to information held by public
authorities and the sharing of information online and via other means. These rights may only be subject to restrictions that meet the basic conditions of legality and necessity for protecting public health.\textsuperscript{24} The HRC emphasized that it could never become necessary to derogate from the freedom of opinion during a state of emergency.\textsuperscript{25}

Accessible information is important at all stages of a crisis. While restrictions on the right to information are permissible during both regular and emergency situations, derogation may be allowed during a state of emergency. In March 2020, international experts issued a joint statement concerning access to information in the context of a pandemic, noting “human health depends not only on readily accessible health care. It also depends on access to accurate information about the nature of the threats and the means to protect oneself, one’s family and one’s community. The right to freedom of expression, which includes the right to seek, receive and impart information...may only be subject to narrow restrictions.”\textsuperscript{26}

### Derogating from Social, Economic, and Cultural Rights

The International Covenant on Economic, Social and Cultural Rights (ICESCR) obligates States Parties to protect the public from epidemic diseases. State obligations associated with the rights to food, health, housing, social protection, water and sanitation, education, and an adequate standard of living remain in effect during situations of emergency. For more on the right to health, see chapter four.

The ICESCR contains a general limitation clause (Article 4) but does not provide for derogation. It permits States Parties to subject the rights enshrined in the Covenant “only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare.”\textsuperscript{27}

The European Social Charter (ESC) permits restrictions on any rights for public health purposes and contains a derogation clause (Article F) with language similar to that of the ICCPR. However, no party has ever requested derogation under the ESC, even during the COVID-19 pandemic. Accordingly, the European Committee of Social Rights (ECSR) has expressed the view that states parties do not regard the COVID-19 pandemic “as constituting a public emergency of a nature such as to justify derogations” from basic social rights, despite its gravity and profound impact on their respective countries.\textsuperscript{28}

### Further Reading

   - The book presents a systematic and comprehensive attempt to conceptualize the theory of emergency powers, combining post-September 11 developments with more general theoretical, historical and comparative perspectives.
   - The book provides a comprehensive analysis of International Human Rights Law. A wide selection of materials from primary and secondary sources (legislation, case law, and academic writings) illuminates key themes.

   - This article explores the question of limitations to and derogations from economic, social, and cultural rights. It analyzes Article 4 of the ICESCR (limitations) and its relationship to Article 2(1) of the ICESCR (progressive realization).

   - This book elaborates on international and European human rights law. Drawing on the jurisprudence of the European Court of Human Rights, it analyses the guiding principles that govern the law of the convention, the control procedure, and the legal regime of guaranteed rights.

   - General Comment No. 29 is an interpretive document that provides detailed guidance related to derogation from human rights codified in the International Covenant on Civil and Political Rights.

   - This HRC statement is intended to remind States Parties of the requirements and conditions laid out in article 4 of the ICCPR and further elaborated by the Committee in its general comments, particularly in general comment No. 29 on states of emergency.

   - The Siracusa Principles, developed by a colloquium of experts in international law, provide guidance on the conditions whereby States may permissibly limit and derogate from certain rights during public emergencies.
The UN Human Rights Committee [hereinafter the HRC] emphasized that the limitation clause (ICCPR, Article 4) is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States.


ICCPR, art. 4.

See e.g., UN Human Rights Committee, CCPR General Comment No. 29, Derogations during a State of emergency (Article 4), CCPR/C/21/Rev.1/Add.11, August 30, 2001, para. 4, https://digitallibrary.un.org/record/451555?ln=en. [hereinafter “CCPR General Comment No. 29”].

Subrata Roy Chowdhury, Rule of Law in a State of Emergency (London: Pinter, 1989), 11.

CCPR General Comment No. 29, para. 3.

Siracusa Principles, para. 39.

In the case-law of ECHR (for ex. Irlande v. UK, January 25, 1976) a concrete link between the derogatory measure and the threat must be established.


Siracusa Principles, para. 52.


UN Human Rights Committee, CCPR General comment no. 36, Article 6 (Right to Life), September 3, 2019, CCPR/C/GC/35, paras. 8, 13, 16. [hereinafter “CCPR General Comment No. 36”].


ICCPR, art. 7.

European Court of Human Rights, Vaváčík and others v. the Czech Republic, Applications no. 47621/13, Judgement, April 8, 2021, para. 310.

UN Human Rights Committee, CCPR General Comment No. 27, Article 12 (Freedom of Movement), November 2, 1999, CCPR/C/21/Rev.1/Add.9, para 11.


ICCPR, art. 19

UN Human Rights Committee, CCPR General comment no. 34, Article 19 (Freedoms of opinion and expression), September 12, 2011, CCPR/C/ GC/54, para. 5.


CHAPTER SIX

Trade Law and Intellectual Property Rights

Introduction

The COVID-19 pandemic demonstrated the crucial role of trade in safeguarding the availability and affordability of medical goods, such as medical devices, protective equipment, pharmaceuticals, and other essential products, as no country has been able to sustain a self-reliant supply of these products and services. In an effort to protect their citizens, some States have applied trade-restrictive measures. However, only certain protectionist policies are regarded as legitimate under the General Agreement on Tariffs and Trade (GATT) of the World Trade Organization (WTO). Under the GATT, trade-restrictive measures to protect public health and public welfare must be implemented in a manner that does not discriminate against other WTO Member States and does not constitute a disguised restriction on international trade.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) plays a crucial role in innovation, promotion, and regulation of medical goods and related equipment by governments and stakeholders to tackle a pandemic. For example, the TRIPS Agreement allows compulsory licensing and government use of a patent without the authorization of its owner under a number of conditions aimed at protecting the legitimate interests of the patent holder.

Export Restrictions on Medicines and Medical Products

As a general matter, WTO law limits the freedom of States to impose prohibitions or restrictions on trade. Article XI.1 of the GATT states that “no prohibitions or restrictions... shall be instituted or maintained by any contracting party on the importation of any product...or on the exportation or sale for export of any product.” However, the GATT permits exceptions from the prohibition of trade-restrictive measures under certain circumstances. Article XI.2(a) provides that Article XI.1 shall not extend to “export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other essential products to the exporting contracting party.” Within the context of a pandemic, medicines (e.g., vaccines), other medical products (e.g., personal protective equipment and ventilators), and related services remain essential to the exporting country, and as such, a protectionist measure can be regarded as legitimate.¹
**Broad Exceptions from the Prohibition of Trade-Restrictive Measures**

In addition to the specific exceptions within Article XI, the GATT provides more general exceptions from the prohibition on trade-restrictive measures. Article XX and Article XXIV of the GATT may permit certain export restrictions, as discussed below.

Article XX of the GATT on “General Exceptions” sets out specific exceptions from the GATT rules, provided that such a protective measure is necessary for several alternative reasons. In the context of a pandemic, trade-restrictive measures could fall under paragraph (b) of the Article, which provides exceptions for the protection of “human, animal or plant life or health.” In addition, a trade-restrictive measure must satisfy the requirements of the introductory paragraph (the “chapeau” of Article XX), such that the measure is neither applied in an arbitrary or discriminatory manner nor is “a disguised restriction on international trade.”

In the case of *Brazil – Measures Affecting Imports of Retreaded Tyres*, the WTO Appellate Body examined Brazil’s trade-restrictive measures on retreaded tyres. The Appellate Body concluded that the import ban was justified as “necessary” within Article XX (b), acknowledging that none of the less trade-restrictive alternatives suggested by the European Communities constituted “reasonably available” alternatives to the import ban. The Appellate body, however, concluded that the “MERCOSUR exemption” would lead to “unjustifiable discrimination” and a “disguised restriction on international trade,” because of the manner in which the import ban was applied, within the meaning of the chapeau of Article XX.

The second exception is Article XXIV on “Territorial Application, Frontier Traffic, Customs Unions (CUs) and Free-trade Areas (FTAs).” Member States can establish either a CU, an FTA, or an interim agreement. A CU is understood to be the substitution of a single customs territory for two or more customs territories. In a CU, duties and other restrictive regulations of commerce are eliminated for substantially all trade between the constituent parties to the union. The duties and other regulations of commerce imposed at the inception of such a CU on non-party states shall not be higher or more restrictive than the duties and regulations of commerce prior to the formation of the CU.

An FTA is a group of two or more customs territories in which the duties and other restrictive regulations of commerce are removed on all trade between the constituent parties. The duties and other regulations of commerce applied at the formation of such an FTA to non-contracting parties shall not be higher or more restrictive than the corresponding duties and other regulations of commerce prior to the formation of the FTA.

The question arises as to whether it is permissible for WTO Member States to take discriminatory measures in favor of a CU or an FTA in order to form a CU or FTA. In the case of *Turkey – Restrictions on Imports of Textile and Clothing Products*, the WTO Appellate Body concluded that Turkey’s measures on quantitative restrictions, imposed on imports of textiles and clothing products from India because of its CU with the European Community, were not justified under Article XXIV. The judgement stated...
that Turkey should have taken alternative available measures, other than adapting the quantitative restrictions, which would have met the Article XXIV.8(a) requirements that were necessary to form a CU. The Appellate Body noted that for a trade-discriminatory measure in favor of a CU or an FTA to be justified under Article XXIV, two conditions should be met: (i) whether a CU, as defined in Article XXIV.8, exists; and (ii) whether the formation of a CU would be prevented without the inconsistent measure. Since the definition of a CU or FTA does not require exclusion from export restrictions, it does not appear that their formation would be prevented by the application of GATT prohibitions on export restrictions.

**TRIPS Flexibilities for Vaccines**

The TRIPS Agreement sets international standards regarding intellectual property rights (IPRs) under the WTO legal system. IPRs are especially relevant for the trade of pharmaceutical products (such as vaccines) because of the knowledge-intensive nature of production and the desire of producers to recover research expenses by patenting the products.

This section first reviews the minimum standards for IPRs protection required by TRIPS, then summarizes the so-called TRIPS “flexibilities.” These flexibilities allow countries to balance IPRs protection and other national concerns, including the promotion of public health.
(a) TRIPS Standards for IPR Protection

TRIPS Article 27 requires Member States to make patent rights available for “any inventions” in all fields of technology. Article 28 requires Member States to confer “exclusive rights” to a patent owner, which prevents third parties from “making, using, offering for sale, selling, or importing” a certain product. Such rights shall be protected for a minimum of twenty years (Article 33).

(b) TRIPS Exceptions and “Flexibilities”

The following provisions set forth conditions under which Member States may be exempt from the requirements stated above, or when Member States may exercise discretion in implementing TRIPS provisions.

(i) Article 30

Article 30 allows “limited exceptions” for exclusive patent rights, while balancing the patent owner’s rights for the “normal exploitation” of the patent and their other “legitimate interests.” The Panel report of the Canada-Pharmaceutical Products case found that “regulatory exceptions,” where manufacturers produce generic versions of patented products for the purpose of seeking regulatory approval, constitutes a “limited exception.”\(^5\) In addition, some Member States have relied on Article 30 for research and development purposes that would allow better understanding of patented inventions, such as vaccines.\(^6\)

(ii) Article 31

Article 31 sets forth conditions for Member States to issue compulsory licenses, which allow non-patent holders to produce patented products without the consent of the patent owner.\(^7\) Compulsory licenses promote accessibility to pharmaceutical products because competitors may utilize existing patent rights to produce cheaper generic products. Conditions that non-patent holders must meet prior to the use of compulsory licensing include:

- making “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions” prior to such use (Article 31(b));
- the use being “authorized predominantly for the supply of the domestic market of the Member authorizing such use” (Article 31(f)), and;
- paying “adequate remuneration” to the patent holder for such use (Article 31(h)).

The condition set forth in Article 31(f) has been controversial in light of public health needs, because countries with insufficient manufacturing capacity for pharmaceutical products cannot benefit from this system. To address this issue, Article 31bis was added to TRIPS to allow “production of a pharmaceutical product(s) and its export to an eligible importing Member(s).” However, this system has only been used once, in 2007, when a Canadian firm produced and exported HIV/AIDS drugs to Rwanda.\(^8\) Studies have noted that the complicated procedures of this system may have hindered its use.\(^9\)
(iii) Interpretative Role of Articles 7 and 8
In international law, a treaty is to be interpreted “in the light of its object and purpose.” TRIPS Article 7 sets outs the objectives of TRIPS and provides that IPRs should be protected and enforced “in a manner conducive to social and economic welfare.” Article 8, labeled “Principles,” stipulates the right of Member States to “adopt measures necessary to protect public health and nutrition.” While these provisions do not waive obligations under TRIPS, they allow Member States to exercise discretion in implementing TRIPS requirements in their national legislations and policies.

(iv) Interpretative role of the Doha Declaration
The Doha Declaration on the TRIPS Agreement and Public Health was adopted at the WTO Ministerial Conference in 2001. Reflecting concerns that patent rules might restrict access to affordable medicines and hinder developing countries’ efforts to control diseases, the Declaration was adopted to clarify ambiguities in how TRIPS flexibilities can be applied to address public health needs. While the Declaration’s formal status as interpretative guidance is uncertain, it argues for finding flexibility in TRIPS. Specifically, the Declaration reaffirms the right of Member States to take “measures to protect public health” and provides that TRIPS should be interpreted and implemented accordingly (paragraph 4). Furthermore, the Declaration reaffirms the right of Member States to make full use of TRIPS “flexibilities” such as granting compulsory licenses and determining situations of national emergency (explicitly including “public health crises”), which would allow Member States to waive certain TRIPS requirements.

(c) Uncertain Relationship with the Right to Health
Maintaining an appropriate balance between IPR protection and public-health needs has been a persistent issue. On one hand, the “right to health” is codified in several international human rights treaties (outlined in chapter four), which create binding legal obligations on parties. For example, the Constitution of the World Health Organization states in its preamble that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.” The exclusivity of patent rights may undermine this objective if they allow high prices of pharmaceutical products.

On the other hand, IPR protection is necessary to promote innovation and spur economic growth. The Doha Declaration states that IPR protection contributes to public health needs as “intellectual property protection is important for the development of new medicines.” In that sense, IPR protection may contribute to promoting health.

Conflict between these two policy goals has emerged in connection with COVID-19. In October 2020, India and South Africa requested a waiver from the implementation, application, and enforcement of relevant TRIPS provisions in relation to prevention, containment, or treatment of COVID-19. Critics of that request assert that TRIPS
provisions already provide enough flexibility for Members to satisfy their public health needs, and undermining IPR would eliminate the incentives to develop products necessary for promoting public health in the longer term.\textsuperscript{13}

**Further Reading**

   - Two trade law scholars provide a clear and concise introduction to the fundamental components and structure of international trade law, elucidating specific GATT and WTO legal rules and institutions.

   - Article XI of the GATT 1994 governs the general elimination of quantitative restrictions (QRs), with some exceptions. This decision, adopted by the Council for Trade in Goods on 22 June 2012, establishes the procedures that Members must follow to notify of all QRs they apply, while also allowing Members to notify of QRs imposed by other Members.

   - Eighty countries and customs territories have adopted export prohibitions or restrictions because of the COVID-19 pandemic. This report focuses on the current lack of transparency in regard to these measures at the multilateral level, drawing attention to long-term risks that the imposed export restrictions present for global supply chains and public welfare.

   - The GATT functioned as a *de facto* international organization for regulating international trade in goods. The Marrakesh Agreement signed at the conclusion of the Uruguay Round (1987-1994) established the World Trade Organization (WTO). The WTO incorporates the rules of the GATT and provides a more comprehensive institutional framework for rules-based international trade.

   - TRIPS sets international minimum standards for IPRs protection and also allows flexibilities for countries to respond to other policy objectives. The amended version of TRIPS, inserting Article 31bis, entered into force in 2017.
   - WTO Members adopted this declaration in 2001 to clarify ambiguities concerning TRIPS provisions and the principles of public health. This declaration refers to the use of TRIPS flexibilities in relation to public health.

   - India and South Africa proposed a waiver from certain TRIPS requirements, arguing that IPRs are hindering or potentially hindering a timely response to COVID-19. As of July 2021, this waiver was still being discussed by the TRIPS Council.

   - Bacchus argues that the TRIPS waiver proposal submitted by India and South Africa is unnecessary, because countries could respond to public health needs by using existing TRIPS flexibilities.
CHAPTER SEVEN

International Humanitarian Law and International Criminal Law

Introduction

This chapter discusses the applicability of International Humanitarian Law (IHL) and International Criminal Law (ICL) in situations of pandemics and health crises. IHL consists of international treaties and customary laws that regulate relations between parties, the conduct of hostilities, and the treatment of persons of various legal classifications in armed conflicts or belligerent occupations. ICL on the other hand is a body of law that provides for the accountability of individuals for the most heinous crimes that concern the international community—namely, war crimes, crimes against humanity, genocide, and the crime of aggression. Conflict zones are powder kegs for pandemics and even though the rules and obligations under IHL and ICL do not change during pandemics, a number of them take on heightened significance for the populations involved.

IHL and Pandemics

IHL broadly distinguishes between two types of armed conflicts—International Armed Conflicts (IACs), including belligerent occupations, and Non-International Armed Conflicts (NIACs). Although the rules governing the two kinds of conflict have converged over time, meaningful differences remain. IACs are armed conflicts between two or more states, whether engaged directly or indirectly through proxies over which they exercise control. NIACs are armed conflicts between states and organized non-state armed groups or between such groups. IHL also applies to all cases of total or partial military occupation (the control of one state’s territory by another, without the former’s consent), even if the occupation does not meet with armed resistance. The IHL rules applicable to NIACs are less detailed than those applicable to IACs.

The applicability of IHL during pandemics raises certain key issues regarding medical personnel and facilities, objects necessary for civilian survival, humanitarian access, and the conditions of detainees, each of which is discussed...
below. Additionally, the foreseeable impacts of hostile activities need to be assessed before attacks for their compliance with the requirements of distinction, precautions, and proportionality, as well as the ban on indiscriminate attacks.

**Key IHL Issues**

1. **Medical personnel, facilities, and transport**
   Medical units and transports must be protected at all times and may not be attacked.\(^5\) In the context of belligerent occupation, the occupying power must maintain medical establishments, public health, and hygiene of the people in the region. The obligations of parties to the conflict do not change during a pandemic but violations may have magnified effects. Pursuant to the proportionality rule, attacks on military objectives are prohibited when the collateral civilian damage expected would be excessive in relation to the concrete and direct military advantage anticipated. Such assessments must account for potential disease outbreaks and the medical capacity to attend to them. Attacks that would destroy or render useless medical units or vaccine centers can significantly impact the disease spread and therefore are likely to be considered disproportionate.

2. **Objects necessary for civilian survival**
   It is prohibited to attack objects indispensable for civilian survival, except in specifically defined circumstances.\(^6\) During health crises, this protected category would likely include medicines and vaccines. The protections under IHL provide strict limitations on the attacks on such objects even if they have become military objectives. Moreover, even in the rare scenario in which damage to such objects would not be prohibited by this rule, the reverberating effects of such an attack in a pandemic would likely be disproportionate and the attack would be prohibited on that basis.\(^7\)

3. **Humanitarian care and relief**
   Populations living in conflict zones are often vulnerable due to the hostilities and limited access to goods and services that are considered basic needs. In all circumstances, parties to the conflict have an obligation to take all possible measures to search for and collect the wounded and sick and to care for them without discrimination.\(^8\) In situations of belligerent occupation, the occupying power must ensure the adequate supply of essential goods to the civilian population and take the prophylactic and preventive measures necessary to combat the spread of contagious diseases; if the population is inadequately supplied, the occupying power must agree to relief schemes by States or humanitarian actors.\(^9\) In IACs (other than belligerent occupations) and NIACs, parties may not arbitrarily decline access to humanitarian actors when the population is inadequately supplied with essentials.\(^10\)

These rules are of particular importance in situations of health crises, when there is a need for greater permeability of relief in conflict zones. The key stumbling block is that humanitarian organizations need to obtain consent from the party to the conflict.\(^11\) Though the parties to the conflict cannot arbitrarily withhold consent and deny humanitarian relief operations, there is no clear definition of what constitutes
“arbitrary.”

The parties may attempt to deny humanitarian relief operations on the grounds of restricted movements to combat the spread of infectious diseases. However, a complete denial of access to humanitarian relief would exacerbate the living and health conditions of the civilians, thereby violating their right to food and right to life under international human rights law. Such denials would likely violate the IHL rules precluding the arbitrary denial of humanitarian access and prohibiting the deprivation of indispensable objects and could amount to the war crime of starvation of civilians as a method of warfare.

4. **Conditions of Prisoners of War**

It is the controlling authorities’ responsibility to treat Prisoners of War (POWs) humanely and maintain their health and hygiene. They should ensure proper hygiene and ventilation of the detention facilities, to prevent the spread of diseases. The rules mandate that camps have adequate heat and light, bedding and blankets, and sanitary conditions be maintained.

a. **Violation of the rule of sanitary conditions for POWs:** During pandemics, hygiene maintenance of the detention facilities and the POWs is of utmost importance to prevent spread of infectious diseases. Further, preventive care is also vital in maintaining good health in a closed environment where diseases can easily spread. Therefore, POWs must be provided with personal protective equipment and space in the detention centers for social distancing.

b. **Disparate application of IHL in IACs and NIACs:** Detainees in NIACs do not enjoy the same rights as POWs in IACs and have rudimentary protections under IHL, customary international law, and human rights law. A few provisions, such as Common Article 3 and Additional Protocol II (AP II), provide certain guidelines and protection to detainees in NIACs. For example, Common Article 3 mandates humane treatment without adverse distinction and AP II includes basic provisions for food, water, health, sanitation, and certain protections for women, children, wounded, and sick. Therefore, in NIACs, the obligations on the State for the protection of the detainees are limited to the same extent as enjoyed by the local civilian population. Non-State Armed Groups (NSAGs) are also obligated to take steps promoting detainee health, but such obligation is proportional to its capabilities. However, in situations involving two or more NSAGs, there is debate on whether Common Article 3 binds them as they are not the Contracting Parties to the Geneva Conventions. A line of thought is that the Contracting States derive their authority from the domestic legislative sovereignty and the territorial requirement of Common Article 3 makes it applicable to NSAGs.

**ICL and Pandemics**

ICL does not explicitly address situations of pandemics and health crises. However, a pandemic context could have particularly significant impacts on several specific international crimes.
Key ICL Issues

1. Crimes against Humanity (CAH)

CAH are acts that are committed as a part of a widespread or systematic attack directed against a civilian population with knowledge of the attack. Two categories of CAH are relevant here: extermination and other inhumane acts.

Extermination is a crime of mass killing. It can be perpetrated via “the intentional infliction of conditions of life, inter alia the deprivation of access to food and medicine, calculated to bring about the destruction of part of a population.” For extermination to apply, the impugned conduct must cause death and must be part of a mass killing of members of a civilian population.

A second relevant category of CAH is that of “other inhumane acts” that “intentionally cause great suffering or serious injury to the body or mental or physical health.” Infecting persons with a disease could satisfy this threshold. If a disease is highly communicable, such infection could easily become ‘widespread.’ A State pursuing a policy of withholding vital public health information could amount to a ‘systematic’ policy exacerbating infection. Those involved in the health administration of the State may be particularly responsible in such a scenario.

For CAH, the mens rea component requires that the accused must have had the intent to commit the offense and must have known that there is an attack on the civilian population and that his or her acts comprise part of the attack. Therefore, material elements of the crime must be committed with intent and knowledge. Ordinarily, this would mean that the perpetrator must have meant to engage in the proscribed conduct and either meant to cause the prohibited consequence (death in the case of extermination or serious injury to physical health in the case of other inhumane acts) or known that such a consequence would occur in the ordinary course of events.

2. War Crimes

War crimes are grave breaches or serious violations of international humanitarian law that create a criminal responsibility under international law. They apply only when there is a nexus between the prohibited conduct and an armed conflict. Article 8 of the ICC Statute provides an exhaustive list of war crimes. The war crimes applicable in IACs are not identical to those applicable in NIACs.

a. War Crime of Starvation (IACs) – The war crime of starvation of civilians as a method of warfare attaches when a perpetrator deprives civilians of indispensable objects with the intent to starve them as a method of warfare. There is a consensus that the term starvation extends beyond deprivation of food and water to include other essential goods such as bedding, clothing, medicines, etc. Art 8 (2) (b) (xxv) of the ICC Statute also states that the prohibited deprivation can occur through the perpetrator willfully impeding relief supplies. Humanitarian relief may be impeded in two manners: first, when the consent is arbitrarily withheld in violation of international law, and second, when the consent is obtained but the parties to the conflict impede the relief operations and fail to provide rapid and
unimpeded passage for the supplies, equipment, and personnel to perform such relief operations.\textsuperscript{30} Unfortunately, there is no clarity on what constitutes arbitrarily withholding consent as this has not yet been addressed before a judicial or quasi-judicial body.

\textbf{b. War Crime of Starvation (NIACs)} – Until recently, the crime of starvation was only applicable to IACs and not to the situations of NIACs. Civilians in NIACs being deliberately starved were not under the purview of the ICC.\textsuperscript{31} In 2019, the Assembly of State Parties to the ICC Rome Statute unanimously voted to include starvation as a war crime in NIACs (Art 8 (2)(e)(xix)). However, only a few countries have ratified the amendment. A foreseeable hurdle in the applicability of crime of starvation in NIACs is Article 121 (5) which states that any amendment to Articles 5, 6, 7, and 8 has to be ratified by the States and if the amendment is not accepted by a State, the Court shall not exercise its jurisdiction in respect of the amendment in the State territory or over its nationals.

\textbf{c. Additional relevant war crimes include:}

- biological experiments: 8(2)(a)(ii) [IAC]
- willfully causing great suffering or serious injury to body or health: 8(2)(a)(iii) [IAC]
- clearly disproportionate attacks [see IHL section above]: 8(2)(b)(iv) [IAC]
- subjecting persons who are in the power of an adverse party to physical mutilation or to medical or scientific experiments of any kind which are neither justified by the medical, dental or hospital treatment of the person concerned nor carried out in his or her interest, and which cause death to or seriously endanger the health of such person or persons: 8(2)(b)(x) [IAC]
- intentionally directing attacks against buildings, material, medical units and transport, and personnel using the distinctive emblems of the Geneva Conventions in conformity with international law: 8(2)(b)(xxiv) [IAC]
- intentionally directing attacks against buildings, material, medical units and transport, and personnel using the distinctive emblems of the Geneva Conventions in conformity with international law: 8(2)(e)(ii) [NIAC]
- subjecting persons who are in the power of another party to the conflict to physical mutilation or to medical or scientific experiments of any kind which are neither justified by the medical, dental or hospital treatment of the person concerned nor carried out in his or her interest, and which cause death to or seriously endanger the health of such person or persons: 8(2)(e)(xi) [NIAC]

\section*{Conclusion}

Pandemics exacerbate the already vulnerable conditions for people in conflict zones. Though IHL and ICL do not have specific provisions that apply to pandemics, violations of either body of law are likely to have amplified and reverberating effects in the context of widespread infectious diseases.
Further Reading

   - This article discusses the applicability of IHL to the non-international armed conflict in Syria, focusing on the unsanitary conditions of detainees.

   - This article addresses several concerns raised by the International Committee of the Red Cross, such as physical and cyber-attacks on the healthcare sector, setting up hospital zones, and the delivery of humanitarian relief.

   - This article addresses evolving understandings of starvation as a war crime.

   - This article discusses the urgency of humanitarian access in light of the COVID-19 pandemic. It focuses on the critical importance of humanitarian access in conflict-affected States such as Yemen and Syria.

   - This article analyzes how wartime detainees are left vulnerable due to inadequate medical services, unsanitary conditions, overcrowding and lack of basic goods and services. The article considers the situations in Libya and Sudan, and also touches upon Guantanamo Bay.

   - This blogpost discusses the elements of crimes against humanity in light of the criminal complaint against President Jair Bolsonaro (Brazil) filed with the ICC. It examines whether Bolsonaro’s actions or lack thereof constitute the “widespread” and “systematic” element of CAH, and whether these actions have been committed intentionally.
Article 54 (2) AP I mentions a few objects indispensable to the survival of civilian population such as foodstuffs, agricultural areas for the production of foodstuffs, crops, livestock, drinking water installations and supplies and irrigation works.


AP I, arts. 3, 8-10; ICRC, Protocol Additional to the Geneva Conventions of 12 August 1949, and relating to the Protection of Victims of Non-International Armed Conflicts (Protocol II), 8 June 1977, 1125 UNTS 609, arts. 3, 7-8. [hereinafter “AP II”]. For non-parties to AP I, the rule regarding civilians is that parties to the conflict must facilitate steps to search for the wounded and sick as mentioned in Article 16 GC IV. Some states also argue that this is the customary rule for non-parties to AP I.


See e.g., GC I-IV, Common Articles 3, 9 and 10; AP I, arts. 70, 71; AP II, art. 18.


GC III, art. 31.


AP II, art. 5 (1).


Choi.


Justin Kamren, “Prosecuting the Pandemic: Strengthening International Public Health Law,” Eyes on the ICC, 8, no. 9, 2020, 164-165.


ICC Statute, art. 30 (1).


Akande and Gillard, 769.

CHAPTER EIGHT

Biological Security Law

Introduction

“We need to pay much closer attention to biological security.” UN Secretary General Kofi Annan made this appeal in the 2004 Report of his High-level Panel on Threats, Challenges, and Change, which was aimed at reforming the United Nations for the twenty-first century.¹

As a consequence of increased development and urbanization, intensifying land use change, technological innovation, and laboratory research advances, biological threats—both naturally occurring and manufactured—create a threat of emerging pandemics. Several international agreements for monitoring and containing biological threats have been established to mitigate these risks. Biosecurity law and biological weapons law provide a framework for reducing pandemic threats as well as managing biological materials and infectious diseases in order to protect human, animal, and environmental health.²

International Biosecurity and Biosafety Law

Biosecurity law, as a unified body of law that regulates industry, trade, and research, aims to minimize the global risk of infectious disease outbreaks. Adopted in 2000, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) is an important regulatory advancement. With 173 parties to date, it serves as a legally binding mechanism that seeks to ensure the safe transfer, handling, and use of living modified organisms (LMOs) created through modern biotechnology. It frames biosafety as a means to protect human health and the environment from potentially adverse effects of biotechnology.³

To accomplish CBD Aichi Targets, the Cartagena Protocol connects biological diversity with infectious disease outbreaks that pose a risk of becoming pandemics. The goal is to address issues efficiently by advancing guidance on monitoring dangerous pathogens and biological products.⁴

Among its mandates, the Cartagena Protocol calls on parties to develop standards for identification, handling, packaging, and transport practices within relevant international bodies (Articles 18 and 20). A Biosafety Clearing-House facilitates scientific, technical, environmental, and legal information-sharing regarding LMOs.

Parties agree to cooperate in strengthening human resources and institutions for biosafety and biotechnology. They also prioritize advancing private sector involvement and supporting developing countries, economies in transition, and small island developing states (Article 22). For conducting risk assessments, Article 15 emphasizes the need to use scientific evidence to “identify and evaluate possible adverse effects of LMOs
on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”

To address unintentional transboundary movements and emergency measures, Article 17 requires parties to immediately notify other States, the Biosafety Clearing-House, and relevant international organizations “of an unintentional transboundary movement of an LMO.” States are required to consult affected and potentially affected States so they can initiate protective action.

Overall, the Cartagena Protocol aims to safeguard biodiversity and human health by facilitating international cooperation for monitoring the movement of LMOs and biological materials. These measures prepare States and international organizations to respond to biological agents with pandemic potential.

Despite its mandate, the Cartagena Protocol faces notable criticism for providing limited guidance on risk assessment. Scholars also argue that the Protocol must be reconciled with international trade law and, further, that liability should be increased for countries taking risks with LMOs. Scientists are also concerned that the risks associated with synthetic biology and genetically modified organisms are inadequately addressed.

International trade is responsible for sending LMOs with potential to affect biodiversity and human health around the world. If these LMOs are infectious among humans, they may cause pandemics. Stricter liability and more detailed guidance on trade of genetically modified organisms could minimize risks of adverse biological events.

Biological Weapons Law

Biological weapons are designed to spread infectious agents. As such, they are a potential source of pandemics. The Biological Weapons Convention (BWC) entered into force in 1975 and has 183 States Parties to date. Several other States have signed but not
ratiﬁed the Convention, including Egypt, Somalia, and Syria. The BWC bans biological weapons while addressing the “dual-use problem” of biological research. It seeks to balance the potential beneﬁts of research advancing legitimate science with the risks of this research being misused to create biological threats.

Article X of the BWC speciﬁcally addresses the dual-use problem, asserting that States Parties have the right to participate in the exchange of “equipment, materials, and scientiﬁc and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.” It aims to regulate these activities without hampering economic or technological development.

Under Article VI of the BWC, States have the right to submit complaints and request UN Security Council investigations of BWC breaches by other States. States Parties also agree to cooperate during investigations. Under Article V, States agree to cooperate bilaterally and multilaterally in solving problems related to BWC application and objectives. Despite these stipulations, the BWC lacks a formal veriﬁcation protocol. There are various explanations for this, including concerns about the feasibility of veriﬁcation, as well as the “possible risks to a country’s security provisions and other national activities.”

Several states fear that veriﬁcation could compromise biodefense programs and related research, citing espionage concerns. Continued debate surrounding the pharmaceutical industry, intellectual property, open information sharing, and the emergence of non-state actors also hinder veriﬁcation. Furthermore, advances in synthetic biology, like gene drivers, can streamline biological weapons development. In the current BWC, this issue is not addressed.

While the BWC lacks legally binding veriﬁcation mechanisms, biotechnology research continues and the dual-use problem persists. Specific concerns about biological weapons arose with the Soviet Union during the Cold War and with Iraq, which was later conﬁrmed by UNSCOM to be operating programs in violation of the BWC during the Persian Gulf War. These veriﬁcation gaps leave biotechnology advancement unregulated and biological weapons programs unmonitored within international agreements. Because these areas can result in the release of manufactured and naturally occurring infectious diseases, inadequate veriﬁcation hurts countries’ abilities to proactively address pandemics.

The Second Review Conference of the BWC introduced Conﬁdence Building Measures (CBMs), which aim to “reduce doubts and suspicions to improve international cooperation in the ﬁeld of peaceful biological activities.” The CBMs address veriﬁcation and non-compliance challenges by including information-sharing mechanisms for research laboratories, defense research programs, infectious disease outbreaks, and vaccine production facilities. The CBMs’ inclusion of infectious disease outbreak notifications enhances pandemic prevention and response capabilities.
‘Securitization of Health’ Debates

Concerns about the “securitization” of global health are a matter of ongoing debate in policy and academic circles. Scholars contend that international biosecurity and biological weapons law must prevent harm without hindering scientific progress. They further argue that biosecurity law is currently too state-centric and needs more multistakeholder governance with participation from NGOs, multinational corporations, philanthropic foundations, and public-private partnerships. There is no question that infectious disease outbreaks can cause pandemics, but scholars continue to debate whether disease surveillance and response should be included within biosecurity law.

Proponents of public health securitization argue that it shines a light on non-medical impacts of health crises. They claim that this balances domestic agendas with international responsibilities in shaping the global health order. They argue that securitization draws high-level attention through initiatives such as the Global Health Security Agenda and allows actors to build capacity across countries to mitigate pandemics. Under the Obama administration, the U.S. shifted from a focus on biodefense to biosecurity, which included biological terrorism, dual-use research, and naturally occurring and deliberate infectious disease outbreaks. Security scholars argue that the UN should adopt this security policy framework in order to foster international cooperation for pandemic preparedness. Under this lens, peacekeeping and peacebuilding operations could be used as tools for capacity-building in conflict-affected states. On the role of the UN Security Council in global health governance, see chapter nine.

Opponents of securitization argue that while it can attract more funding and resources, the drivers of disease within developing countries, as well as the need to build resilient and equitable health systems, can still be ignored. Securitization may also detract from endemic disease burdens due to its focus on outbreak containment within a policy frame of “external threats” and an “us versus them paradigm.” Furthermore, researchers assert that greater regulation may increase costs and deter progress in the defense research field.

The securitization debate is likely to grow sharper as lessons from the COVID-19 pandemic are assimilated. Importantly, this is only one component within international biosecurity and biological weapons law that will need to be considered in future policy development. Moving forward with pandemic preparedness, the connections between naturally occurring disease and its possible weaponization, as well as addressing the drivers of and risks posed by both, will require thorough examination.

Further Reading

   • This appendix provides brief summaries of legislation, regulations, and other guidance relating to biological agents.

- This blog post discusses the relevance of the BWC to epidemic outbreaks, arguing that the BWC is complementary to the IHR as a legal framework for global disease surveillance despite being constrained by a lack of robust verification.


- This article analyzes the role and significance of the BWC in regard to infectious disease surveillance and response to outbreaks, focusing on enhancing capacity for disease surveillance and response as well as responding to allegations of biological weapons use and investigating suspicious outbreaks.


- This article provides commentary on the development of measures by BWC treaty members that would influence scientists’ behavior, such as codes of conduct and increased pathogen security. It also includes a history of the BWC, discussing limitations and relevance to life scientists.


- Tucker discusses the need for global biosecurity standards in order to prevent the misuse of pathogens. He argues that, ultimately, the success of such standards will depend on buy-in and voluntary cooperation from microbiologists and laboratory administrators worldwide to ensure that the resulting guidelines are workable and cost effective.


- This handbook presents an overview of research in the field of global health security, introducing key topics, related debates, and recommendations for future research. It is organized in four sections: health securities, threats, responses, and controversies.


- This article explores the link between biodiversity and emerging diseases and whether that information can be used to predict and stop future outbreaks.
   - This paper examines two cases of securitizing infectious disease by the Chinese government and discusses the pros and cons of such action.

   - This book explores the transformations reshaping how the international community addresses biological weapons and infectious diseases. Fidler and Gostin argue that the approach outlined in the BWC is no longer dominant and outline four emergent policy trends.
Global Institutions: Inter-governmental Organizations

Introduction
Responsibility for addressing global public health is in the original mandates and evolving missions of the World Health Organization (WHO) and the World Bank Group. These intergovernmental organizations play a central role in managing and preventing infectious diseases around the world. Specifically, the WHO’s 1946 Constitution articulates an international vision of health cooperation and an “all-encompassing notion of health” as a basic human right. This framework has brought useful structure to the institutional architecture for how other intergovernmental organizations as diverse as the World Trade Organization, the United Nations Office of the High Commissioner for Human Rights, UNICEF, regional bodies and even the UN Security Council approach global public health. However, the arrangement of intergovernmental organizations concerning global public health and, particularly, global health crises such as pandemics are not necessarily cohesive or unified.

The lack of cohesion results in distinct and sometimes competing approaches to global public health. Such debates have emerged around the “securitization of health,” the practice of monitoring compliance with global health law, and the tension between building capacity to respond to outbreaks and building resilient and equitable healthcare systems to prevent pandemics.

The World Health Organization
In 1946, members of the International Health Conference drafted the WHO Constitution. The Executive Secretary and later Director-General of the WHO, Dr. Brock Chisholm, described the organization as born out of the notion,

... that the peoples of the world cannot exist half sick and half well, any more than they can exist half slave and half free; those problems which are no longer purely national must be solved not only by international action, but on a worldwide basis.

The WHO currently describes its mandate as primarily “… to direct and coordinate international health within the United Nations system.” Preparedness, surveillance, and response to communicable and non-communicable diseases is a top priority within its portfolio. Yet, its mission extends beyond addressing pandemics to include broader goals such as improved access to essential health care services through its “universal health coverage” programs, and attention to the determinants of health, such as nutrition, water and sanitation, and gender equity. The WHO not only runs programs...
itself (for example, polio eradication) but also monitors health trends around the world and provides expert advice on how to manage them.

The WHO is headquartered in Geneva, with six relatively autonomous regional offices and about 150 country offices. This decentralized structure has benefits given the diverse health needs of the six regions, but it does create some inefficiencies.6 The organization is funded out of a mix of assessed contributions from Member States (20% of the total budget) and voluntary contributions from States and other donors (80%). For the last several years, the Gates Foundation has been the WHO's second or third largest donor.

The World Health Assembly (WHA)7 can adopt regulations, conventions, and agreements under Articles 19 through 23 in the WHO Constitution.8 As covered in detail in chapter one, the 2005 Revised International Health Regulations (IHR) replaced the previous 1969 IHR giving new breadth to the WHO's oversight function and Member States' obligations.9 The revised IHR (2005) include a significant update to State Party obligations, requiring notification to the WHO in the case of outbreaks in which there is a risk of severe public health impact, unusual or unexpected characteristics, risk of international spread, and risk of interference with international travel or trade.10

As discussed in further detail in chapter ten, public-private partnerships have played an increasing role in how the WHO addresses public health issues and the outbreak of infectious diseases. The Vaccine Alliance (GAVI) is one such partnership, whose participants include the WHO, UNICEF, the World Bank, and the Gates Foundation. Its purpose is to allocate and ensure vaccines for nearly half the world’s children.11 The WHO, a founding and permanent member of GAVI, provides financial support and research facilitation for vaccine development. The WHO’s Vaccine Advisory Committee, acting as a technical specialist, provides guidance to GAVI about which vaccines to support. COVAX, the GAVI and WHO-backed vaccine “insurance policy,” which aims to ensure fair and equitable distribution of COVID-19 vaccinations to low-income countries, is a prime example of a contemporary public-private partnership.12

Since 2005, the WHO Director-General has declared six Public Health Emergencies of International Concern (PHEIC): H1NI, Polio, Ebola in West Africa, Zika, Ebola in the Democratic Republic of the Congo, and COVID-19.13 In the lead-up to the 2005 revision to the IHRs, several decades of experience in managing infectious disease outbreaks compelled the World Health Assembly to promulgate these new regulations.14 Scholars who reviewed nine Emergency Committees convened by the Director-General have critiqued the inconsistencies and alleged lack of clarity when a PHEIC is declared and when it is not.15 Others have levied blame on the IHR reporting system, noting that fewer than half of WHO Member States comply with the IHR's core capacities requirements.16

**World Bank**

In 1944, the UN Monetary and Financial Conference met and devised the would-be World Bank Group mandate. The Articles of Agreement for the constituent instruments of the two main World Bank bodies (i.e., International Bank for Reconstruction and Development and
the International Development Association) highlight that “considerations of economy, efficiency, and competitive international trade without regard to political or other non-economic influences” shall be the driving force of the World Bank Group.\(^7\)

While the World Bank initially focused on large infrastructure and development projects, between 1980 and 2003 the Bank’s financing of health, nutrition, and population services and programs grew from 5 percent to 22 percent of its portfolio.\(^8\) Beginning with Robert McNamara’s tenure as World Bank President in 1968, an emphasis on development took hold, centered on social sector lending.\(^9\) The Bank’s unique ability to mobilize financial resources has made it the largest funding source for health and nutrition programs in low and middle-income countries.\(^10\)

Moving into the second decade of the twenty-first century, the World Bank refocused its goals in the field of global public health. Stemming from the commitment of the World Bank Group to UN Sustainable Development Goal 3 — “[t]o ensure healthy lives and promote well-being for all at all ages” — the World Bank has restructured its approach over the past decade.\(^11\) The Bank has now aligned its lending with the goal of Universal Health Coverage (UHC), including support for pandemic preparedness and response.\(^12\)

Since 2010, the International Development Association has financed USD 13.5 billion in “essential health interventions for 770 million people, and immunizations of 330 million children.” The World Bank reports that the share of health funding has increased by 60 percent in that same time frame.\(^13\) To this end, new programs have been created and financed, including the World Bank’s pandemic response initiatives and programs. The chief actors are the Pandemic Emergency Financing Facility (PEF), the Global Preparedness Monitoring Board (GPMB), the Regional Disease Surveillance Systems Enhancement (REDISSE), and the African Centers for Disease Control and Prevention Regional Investment Financing Project (ACDCP).

PEF is an insurance-based financial strategy that emerged in the aftermath of the 2014-2016 Ebola outbreak.\(^14\) The World Bank developed PEF in consultation with the WHO, other major development agencies, and private sector partners. The central aim of PEF is to ensure emergency funds for pandemic response, emphasizing the importance of preparedness for outbreaks.\(^15\) Second, PEF aims to bolster ongoing programs to achieve Universal Health Coverage, or UHC 2030.\(^16\) Low-income countries, especially those eligible for the IAD credits from the World Bank, are the primary beneficiaries. In late April 2020, PEF announced that it was allocating USD 195.84 million to 64 low-income countries with the intention to provide financing for medical equipment, medicine, and support to health workers.\(^17\)

The GPMB is an independent board that provides an appraisal of global preparedness and response capacity of global health emergencies, particularly disease outbreaks. In response to the 2014-2016 Ebola outbreak, GPMB was co-convened by the World Bank and WHO at the recommendation of the UN Secretary General’s Global Health Crisis Task Force. It was designed to fill the key role of monitoring and appraisal of national and intergovernmental financial preparedness for outbreaks and health crises.\(^18\) However,
the board’s 2020 recap report emphasized responsible leadership and principles of governance as well as resource and financial preparedness.\(^{29}\)

In 2016, the World Bank approved the REDISSE, leveraging USD 670 million to bolster regional disease surveillance and laboratory capacity in West Africa.\(^{30}\) The disease surveillance and screening techniques and the financing of laboratories, such as the Institut Pasteur in Dakar, have proven instrumental in the REDISSE-funded countries’ response to COVID-19.\(^{31}\) Funding through REDISSE is more than a relief package; it is part of a comprehensive preparedness plan intended to respond to immediate needs and to fortify long-term national health systems in a push for strengthened global health security. Relatedly, the ACDCP was approved in late 2019 to bolster disease surveillance, prevention, and response across the African continent. The project meshes both with the African Union’s Agenda 2063 to mitigate all infectious diseases on the continent and the World Bank’s goal of eliminating extreme poverty on the continent by 2063.\(^{32}\)

The UN Security Council

Pandemics like Ebola and COVID-19 also have security implications. The UN Security Council (SC) first got involved in global public health issues in 2000 when it adopted a resolution on the impact of HIV/AIDS (SC Resolution 1308). Its 2014 response to the outbreak of Ebola and its belated response to the COVID-19 pandemic illustrate the far-reaching implications of public health crises, and the importance as well as difficulty of coordination from the top.\(^{33}\) The Council’s Resolution 2532 of July 2020 demanded “a general and immediate cessation of hostilities in all situations on its agenda.”\(^{34}\) It asserts that global public health concerns relating to pandemics are simultaneously security concerns. This approach, tying security to global public health, has been both lauded and criticized, as demonstrated during the 2014 Ebola outbreak, for example.\(^{35}\) More recently,
in February 2021, the Council again expressed concern regarding the spread of COVID-19 caused by armed conflict, calling for “general and immediate cessation of hostilities.”

**Conclusion**

The COVID-19 outbreak underscores the fragility of global public health and the fault lines that exist between the aspirations of global institutions like the WHO and the World Bank on the one hand and, on the other, the harsh reality that infectious diseases can defy the surveillance, detection, and control mechanisms established by global actors and national governments. As a result, possible reforms to the legal and institutional architecture for global health governance are being intensely debated. While the response to COVID-19 was slow, the WHO, World Bank, and other financial institutions (including the International Monetary Fund) are pushing hard for widespread vaccination in developing countries. Both logistically and politically, the challenges ahead regarding equitable vaccine rollout highlight the need for cohesion among global institutions and their Member States.

**Further Reading**

   - This article examines the available legal powers as provided in the WHO constitution and considers the limited impact that these powers have had to-date.

   - This article introduces a forum in which scholars, practitioners and advocates reflect on WHO’s response to the complex global crisis of COVID-19 “within the context of broader conversations on global health, security and development, and contemporary threats to multilateralism and global solidarity.”

   - This article provides a brief history of the WHO and outlines its programs and accomplishments in the first few years of existence.

   - This paper series comprises contributions from thirteen Council of Councils institutes. Eight papers consider the broader implications of the pandemic for international cooperation and the trajectory of the global system. The other five examine major gaps in the international management of global public health emergencies and propose reforms.
   - This article examines the growing phenomenon of public/private partnerships within the field of international public health cooperation. It highlights the remarkable developments in international health governance that public/private partnerships have ushered in as well as the role played by the World Health Organization.

   - This article provides analysis and commentary on the global health landscape, including development and environmental efforts, during the time when the trend toward populism was beginning to grow.

   - This article critiques the WHO and IHR, particularly surrounding the response to COVID-19, and discusses suggestions for reform.

   - The Independent Panel has developed a number of important resources based on in-depth research, including: an authoritative chronology of the early pandemic response, recommendations to curb the pandemic, a policy brief describing the global architecture for pandemic preparedness, a final report, and a series of background documents.

   - This report evaluates the roles and contributions of the World Bank Group in supporting health services in client countries, assesses findings, and provides recommendations for achieving greater development effectiveness going forward.

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7 Winslow, 118.
10 Plotkin, 259.
15 Mullen et al., 9.
17 IDA Articles of Agreement, art. V 1(g); see Daniel D. Bradlow, “The World Bank, the IMF, and Human Rights,” Transnational Law & Contemporary Problems 6, no. 1 (Spring 1996): 54 describes the mandate as self-limiting to economic sphere referencing Articles of Agreement IBRD Art. III 95(b) and identical Articles of IDA Art. V 11(g).
19 Ruger, 65.
20 Ruger, 67.
26 World Bank Group, “Pandemic Emergency Financing Facility.”
CHAPTER TEN

Global Institutions: Transnational Networks

Over the last three decades, transnational global health networks have dramatically changed the landscape of global health governance. Thirty years ago, intergovernmental international organizations (e.g., World Health Organization and World Bank) working bilaterally with nations, carried out most global health initiatives. However, beginning in the 1990’s donor nations began to lose their trust in the ability of international organizations to effectively close the vaccine gap or combat emerging and reemerging diseases. UN agencies themselves acknowledged the need for new partnerships to tackle the complex health problems facing the world, as the UN Millennium Declaration (2000) made AIDS, tuberculosis, malaria, and maternal and child mortality priorities on the development agenda. Globalization highlighted the need for more collaboration as health risks in one part of the world were shown to exacerbate risks elsewhere.¹

Collaboration came in the form of global health networks, defined as: “national webs of individuals and organizations linked by a shared concern to address a particular health problem global in scope.”² These networks leverage the legitimacy of intergovernmental partnerships and incorporate the efficiency of the private sector by uniting international organizations, international financial institutions, non-governmental organizations (NGOs), bilateral and private donors, philanthropic foundations, medical associations, research institutions, and think tanks. Together they advocate, fundraise, create policy recommendations, operationalize health initiatives, and augment knowledge sharing to enhance research and development. The emergence of networks like GAVI, the Vaccine Alliance and the Global Fund to Fight AIDS, Tuberculosis, and Malaria were groundbreaking in the global health sphere and have many advantages compared to the older model. While networks have emerged for most high burden diseases, such networks differ in their ability to generate attention, draw in funding, develop health interventions, and persuade national governments to adopt policies and institute programs, so it can be difficult to accurately measure their effectiveness. But overall, transnational networks allow for a dramatic growth in global health funding, improved collaboration, and stakeholder diversification.

COVID-19 confirms the need for transnational networks to collaborate alongside countries and international organizations to synergize global health efforts. This chapter focuses on networks that target pandemics and vaccines. Key networks in this space include GAVI, CEPI, COVAX, and GHSA.

GAVI, the Vaccine Alliance

Dedicated to “immunization for all,” the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization), is a global health partnership of public and private
sector organizations, with a governing board that also includes individual experts and representatives of civil society. GAVI aims to protect people’s health and save children’s lives by increasing access to immunization in low-income countries. GAVI and its partners provide funding for vaccines and intellectual resources for care advancement. In 2020, 67 of the 73 countries that GAVI supports have confirmed cases of COVID-19. GAVI provides immediate funding to their health systems, enabling these countries to protect healthcare workers, perform vital surveillance, conduct training, and purchase detection agents. GAVI also supports countries to maintain and restart immunization services as well as strengthen community trust and care for vulnerable groups while investing in immunization systems. GAVI is co-leading COVAX to secure an effective and fair global response to COVID-19, using its unique expertise to help quickly accelerate development, production, and equitable delivery of COVID-19 vaccines.

Through a private-public partnership, GAVI increases funding and brings significant private sector expertise and skills to its work. In 2020, Reed Hastings and Patty Quillin donated $30 million to GAVI. Through the Global Vaccine Summit, hosted by the UK, GAVI raised an additional $8.8 million. GAVI has approved applications from 13 countries including Myanmar and Ethiopia to fund them with PPEs and supply of vaccines.

GAVI is also engaged in data management, coordination, media, training and technical support mechanisms with the help of UN agencies and the Expanded Program on Immunization (EPI). It works with governments to track COVID-19 related data, monitor hospitals’ readiness and build databases and platforms. GAVI also provides training for governments’ leadership and organizes live sessions for scientists and doctors to hold discussions.

**Coalition for Epidemic Preparedness Innovations (CEPI)**

CEPI launched in 2017, is an innovative global partnership among public, private, philanthropic, and civil society organizations that aims to develop vaccines and prevent future pandemics.

In response to COVID-19, CEPI has offered $140 million to support research on the vaccine. Programs supported by CEPI can advance current study on COVID-19 immunization by providing data on demographic groups which are currently not eligible to receive doses of COVID-19 vaccines. CEPI has also established a global network to compare different kinds of COVID-19 vaccines. Five labs, including Public Health England in the UK, Nexelis in Canada and Srl in Italy have been centralized to measure the immunogenicity of multiple COVID-19 vaccine candidates.

**COVAX**

COVAX was launched by CEPI, GAVI, and WHO in response to the COVID-19 pandemic with the mission to ensure equitable access to the COVID-19 vaccine and end the pandemic by the end of 2021. COVAX is a pillar of the Access to COVID-19 Tools (ACT) Accelerator launched by WHO, the European Union and France in April 2020. ACT
aligns governments, global health organizations, manufacturers, scientists, private sector, civil society, and philanthropy all under the goal of equitable access to COVID-19 diagnostics, treatments, and vaccines.\textsuperscript{12} COVAX acts as a platform, supporting research and development of a wide portfolio of vaccine option, and pools the investments of nations to build the infrastructure necessary for rapid vaccine manufacturing and distribution.\textsuperscript{13}

COVAX is an example of an Advance Purchase Agreement (APA), a legally binding contract where one party commits to purchasing a specific number of doses of a vaccine candidate at a pre-negotiated price if it is successfully licensed and manufactured.\textsuperscript{14} Historically, bilateral APA’s have been used to secure priority access to vaccine and manufacturing capacity, with high income countries (HICs) securing vaccines through bilateral agreement and outcompeting lower income countries. Vaccine nationalism can also lead to embargos or requisition of vaccines, delaying global distribution. During the 2009 influenza A H1N1 pandemic, for example, APAs held by HICs secured priority access to vaccines at the detriment of lower-income countries because they restricted manufacturers from exporting vaccines.\textsuperscript{15} APAs can be used to ensure vaccine equity. This requires multilateral commitment to APAs, especially from HICs, as well as governance principles such as accountability, transparency, and participation, defined decision makers, increased country commitments to financing, set principles, commitment to acceptable conduct, and a mechanism for equitable distribution within and between countries.\textsuperscript{16}

COVAX’s APAs are managed and funded by the COVAX Facility, through which participating countries receive access to a large, diverse portfolio of COVID-19 vaccines. The Facility relies on the collective purchasing power of countries to negotiate with manufacturers. Competitive prices are then shared with all participants. However, the COVAX Facility allows self-financing countries to request vaccine doses sufficient to vaccinate only 10-50\% of their populations, and the doses they receive reflects the amount they pay into the Facility. Additionally, within the Facility exists a separate funding mechanism that ensures countries lacking the ability to self-finance have access to vaccines. COVAX utilizes the donor-funded Advanced Market Commitments (AMC) to enter APAs with vaccine manufacturers and supply a guaranteed number of vaccine doses to low-income and middle-income countries. The COVAX AMC is not subsidized by self-financing participants, rather it is funded by the Official Development Assistance and donations from private sector.\textsuperscript{17}

For lower-income countries or countries without bilateral deals with manufacturers, COVAX may be the only way their citizens can gain access COVID-19 vaccines. For wealthy, self-financing countries, COVAX provides extra protection by securing
additional vaccine doses at a competitive price. It also acts indirectly by ensuring that the rest of the world gets access to the vaccine, thereby reducing the probability of a global viral resurgence.18

**The Global Health Security Agenda (GHSA)**

The GHSA is a group of 69 countries, international organizations, non-governmental organizations, and private sector companies, formed to improve IHR implementation by leveraging and complementing multisectoral and multilateral partners. A Steering Group of 15 countries, international organizations, and/or non-governmental stakeholders governs GHSA, while the WHO, FAO, and the OIE act as permanent advisors.19 The GHSA assesses priorities and gaps in global health and builds countries’ capacity to prevent, detect and respond to infectious diseases by accelerating the core capacities defined in the WHO Joint External Evaluations and the World Organization for Animal Health Performance Veterinary Services Pathway.20 The GHSA targets 4 priorities: antimicrobial resistance, biosecurity and biosafety, zoonotic diseases, and immunization coverage.21 It relies on Action Packages to secure multilateral commitments. These are multi-stakeholder, multi-sectoral working groups dedicated to antimicrobial resistance, Biosecurity and Biosafety, Immunization, Laboratory Systems, Surveillance, Sustainable Financing, Workforce Development, or Zoonotic Diseases.22

While the emergence of SARS-COV-2 and rapid spread of COVID-19 indicate gaps in global outbreak mitigation and preparedness, the efforts of the GHSA have assisted in response because their knowledge of global health infrastructure has helped the international community direct the assistance to where it is needed most. Action Packages have also increased the coordination of medical supplies, knowledge sharing, and improved contact tracing systems. Lastly, the GHSA will help the international global health community learn from gaps identified throughout the COVID-19 pandemic and build resilience measures.23

**Conclusion**

While the rapid global spread of SARS-COV-2 illustrated significant gaps in global health surveillance and mitigation, the COVID-19 pandemic has also presented an opportunity to assess how effective current transnational networks respond to global health emergencies. GAVI provided funds for vaccines and funded the health system in low-income countries through a private-public partnership. CEPI offered $140 million on the research of COVID-19 and it launched the program to compare different kinds of vaccines. Transnational networks CEPI and GAVI quickly collaborated with the WHO to form COVAX to promote vaccine development and equity through multilateral Advanced Purchase Agreements, such as the COVAX Facility and COVAX AMC. Meanwhile, the work of the GHSA helped streamline communication, transport of supplies, and direct aid. While it is too early to determine the efficacy of COVAX in ensuring vaccine equity, the coordination of multilateral Advanced Purchase Agreements will be a foundation of future pandemic response. Furthermore, efforts by the GHSA will be essential in
strengthening country capacity and the international global health community in the post COVID-19 era. These networks, as well as their partners, have and will continue to be instrumental in all aspects of pandemic preparedness and response.

**Further Reading**

   - This article written by the CEO of GAVI provides a detailed account of the COVAX Facility and the COVAX AMC.

   - This chapter compares “old” and “new” actors in global health governance. It highlights the emergence of transnational networks GAVI and The Global Fund to Fight AIDS, Tuberculosis and Malaria and assesses some of the advantages these networks have over more traditional international organizations like WHO and World Bank.

   - This article provides an overview of the emergence and effectiveness of global health networks addressing tobacco use, alcohol harm, maternal mortality, neonatal mortality, tuberculosis and pneumonia. It examines how global health networks emerge, evolve, secure attention and funds, and influence policy.

   - Shiffman et al. introduce a conceptual framework that explains why networks form around some issues compared to others. It also explores why some networks are better suited to influence policy and health outcomes.

   - This *Lancet* article reviews how Advanced Purchase Agreements have created barriers to vaccine access in the past and discusses how the COVAX facility has been designed to improve vaccine access throughout COVID-19.

- Meier et al. introduce the legal domains required to meet each of the GHSA Action Package’s targets, developing an assessment tool to determine if national legislation has these attributes. The article provides the example of twenty Sub-Saharan African countries and emphasizes specific laws that reflect attributes of the legal domains.