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# The legal determinants of health: harnessing the power of law for global health and sustainable development



Lawrence O Gostin, John T Monahan, Jenny Kaldor, Mary DeBartolo, Eric A Friedman, Katie Gottschalk, Susan C Kim, Ala Alwan, Agnes Binagwaho, Gian Luca Burci, Luisa Cabal, Katherine DeLand, Timothy Grant Evans, Eric Goosby, Sara Hossain, Howard Koh, Gorik Ooms, Mirta Roses Periago, Rodrigo Uprimny, Alicia Ely Yamin

## Executive summary

Health risks in the 21st century are beyond the control of any government in any country. In an era of globalisation, promoting public health and equity requires cooperation and coordination both within and among states. Law can be a powerful tool for advancing global health, yet it remains substantially underutilised and poorly understood. Working in partnership, public health lawyers and health professionals can become champions for evidence-based laws to ensure the public's health and safety.

This *Lancet* Commission articulates the crucial role of law in achieving global health with justice, through legal instruments, legal capacities, and institutional reforms, as well as a firm commitment to the rule of law. The Commission's aim is to enhance the global health community's understanding of law, regulation, and the rule of law as effective tools to advance population health and equity.

The term law throughout is used to mean legal instruments such as statutes, treaties, and regulations that express public policy, as well as the public institutions (eg, courts, legislatures, and agencies) responsible for creating, implementing, and interpreting the law. By establishing the rules and frameworks that shape social and economic interactions, laws exert a powerful force on all the social determinants of health. Well designed laws can help build strong health systems, ensure safe and nutritious foods, evaluate and approve safe and effective drugs and vaccines, create healthier and safer workplaces, and improve the built and natural environments. However, laws that are poorly designed, implemented, or enforced can harm marginalised populations and entrench stigma and discrimination.

This Commission brings together global leaders in the fields of health, law, and governance. We make the case for better, more strategic linkages between health and law, and the professionals who work in both fields. We begin by providing a short explanation of legal terms and concepts, and the actors and institutions that govern health. Our report is structured around four legal determinants of health, each of which powerfully affects health outcomes. We use the term legal determinants of health because it demonstrates the power of law to address the underlying social and economic causes of injury and disease. These four legal determinants show how law can substantially influence health and equity. We do not endeavour a systematic review of law in global health, but rather to advocate for, and demonstrate, the crucial value of law in advancing global health with justice. Finally,

drawing on identified areas for reform, as well as principles of good governance and the right to health, we offer seven concrete recommendations for action.

Legal determinant 1 states that law can translate vision into action on sustainable development. The UN Sustainable Development Goals (SDGs) present a bold and unifying vision for global health and development. Law offers the mechanisms, frameworks, and accountability measures to achieve this vision. In particular, law can be used to lay the foundations for Universal Health Coverage (UHC), which is a crucial element of sustainable development. We show how the power of law can be used to achieve health with justice through a case study of how law can build and implement UHC. We make two recommendations for action.

Recommendation 1 suggests that the UN, WHO, and international partners should set standards to support the implementation of, and objectively evaluate compliance with SDG 3·8 (UHC), as well as the upcoming UN political declaration on UHC in 2019.

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O'Neill Institute for National and Global Health Law, Georgetown University Law Center, Washington, DC, USA (Prof L O Gostin JD, E A Friedman JD, K Gottschalk LL.M); Office of the President (J T Monahan JD) and Center for Global Health Practice and Impact (S C Kim JD), Georgetown University, Washington, DC, USA; School of Law, University of Tasmania, Hobart, TAS, Australia (J Kaldor LL.B); Health and Environment, Government of Iraq, Baghdad, Iraq

## Key messages

- 1 Law affects global health in multiple ways, by structuring, perpetuating, and mediating the social determinants of health.
- 2 Although law has been central to major public health achievements in the past, its capacity to advance global health with justice remains substantially underutilised, particularly among professionals in the fields of health and science.
- 3 The right to health, a legally binding norm, provides a foundation for advancing global health with justice and should underpin health-related legal reforms.
- 4 Every human being has a right to affordable, high quality health services. By embedding equity and accountability in all health systems, the law and the rule of law can achieve health coverage that is truly universal—delivering the Sustainable Development Goals' promise to leave no one behind.
- 5 Although the ability to enforce compliance with international legal obligations is generally limited, and largely dependent on power dynamics and political will, creative mechanisms can foster compliance and help establish impetus for action.
- 6 Law can address the pressing health concerns of the 21st century, across diverse areas. From tobacco control, non-communicable diseases, and road safety, to health emergencies, law can implement fair, evidence-based interventions to save lives. The global health community should champion evidence-based legal interventions and build the research case for legal action.
- 7 Laws that stigmatise or discriminate against marginalised populations are especially harmful and exacerbate health disparities. The global health community must oppose laws that undermine the right to health and to equity.
- 8 To realise the full potential of law to advance global health with justice, the global health community should build legal capacity and establish a sustained dialogue with legislators, regulators, judges, civil society, and researchers.

(Prof A Alwan MD); University of Global Health Equity, Kigali, Rwanda  
 (Prof A Binagwaho PhD); Global Health Centre, Graduate Institute of International and Development Studies, Geneva, Switzerland (G L Burci JD); UNAIDS, Geneva, Switzerland (L Cabal LL.M); DeLand Associates LLC, Geneva, Switzerland (K DeLand JD); Health, Nutrition and Population Global Practice, World Bank Group, Washington, DC, USA (T G Evans MD); School of Medicine, University of California San Francisco, San Francisco, CA, USA (Prof E Goosby MD); Supreme Court of Bangladesh, Dhaka, Bangladesh (S Hossain MA); Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School, Cambridge, MA, USA (A E Yamin JD); Harvard T H Chan School of Public Health (Prof H Koh PhD; A E Yamin), Boston, MA, USA; Global Health and Development, London School of Hygiene & Tropical Medicine, London, UK (Prof G Ooms PhD); National Academy of Sciences of Buenos Aires, Buenos Aires, Argentina (M Roses Periago MD); Dejusticia, Bogota, Colombia (Prof R Uprimny PhD); and Northwestern Memorial Healthcare, Chicago, IL, USA (M DeBartolo JD)

Correspondence to: Prof Lawrence O Gostin, O'Neill Institute for National and Global Health Law, Georgetown University Law Center, Washington, DC 20001, USA [gostin@georgetown.edu](mailto:gostin@georgetown.edu)

Recommendation 2 advises that governments should strengthen or create a legal framework, such as a constitutional or statutory right to health, to ensure rights-based UHC on the basis of principles of equity and non-discrimination, including affordability, financial protection, transparency, accountability, participation, privacy, and sustainable financing.

Legal determinant 2 states that law can strengthen the governance of national and global health institutions. Law can be used to structure and clarify the complex web of institutions, norms, and processes that govern global health. We identify three key governance challenges that undermine coordinated action for health, as well as ways in which law can ensure good governance for health. First, where the mandates of global health actors overlap, conflict, or leave gaps, law can harmonise mandates and provide mechanisms to promote cooperation. Second, innovative legal and governance strategies can foster state compliance and strengthen existing international rules. Third, law can increase transparency, openness, inclusiveness, and accountability. We make two recommendations for action.

Recommendation 3 suggests that the UN, WHO, and international partners should use their respective powers and influence to safeguard the public's health and safety through the creation or adoption of good governance standards, embracing the highest principles of equity, inclusive participation, transparency, and accountability.

Recommendation 4 advises that governments should develop legal frameworks that establish principles of good governance throughout national health systems and policy making, form a country-appropriate mechanism to advise on legal interventions with high health impact, and adopt legislation requiring health impact assessments for policies, programmes, and projects that might seriously affect health.

Legal determinant 3 states that law can implement fair, evidence-based health interventions. Evidence-based laws, effectively implemented and fairly enforced, can create the conditions for good health. We provide a framework for evaluating health laws and identifying those laws that advance health with justice. We offer concrete examples of such laws, across three domains of health: infectious diseases, non-communicable diseases, and injuries. In each domain, we discuss the ways in which international and domestic laws interrelate and inform one another. We also show how laws that are not informed by evidence and human rights could instead undermine health and justice, entrenching inequality and discrimination. We make one recommendation for action.

Recommendation 5 suggests that WHO should increase its legal capacity to enable it to spearhead development of a global evidence-base for public health laws and to support the enactment and implementation of national and global health laws that are effective and sustainable.

Legal determinant 4 emphasises the importance of building legal capacities for health. Strong legal capacities

are a key determinant of progress towards global health and sustainable development. Yet, too often, countries lack either the basic legal infrastructure or the capacity to build it. We make the case for productive, mutually reinforcing linkages between law and health, and identify three aspects of legal capacity-building for health: improving legal environments, growing the evidence-base with high quality effectiveness research, and training key actors in law-making and law-implementing skills. We make two recommendations for action.

Recommendation 6 suggests that governments should build national capacities to enact and effectively implement public health laws.

Recommendation 7 suggests that WHO and *The Lancet* should partner with legal and health experts to create an independent standing commission on global health and the law that would advance the health-related SDGs by proposing evidence-based legal interventions for addressing major global health challenges, reforms of the global health architecture and international law, and strategies to build and strengthen global and national health law capacities.

In making these recommendations, we acknowledge that law reform is a complex and drawn-out process, presenting both technical and political challenges. Achieving global health with justice will require international and interdisciplinary cooperation, as well as leadership at all levels. However, as we underline in this report, law reform holds enormous promise. With the ability to effect real change at the population level, we argue, law should be considered among the key tools of the global health community. By providing insight on the legal determinants of health, our aim is to empower the global health community to strengthen its legal capacity, and to use law more strategically in the pursuit of health and equity. Globalisation has heightened risks to our health, but it also presents unprecedented opportunities to confront global health threats collaboratively, drawing on expertise and lessons learned within and among nation states. No government acting alone can achieve health with justice. Instead, we need laws and policies at every level—local, national, and global—to achieve a world that is healthier and safer.

## Introduction

### Health with justice

Health in the 21st century is being shaped by rapid globalisation. The unprecedented movement of people, money, technology, and ideas around the world is changing the profile of health and disease. Although previous decades have seen substantial reductions in major global risk factors such as unsafe sanitation, and malnutrition, new threats have emerged.<sup>1</sup> Global health hazards nowadays share four important features: (i) health hazards are not bound by borders, ranging from infectious diseases, to non-communicable diseases, and injuries; (ii) they have common underlying causes, such as

dangerous pathogens, unhealthy behaviours, or unsafe environments; (iii) they are exacerbated by inequities linked to the socio-economic determinants of health; and (iv) they require a coordinated, multi-sectoral global response.<sup>2-4</sup> A crucial element of that response will be the strategic use of law at all levels—local, national, and international—resting on stronger cooperation between the legal and health professions. Just as the interdependence of states and people heightens health risks, it also presents unprecedented opportunities to confront global health threats collaboratively, drawing on expertise and lessons learned within and among nation states.

The mission of the *Lancet*-O’Neill Institute of Georgetown University Commission on Global Health and Law (the Commission) is to articulate a compelling vision of the role of law in global health. In this report, we explain key legal concepts, offering important ways in which law can be wielded to advance health and equity—not for an audience of legal scholars, but for the global health community. Although many global health professionals will be familiar with legal measures as an emergency response to health crises, this is only one facet of law.<sup>5</sup> Less well understood is the role of law in governing global health institutions, in resolving disputes, and in health promotion and protection. Even less visible are those uses of law that, while not necessarily designed to affect health, have a profound impact upon it. Understanding these forces, and how to harness them, will be vital to improving population health in the 21st century.

### Law and global health

We define global health as: study, research, and practice with the objective of preventing injuries and diseases and promoting the public’s health, while achieving equity in health for all people worldwide—both within and among states.<sup>6</sup> In adopting this definition, our report builds on the 2014 *Lancet*-University of Oslo Commission on Global Governance for Health (*Lancet*-Oslo Commission), which concluded that “we must no longer regard health only as a technical, biomedical issue, but acknowledge the need for global cross-sectoral action and justice in our efforts to address health inequality.”<sup>4</sup> Global health is infused by the value of social justice, aiming to address gaping health disparities within and among countries.<sup>7</sup> It strives to realise the universal right to health, grounded in international human rights.<sup>8</sup>

Law is a key determinant of health. By law, we mean the statutes, regulations, and rules that express public policy. We also include the public institutions such as legislatures, agencies, and courts in our definition, which are responsible for creating, implementing, and interpreting the law.<sup>9</sup> Law exerts a powerful influence on health by structuring, perpetuating, and mediating the risk factors and underlying conditions known as the social determinants of health:<sup>10</sup> education, food, housing,

income, employment, sanitation, and health care. The impact of law is felt not only in individual decisions (eg, of courts and tribunals) but also in statutes and regulations that operate at the population level (eg, agricultural subsidies, Universal Health Coverage [UHC], or mandatory seatbelt usage). As such, law can be a powerful tool for securing and advancing health and equity. It can be used to set and defend the norms and standards of good health, to establish and strengthen resilient health systems, and to hold actors and institutions accountable.

However, law can also be a formidable barrier to achieving global health and equity. Throughout history, misguided, out-dated, arbitrary, or discriminatory laws have caused great harm. Punitive laws, for example, can discourage marginalised individuals from accessing care, restrict reproductive rights, and enable discrimination in employment or insurance. Whether driven by animus or unsupported by scientific evidence, bad laws can undermine individual and population health, while entrenching inequalities. They can exclude, stigmatise, and inappropriately punish individuals. Furthermore, they can constrict the space for dissent and debate, for an independent press, and for social action. In such cases, law reform is crucial—but often difficult. The process of overturning old national legislation or adopting revised or new treaties often involves bitter and drawn-out struggles. New or better health laws can threaten the interests of powerful actors, including states, businesses, and lobbyists, who will vigorously oppose reform. Even if law reform is possible, once in force, new laws face challenges of monitoring and enforcement, in arenas often characterised by fragmentation and contestation.

### Approach and aims

The Commission views law and health as mutually reinforcing, and urges the legal and health communities to work cooperatively toward a common goal of “global health with justice”.<sup>8</sup> Working together, law reform should afford people “a fair and just opportunity to be as healthy as possible”.<sup>11</sup> Law reform should also seek to eliminate the “systematic and potentially remediable differences in one or more aspects of health across socially, demographically, or geographically defined populations or population subgroups,”<sup>12</sup> as well as inequalities or differences in health that are “avoidable, unfair or [which stem] from some form of injustice”.<sup>13</sup> This vision is expressed in the United Nations Sustainable Development Goals (SDGs), which view health as a key component of a comprehensive, universal development agenda. The SDGs envision “justice for all”, resting on “transparent, effective, and accountable institutions”.<sup>14</sup>

The multiple actors, institutions, and sectors in global health offer great promise to achieve health with justice, but also face steep challenges. Governments and international institutions do not harness the full power of law to improve health and save lives—whether by dismantling barriers or by enacting affirmative reforms to safeguard

population health. Therefore, ensuring that the global health community clearly understands the role of the law, and how best to use it, is imperative. This report makes the case for the power of law to improve health, by informing the global health community about the effects of law on health (through what we describe as the legal determinants of health); exploring real-world case studies, opportunities and challenges; linking the health and legal communities, while building shared capacity (ie, infrastructure and resources); and empowering communities, countries, and global health institutions to use law to advance global health with justice.<sup>9</sup>

The Commission assembled a multidisciplinary team of experts from diverse backgrounds, including law, health, policy, economics, and governance. While reflecting this richness of expertise, our Report sits within the disciplinary tradition of public health law scholarship,<sup>15</sup> and the emerging field of global health law scholarship.<sup>7</sup> Public health law is “the study of the legal powers and duties of the state to ensure the conditions for people to be healthy ... and the limitations on the power of the state to constrain the...legally protected interests of individuals for the common good.”<sup>15</sup> Global health law, as a related field of study, uses a similar analytical orientation, but focuses on the relationship between international law and health.

Law is the primary topic of analysis in our report. Public health law predominantly uses legal doctrinal methods, informed by analytical frameworks from epidemiology and population health. Public health law is beginning to incorporate empirical methods, designed to evaluate the effects of law on public health,<sup>16</sup> and has a strong normative dimension: the view presented in this Commission is that not only is law a powerful tool for achieving global health with justice, but also that law should be used for this purpose. The universal right to health is a core standard against which legal interventions should be assessed.

As the *Lancet-Oslo* Commission powerfully emphasises, issues far removed from the traditional public health context—for example, market forces, income inequality, and global governance structures—have a substantial effect on health. Law stands to influence almost every one of these, meaning that the subject of global health and the law is potentially vast. Therefore, the Commission has had to be selective, and, for this reason, is necessarily limited in scope. Our concept of legal determinants is not the only way to frame the topic. Rather, it reflects the Commission’s views of what constitute the major dimensions of law in global health, in the present era. The Commission has identified areas of law that most directly affect population health, and which lie within the remit of public health authorities. We do not purport to offer a systematic review, but rather to enunciate core legal concepts, building the case for the value of law in global health.

### The legal determinants of health

Our Report begins with a short explanation of relevant legal terms and concepts: discussing where and how

law works locally, nationally, and internationally, and why the rule of law is essential for health, development, and justice. We also describe the main actors in global health. This provides a foundation for our four key legal determinants of health: the areas identified in which stronger, more strategic linkages between health and law could substantially strengthen the overall global health agenda.

The first legal determinant is that law can translate vision into action regarding sustainable development. Law can help to achieve the SDGs’ unifying vision for global health and development. We illustrate the potential of law in advancing the SDGs through a case study on UHC. The second legal determinant is that law can strengthen the governance of national and global health institutions. The field of global health is complex, comprising a web of institutions, norms, and processes at the global, national, and subnational levels. Weak governance undermines leadership and coordinated action for health. Law can strengthen health governance, including transparency, benchmarks, and monitoring, with ongoing evaluation, civil society engagement, and accountability. The third legal determinant is that law can implement fair, evidence-based health interventions. Evidence-based public health laws—effectively implemented and enforced—can create the conditions for healthy populations. We offer key examples of effective laws across three health domains: infectious diseases, non-communicable diseases, and injuries. We also show how law can undermine health and justice. The final legal determinant is that law can be used to build legal capacities and reinforce all the legal determinants of health. All the aforementioned determinants require stronger, mutually reinforcing linkages between law and health. Effective health laws are guided by science and translate the best available evidence on health improvement. Legal capacity building includes stronger legal institutions (legislatures, agencies, and courts), expanding the evidence-base with research evaluating the effectiveness of laws, and training key actors in law-making and law-implementing skills.

In section 6, we offer seven recommendations, drawing on the major concepts identified throughout the report. The recommendations encompass these four legal determinants of health, covering rights-based UHC, good governance standards, fair and evidence-based interventions, and building legal capacity.

### Section 1: the legal system for global health

The concept of law has long been debated among legal scholars, as have modes of interpretation. For the purposes of this report, the Commission proposes a “Primer on Law” intended to be understandable to a public health audience. In this section, we define law and explain how it is created, implemented, and enforced at the domestic and international levels; describe the essential idea of the “rule of law”; articulate the obligations of the state to ensure the conditions for health; and explain how law

functions as a tool to shape health outcomes. Finally, we identify the key actors and institutions in global health.

### What is law? How is it created, implemented, and enforced?

Although not always perceptible, law is all around us. The most common definition of law is a body of norms (or rules of conduct) of binding force and effect, specified and enforced by a recognised authority. Law is used to create rights and duties, which should be applied fairly and consistently throughout society. Once implemented, people experience the effects of law every day, as it shapes their lives through the enforcement of legal standards and accompanying policies. This understanding of law is best illustrated at the domestic level, where the recognised authority is the sovereign state—the supreme authority within that territory. Because nation states have sovereign authority, they can enact and enforce laws. However, no sovereign authority exists at the international level, and the law requires states to agree to the terms of the legal instrument. Even when governments do assent to international agreements, these can be hard to enforce. Nevertheless, international legal norms remain essential for advancing health rights.

Domestic and international law are interrelated and bi-directional in their impact on health and justice. Innovations in domestic law and policy can offer a model for other cities, countries, or regions to follow, or have a global effect; high-impact litigation in one jurisdiction can empower advocates in other jurisdictions to undertake similar action. International law, in turn, influences domestic law and policy by creating widely accepted standards. Domestic legal norms diffuse to other jurisdictions and up to international institutions, while international norms diffuse down to influence local and national laws, regulations, and policies.

#### Domestic law

Law is used to establish norms, rules, and systems. In the health context, these rules should seek to reduce or prevent risks of injury and disease equitably across populations.<sup>17</sup> In addition to imposing obligations on individuals and businesses in a society, law also confers rights; for example, in many countries, every inhabitant has the right to health care and public health services, and to equal justice under the law. The state holds the primary obligation to fulfil these entitlements. Domestic law encompasses the following sectors, each derived from different sources. Constitutions are the highest law of the land. Statutes, regulations, and case law must conform to constitutional norms and principles. Statutes (also called legislation, acts, laws) enacted by legislatures such as Parliament or the Congress express public policy. Regulations, also termed delegated legislation, from executive or administrative agencies safeguard the public's health and safety (legislative bodies typically empower agencies to act). Case law, from courts and other tribunals, interprets and applies

the constitution, statutes, and regulations to specific cases and sets judicial precedent. Beyond individual cases, the effect of case law differs from country to country, depending on its constitutional and legal traditions.

Constitutional law is widely regarded as the supreme law of the land. For the other three sources of law, different jurisdictions might accord them different importance or priority. We use the term “law” to encompass all four sources—each of which can substantially affect health—as well as their interactions.

#### International law

International law does not take the same form as domestic law. The simplest definition of international law is a set of norms or rules generally regarded and accepted as binding, in relations between states and other groups such as international organisations. International law primarily governs the conduct of states but can also substantially affect private parties such as corporations (eg, in relation to trade law) and individuals (eg, in relation to human rights law). Article 38 of the Statute of the International Court of Justice offers the most authoritative statement of the sources of international law, listing three primary sources: treaties, customary international law, and general principles.<sup>18</sup> (panel 1).

Unlike in domestic law, there is no distinct international sovereign authority, and no global government steers international relations and transnational cooperation. Instead, various international institutions such as the UN, WHO, and the World Trade Organization (WTO) have law-making powers or act as forums to facilitate negotiation of treaties by member states. Additionally, states themselves might negotiate bilateral or multilateral treaties or other transnational agreements.

Trade is an example within which various forms of international law are evident. The WTO oversees several multilateral treaties, to which its member states adhere.

#### Panel 1: Sources of international law: treaties, custom, and general principles

Treaties are international agreements (which might also be referred to as conventions or covenants), concluded between states in written form, and governed by international law. However, States must give their consent to be bound—and even if they do so, they might express reservations to exclude or to modify their legal obligations. A country that has ratified or acceded to a particular treaty, and is therefore legally bound by its provisions, is described as a state party. Certain international institutions have law-making power. WHO has adopted two major treaties under its Constitution: the Framework Convention on Tobacco Control (adopted under Article 19) and the International Health Regulations treaty (adopted under Article 21).<sup>18</sup>

Customary international law refers to legal norms that have emerged from general and consistent state practice. Customary law is binding on all states, except those that persistently object.

General principles of law refer to an amorphous body of law that emphasises broad principles recognised in national legal systems such as common law, civil law, or Islamic law (Sharia). Given the proliferation of treaty law, modern tribunals rely less on general principles and consider them to be a secondary source of law.

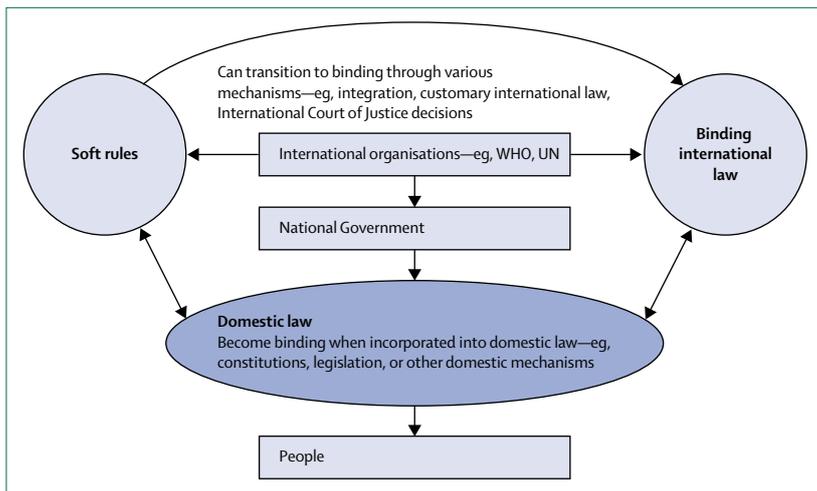


Figure 1: Relationship between domestic and international law

States are also free to negotiate their own trade agreements (FTAs), such as regional compacts (eg, the United States–Mexico–Canada Agreement) or bilateral agreements, which might create additional norms to those found in WTO treaties. Even though these agreements are usually outside the sphere of the WTO, they must be consistent with WTO rules.

In the absence of a sovereign authority and a clear hierarchy of norms and rules, international law faces multiple governance challenges, including ensuring efficient implementation and compliance (see section 3). For example, international human rights are a central goal of many global health organisations and an important commitment for countries. However, states’ compliance with human rights has been highly variable, often undermined by powerful political and economic interests.

Across sectors, contemporary governance is characterised by the increasing use of non-binding instruments adopted with a normative intent. These instruments aim to guide, urge, or discourage particular behaviours. Soft legal instruments, covering a broad range of topics, are known by various terms,<sup>19</sup> and we have chosen to use the term soft rules throughout this report.

The broad category of soft rules includes “any written international instrument, other than a treaty, containing non-binding principles, norms, standards, or other statements of expected behaviour.”<sup>20</sup> Codes of practice, global strategies, declarations and resolutions can all be described as soft rules, as can recommendations, guidelines, and frameworks. UN and WHO resolutions, although agreed through a formal legal process, usually do not create binding legal obligations for member states. However, although not legally binding, these instruments can have practical effects comparable to those of binding law, and are especially important to benchmarking, monitoring, and transparency.

Soft rules have several advantages over formal law. They are usually less costly (in both economic and

political terms) and quicker to negotiate; they can be less rigid, and therefore easier to amend; and they can reflect more ambitious targets. Governments are often more willing to sign up to goals that are framed as targets or declarations rather than obligations.<sup>21</sup> Furthermore, processes to develop soft rules can include a more diverse coalition of actors beyond nation states, including voices from civil society that are traditionally marginalised in treaty negotiations.<sup>22</sup>

The relationship between soft rules and hard law is fluid. Soft rules can form a basis for the development of formal international law, or international governments could adopt non-binding standards into their legal instruments. For example, WTO’s Agreement on Sanitary and Phytosanitary Measures incorporates the non-binding guidelines of the Codex Alimentarius Commission—a collection of internationally recognised standards, codes of practice, and guidelines that apply throughout the food supply chain.<sup>23</sup> The United Nations Political Declaration on the Prevention and Control of Noncommunicable Diseases (September 2011) offers another example of soft rules. Negotiated through the General Assembly, the Declaration contains member states’ commitments to prevent and control non-communicable diseases.

Perhaps most importantly, soft rules can be adopted into domestic law through a nationally sanctioned process (eg, through legislative or judicial decrees). Many soft rules aim for national-level implementation, including the Joint United Nations Programme on HIV and AIDS (UNAIDS) guidance on the prevention and treatment of HIV, and WHO’s guidelines on salt and sugar consumption. Countries have discretion to select which soft rules to adopt domestically. Figure 1 shows the relationship between international and domestic law, including the translation of soft rules into domestic law.

**The rule of law**

To earn and maintain the trust of the public, law makers—including legislatures, administrative agencies, courts, and international bodies—must create, enforce, and interpret the law impartially. These actions are the fundamental precept of the rule of law. Under the rule of law, no individual, business, institution, or government official is above the law: governments and public officials must be held legally accountable to act in the public interest (panel 2).

SDG 16 links the rule of law to development, as a crucial foundation for the creation and maintenance of “just, inclusive and peaceful societies”.<sup>25</sup> In the absence of the rule of law, neither health nor development can be fully realised.

**State obligations to support the right to health**

Governments in virtually every legal system have both the authority and the duty to safeguard the health of the

population.<sup>15</sup> This authority derives from domestic and international norms. Nation states derive their authority through the concept of sovereignty: sovereign governments have sole authority to make laws and regulations regarding the public's health. This principle recognises that certain risks—such as infectious diseases, natural disasters, industrial hazards, contaminated food and water—as well as the measures needed to prevent or reduce those risks, are outside the control of individuals or groups. No individual acting alone can assure the conditions for health and safety; only the State has the power necessary to intervene at the population level, through coordinated action.

Many international instruments, including WHO's constitution and treaties, contain state obligations to safeguard health-related rights. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) from 1966 contains the foundational expression of the right to health.<sup>26</sup> General Comment no. 14 of the Committee on Economic, Social and Cultural Rights (a body comprising 18 independent experts that monitor state implementation of the ICESCR by states parties) interprets and elaborates on Article 12.<sup>27</sup> General Comments offer guidance to states, clarifying treaty obligations and how they should be implemented.<sup>28</sup>

According to the ICESCR and General Comment no 14, the right to health is a “fundamental human right indispensable for the exercise of other human rights”, and “every human is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity”.<sup>29</sup> States have an obligation to ensure available, accessible, affordable, and acceptable health facilities.

The state's primary obligation is to protect the health and safety of its inhabitants, not only citizens and lawful residents, but also asylum seekers, refugees, and undocumented immigrants. Traditionally, states do not have duties toward individuals in other jurisdictions. However, humanitarian law, human rights law, and WHO treaties can imply or even explicitly prescribe transnational obligations. For example, states have a duty not to make, store, or deploy banned weapons (such as chemical weapons), and not to violate fundamental human rights. The International Health Regulations (IHR) contains non-binding language encouraging state parties to help build health system capacities in lower-income states. Soft rules, such as the Pandemic Influenza Preparedness (PIP) Framework, require parties to share novel flu virus specimens and provide reciprocal benefits to other states.

When states act to ensure the public's health and safety, they can impose restrictions on private interests.<sup>30</sup> Public health interventions can constrain personal autonomy, privacy, or liberty, and can limit businesses' economic freedom. Finding a balance between protecting liberties and securing population health is an enduring theme in public health law and ethics.<sup>31</sup> Failing to strike an appropriate balance might result in disproportionate

#### Panel 2: The rule of law

We adopt the definition used by the UN in its 2004 report, *The Rule of Law and Transitional Justice in Conflict and Post-Conflict Societies*:

“A principle of governance in which all persons, institutions and entities, public and private, including the State itself, are accountable to laws that are publicly promulgated, equally enforced and independently adjudicated, and which are consistent with international human rights norms and standards. It requires, as well, measures to ensure adherence to the principles of supremacy of law, equality before the law, accountability to the law, fairness in the application of the law, separation of powers, participation in decision making, legal certainty, avoidance of arbitrariness and procedural and legal transparency.”<sup>24</sup>

personal burdens, especially on marginalised populations. However, often, no conflict exists between individual and collective interests. For example, protecting the rights of individuals living with HIV or AIDS empowers them to access treatment, which both improves their health and reduces the likelihood of transmission. The role of the law, then, is to safeguard the health and safety of individuals and communities, while not restricting personal freedoms more than strictly necessary to fulfil health objectives.

The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights (ICCPR) 1985 guide states in striking the delicate balance between protecting liberties and securing population health.<sup>32</sup> The Siracusa Principles were developed in response to concerns about governments illegally or unjustifiably declaring martial law or a state of emergency to deny fundamental rights and freedoms. The Principles were established to determine when such departures from the ICCPR might be permissible. Restrictions might be justifiable when they are in accordance with the law; based on a legitimate objective; strictly necessary in a democratic society; the least restrictive and intrusive means available; and not arbitrary, unreasonable, or discriminatory.<sup>33</sup> Under international law, the Siracusa Principles are persuasive but non-binding, meaning that states should strongly consider but are not legally required to follow them.

#### Functions of law

Law has numerous functions, many of which directly or indirectly affect health. By “functions of law”, we mean how the law shapes societal interactions.<sup>34</sup> The Commission chose to focus on three crucial functions. Law can be used to establish standards and norms that guide conduct, resolve disputes, and govern public and private institutions. Throughout this report, we draw on these three functions, explaining their relationship to global health.

*Establishing norms and standards in domestic and international law*

In domestic law, the first duty of sovereign states is to protect the health, safety, and welfare of the population. Governments fulfil this duty principally by developing and enforcing rules and standards that structure the physical and social environment, guiding behaviour of individuals and the conduct of organisations. National constitutions typically empower governments to safeguard the public's health and might also allocate responsibilities between states or provinces and the federal government, and between legislatures, agencies, and courts.

In the health context, states set norms and standards using the following powers.<sup>15</sup> The power to tax and spend creates economic incentives (eg, agricultural subsidies) or disincentives (eg, tobacco taxes) for individual and corporate conduct that affects health. The power to alter the information environment and inform the public about the health effects of products (labelling, warnings, health education) or restrict deceptive marketing such as cigarette advertising. The power to alter the socioeconomic environment can create more equitable societies with fairer access to public goods (redistributive taxation, safety nets, and social welfare policies). The power to alter the physical and built environment can improve the quality of water and sanitation in communities, or can create liveable spaces and communities that are conducive to physical activity, including parks, playgrounds, or bike paths. Governments use direct regulation of people, professionals, and businesses to set and enforce rules for numerous purposes—some of these include mandating childhood vaccinations or seatbelts, establishing systems for credentialing and licensing health professionals, or determining standards for motor vehicles or pharmaceuticals.

Indirect regulation through the tort system such as product liability and tobacco litigation creates disincentives for businesses that make and sell unsafe or hazardous consumer products. Finally, legal or regulatory reform provides substantive rights in relation to health and to justice (eg, informed consent, confidentiality, privacy, non-discrimination); or deregulation, in cases where existing laws or regulations impede public health (such as law banning distribution of sterile injection equipment) or stigmatise marginalised communities (such as criminal penalties for engaging in same-sex behaviour).

States could also use inward-facing regulation to improve the machinery of government.<sup>35</sup> States should ensure the good governance rule of law, consisting of inclusive participation, honest stewardship of public resources, and accountability, in addition to strong regulatory capacities. For example, in 2011, the South African Constitutional Court held that the nation's constitution contained an implied governmental obligation to establish an effective anticorruption unit.<sup>36</sup> Inward-facing regulation can also improve the delivery of health goods and services by ensuring a strong,

well-funded health system. Inward-facing regulation is related to the third function of law (governing institutions).

International law also sets norms and standards that have a direct or indirect effect on health and safety, and with which states should, or must, comply. International health-related norms include protecting the child's best interests and capacities,<sup>37</sup> prevention and control of non-communicable diseases, and access to essential medicines.<sup>38</sup> Standards that directly affect health include those for sanitary, which relate to animals; phytosanitary, which relate to plants; environmental pollution levels, and classification of diseases.<sup>23</sup> WHO oversees three major international legal instruments,<sup>39</sup> to which we refer throughout this report. The first is The Framework Convention on Tobacco Control (FCTC), an international treaty and thus legally binding; the IHR, another legally binding treaty; and The PIP Framework, which is not a formal treaty.

Many international rules were not created for a health purpose but have a profound impact on health. International trade rules (including intellectual property agreements), have far-reaching consequences for health. The relevant international regimes, their rules, and their intersection with health are described in the appendix.

Countries often have broad discretion as to how, and to what extent, they conform to international norms and standards. Full conformance often requires states to translate international norms and standards into national legislation. For example, WHO's FCTC (2003) requires states parties to adopt and implement effective national measures to ensure that tobacco product packaging and labelling do not promote tobacco products by false, misleading, or deceptive means.<sup>40</sup> States must act within their own legal systems to comply with international law. However, states retain sovereignty in deciding whether to ratify the treaty and in how they incorporate its requirements into their domestic law.

Domestic law can also provide greater precision than that which is expressed in expansive legal instruments. International health-related rights—such as the rights to health, privacy, and non-discrimination—are enshrined in many regional and domestic legal frameworks, including national constitutions.<sup>41,42</sup> To fully realise the right to health, governments must implement measures through domestic law and regulation (panel 3). Broad international guidance requires detailed national policy making.

*Resolving disputes at national and international levels*

The second crucial function of law is as a tool to resolve disputes between individuals, organisations, and governments. This role of the law can occur in diverse venues, including traditional courts of law, and via alternative dispute resolution mechanisms, such as mediation or arbitration. Although dispute resolution typically involves specific parties, the outcomes can reach well beyond these parties. In the following sections, we examine how two important forms of dispute resolution—strategic national

See Online for appendix

**Panel 3: Case study of legal responses to infectious disease (hepatitis C)**

Despite enormous gains in the treatment of disease, the increasingly globalised nature of the world nowadays has made the spread of infectious diseases across borders a persistent, global public health challenge. In seeking to contain the spread of infectious disease, countries leverage a broad array of tools at their disposal. One important tool is the law, which poses unique challenges and opportunities in its role to help contain infectious disease. The global response to hepatitis C exemplifies some of these challenges and opportunities.

Worldwide, approximately 70 million people live with chronic hepatitis C virus infection.<sup>43</sup> In the last decade, the development of direct-acting antivirals has provided an effective cure in the form of oral, well tolerated treatment regimens for people with chronic hepatitis C virus infection; cure rates of over 95% have been achieved with direct-acting antiviral regimens.<sup>44</sup> Despite the existence of an effective cure, the number of people treated for hepatitis C still remains a relatively small fraction of those infected or diagnosed.<sup>45,46</sup> Patent-related barriers that keep prices high substantially contribute to this problem.<sup>46</sup>

Direct-acting antivirals have a wide range of patents, covering the chemical molecules, manufacturing processes, methods of treatment, and formulations.<sup>47</sup> Patents covering various aspects of direct-acting antivirals prevent the entry of competitors, allowing originator companies to select the price for the market.<sup>48</sup> Although these patents cover a broad range of features, the reality of country-specific patent regimes means that a patent granted in one country might not be granted by, or even filed in another country. In countries where patents are not filed or granted, local production or importation of generics is possible, and the competition from these generics, in turn, drops the price and increases access to the drug. An example of this was observed in Georgia and Morocco;<sup>49</sup> in both countries, primary patents for the direct-acting antiviral sofosbuvir were not filed. As a result, generic companies could produce that drug, enter the market, and decrease the price of the drug.

In countries where patents are issued, another set of options have been utilised by groups and countries to mitigate patent-related barriers. For example, some non-governmental organisations have been attempting to systematically test or undermine patents issued in certain countries to facilitate

competition and access.<sup>46</sup> Many national patent regimes provide the opportunity for third party filings, which serve as a way to register concerns about whether the compound has sufficiently met the requirements of patentability.

Non-governmental organisation attempts to undermine patents have led to the rejection of key patent applications for direct-acting antivirals in Brazil, China, Egypt, and Ukraine.<sup>46,50-58</sup>

Where patents exist and have been unsuccessfully challenged, another option available to groups and countries is voluntary licence agreements. These agreements formalise originator companies' permission to manufacture and sell generic versions of their drug regimens in specific countries or regions. As a result, countries included in originator companies' voluntary licensing agreements are able to access generic direct-acting antivirals from licencees at lower prices.<sup>53</sup> For example, one manufacturer licenced its products to eleven generic manufacturers in India, facilitating the sale of generics in more than 100 countries.<sup>53</sup>

Countries not included in voluntary licence agreements can still increase competition and access by way of other strategies. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),<sup>54</sup> an international legal agreement between all the member nations of the World Trade Organization, acts to constrain actions for countries with respect to patents. However, countries do have the right under TRIPS to grant government use or compulsory licences in certain circumstances.<sup>54,55</sup> In September, 2017, Malaysia became the first country to issue a compulsory licence for a direct-acting antiviral.<sup>46,52</sup> After issuing the licence, Malaysia was then included in the voluntary licence agreement of some manufacturers.<sup>56</sup>

The net effect of this global patchwork of patent laws and policies is, on the one hand, a steep price cut in low-income and middle-income countries, and, on the other hand, a slowly declining price trend in upper middle-income and high-income countries.<sup>46</sup> The former is promising because more than 60% of people with hepatitis C nowadays live in a country that could access generic direct-acting antivirals.<sup>46</sup> However, not all countries that can access more affordable generic treatments do, and, still more troubling, although some competition has altered prices in upper middle-income and high-income countries, high prices of direct-acting antivirals continues to impede access to an effective cure.<sup>46</sup>

litigation and international dispute resolution—have been used in the health context, and how their outcomes have been leveraged as broad public policy tools.

Strategic national litigation is the first important form of dispute resolution. Despite landmark public health litigation—on issues ranging from mental health and tobacco control, to access to medicines—the legal and public health communities continue to debate the strategic value of litigation in pursuit of public policy goals or other systemic change. Litigation is time-consuming, expensive, and technical, with unpredictable outcomes.

Any individual or corporation can bring a court case, potentially furthering private interests inconsistent with the public's health. Corporations can use the courts to overturn or diminish the effect of health and safety laws, or to defend marketing unsafe or unhealthy products.

Moreover, public policy requires balancing competing interests, and courts are generally not well suited to such determinations. In right-to-health litigation, courts are charged with deciding which individuals are eligible to receive a specific health service or product. However, judges have limited facts and perspective: they must

**Panel 4: Litigation as a tool to define the right to health**

In 1991, Colombia enacted a new Constitution followed by a series of reforms intended to extend health insurance to all citizens. The 1991 Constitution enshrined economic and social rights, establishing a Constitutional Court as a specialised tribunal to oversee the new constitutional jurisdiction. This gave individuals the right, when economic and civil rights were not being met, to take the government to court through a writ called a *tutela*.<sup>69</sup> *Tutelas* give citizens an avenue to ensure that the government actively provides for their constitutional rights, including rights to health care.

However, health-related *tutelas* rapidly overwhelmed the tribunal. According to a report by the Human Rights Ombudsman's Office, between 1999 and 2008 there were 674 612 actions for protection of constitutional rights in relation to health issues.<sup>70,71</sup> Additionally, rather than creating a more equitable dispute resolution system for all Colombians, *tutelas* were often exploited by members of the wealthier class.<sup>72</sup> The Colombian Constitutional Court subsequently issued a sweeping decision to improve the equity and oversight of the health system and stem the tide of litigation.<sup>73</sup>

The decision provided necessary definition and limits to the right to health for Colombia. Moreover, the Colombian Court had to carefully assess the practical and financial burden its decision would have on the government. As scholars have noted, "if health-related rights are treated as unconditional and not limited by resource capacity, this can put an unsustainable burden on public insurers and undermine the ability to [act] as wise stewards of public resources through negotiating prices or resisting patent extensions and so forth".<sup>68</sup>

adjudicate according to the parties and evidence in front of them, rather than considering issues at the population level. Are judges better placed to decide on the allocation of scarce health resources than elected officials? When is it appropriate for a court to decide that an individual litigant is entitled to access pharmaceuticals not listed on the government's or WHO's essential medicines registries?

While acknowledging these weaknesses, and others, we believe that well targeted strategic litigation—eg, proceedings that seek systematic change and remedies that extend far beyond the individual litigants—can be effective in advancing public health, complementing other approaches.

Tobacco litigation is perhaps the most familiar example of successful strategic litigation to drive public policy.<sup>57</sup> In the USA, advocates and state attorney generals brought class action litigation against tobacco companies after pursuing numerous other legal and policy avenues. Tobacco control litigation, still in process, has produced two well known outcomes. The first was the 1998 Master Settlement Agreement, which forced tobacco companies to curtail marketing and to make annual payments, in perpetuity, to US states, and the second was the "Tobacco Papers", a vast cache of internal industry documents uncovered in 1994 that revealed duplicitous industry actions such as concealing the harms of tobacco use and the addictiveness of nicotine, and marketing directed toward children and adolescents.<sup>58</sup>

Tobacco litigation has had enduring effects on public health. The litigation exposed the unethical behaviour of industry executives, informed the public of the

devastating dangers of tobacco smoke, and secured industry funds for health promotion. The Tobacco Papers are housed in a public repository, informing subsequent tobacco control measures throughout the world.<sup>59</sup> The FTC emphasises the value of domestic litigation, asking parties of states to share information and strategies.

Strategic litigation can also precisely interpret broad or abstract principles, such as the right to health, leading to improved health care. Litigation on access to anti-retroviral drugs is one area in which notable success has been achieved. In Minister of Health versus Treatment Action Campaign (2002), the Constitutional Court of South Africa held that government limits on the public sector provision of nevirapine were unreasonable and unconstitutional. Nevirapine halves perinatal HIV transmission rates. The Court found that limiting access was a breach of the right to health care, which was not consistent with a positive state obligation to progressively realise the rights of mothers and infants to essential health services.<sup>60</sup> Similarly, the Venezuelan Supreme Court (1999) required the State to provide HIV treatment and to develop social awareness campaigns.<sup>61</sup> In 2000, the Argentine Supreme Court found that the "right to health falls within the right to life...the first natural right of the individual", and directed the government to provide HIV treatment.<sup>62</sup> These cases, along with other right to health litigation, have contributed greatly to social movements.<sup>63</sup>

Controversies in public health litigation have also been reported. Modelled on the cases described above, individuals have increasingly launched health rights litigation around the world on issues including reproductive rights, mental health, and smoking in public places.<sup>64</sup> Notably, this litigation often occurs in the context of democratic failure: litigants turn to the courts because corruption, autocratic practices, and the dominance of powerful interests provide little opportunity for changing policies through the political system.<sup>65</sup> Although gaining traction,<sup>66</sup> the justiciability of the right to health (ie, the question whether or not a court can adjudicate a claim brought on the basis of the right to health) remains a contested issue in many jurisdictions.<sup>64</sup> The long-term effects of litigation on equity and justice are not yet clear,<sup>64</sup> and are dependent on context. For example, one study of litigation in a southern Brazilian state concluded that "judicialization largely serves the disadvantaged who turn to the courts to secure a wide range of medicines."<sup>67</sup> However, in other cases, courts have granted individuals access to expensive medications, some of which have little demonstrated value. When courts override careful policy assessments by the legislature, they might divert resources for health that could otherwise have been used for more cost-effective interventions. Consequently, scholars have noted: "Courts in adjudicating health human rights need to frame the right in the context of

the larger equity and solidarity goals of a public health care system...one danger with a rights-based approach is that it can reinforce the individual demands for high-priced treatments, thus exacerbating the difficulties governments have in running fair and efficient health care systems.<sup>76</sup>

This danger was realised in Colombia, where individuals bringing legal actions known as *tutelas* overwhelmed the public health system in the 1990s and 2000s, requiring a judicial ruling on the limits and definition of the right to health (panel 4).

However, individuals in many of these cases were simply seeking the treatments and other services to which they were already legally entitled.<sup>74</sup> As scholars from multiple disciplines have recognised, there is no inherent conflict between right to health adjudication and efficient and equitable priority setting.<sup>75</sup>

Furthermore, litigation can be time-intensive, costly, and unpredictable, dampening its potential benefits. In the US tobacco litigation, industry defendants imposed enormous delays and high costs over the course of decades and multiple waves of litigation before health advocates eventually gained traction in the courts.<sup>76</sup>

Many industries, including the food, beverage, alcohol, and tobacco industries often use litigation to diminish innovative public health laws. In 2012, tobacco companies successfully halted US Food and Drug Administration (FDA) regulations to mandate graphic warnings. The US Supreme Court found that the FDA rule violated the companies' constitutional commercial speech rights. Industries' use of the commercial speech doctrine has also undermined public health regulations designed to prevent obesity and other non-communicable disease risk factors.

At the international level, multiple dispute resolution systems exist, with varying degrees of effectiveness. The WTO's is among the most robust, with three main stages: first, consultations between the parties; second, adjudication by panels, followed by the Appellate Body; and finally, implementation of the ruling, including countermeasures if the losing party fails to comply. The World Bank's International Centre for Settlement of Investment Disputes (ICSID) offers another venue for transnational litigation. The ICSID is charged with interpreting bilateral or multilateral investment treaties designed to protect industry investments in governments that are parties to those treaties.

The WTO and ICSID, as tribunals, must reach judgment on the individual cases before them and not on their possible implications for public policy. In some cases, they have protected industry interests over the public's health. Tobacco companies have used both ICSID and WTO processes to challenge tobacco control laws in Uruguay (marketing restrictions) and Australia (plain packaging). The ICSID arbitration panel ruled decisively in Uruguay's favour in July, 2016, requiring Philip Morris to pay the costs of the defendant and the court.

In contrast to certain well established dispute settlement systems, WHO's treaty dispute mechanisms are weak. Under Article 27.1 of the FCTC, the parties must try to settle their disputes "through diplomatic channels", using negotiation or mediation. If the parties cannot settle their dispute in this way, the FCTC envisages ad-hoc arbitration with the exclusive jurisdiction of an arbitration panel. However, only three countries have formally agreed to be bound by this arbitration, and the mechanism has never been used.

The IHR (2005), the WHO treaty aimed at global health security, include a dispute settlement process between state parties (Article 56), which is voluntary. State parties should first seek to resolve the dispute through negotiation or mediation, after which the matter might be referred to the Director-General. However, this voluntary dispute settlement system has never been used.

WHO's PIP Framework uses a combination of non-binding norms and legally binding contracts to achieve its aims. The PIP Framework was devised to forge a compromise among higher and lower-income countries on virus sharing and equity. The associated contracts, known as Standard Material Transfer Agreements (SMTAs), are used to bind non-state actors who would not usually be subjects of international law, such as pharmaceutical companies or academic institutions.<sup>39</sup> The SMTAs include a binding arbitration clause: "if a dispute cannot be resolved through negotiations or other non-binding means of the parties' choice, disputes shall be subject to binding arbitration on conditions that are mutually agreed by the parties."<sup>77-79</sup>

Other dispute resolution models beyond international legal instruments include public-private partnerships (PPPs), such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; and Gavi, the Vaccine Alliance, as well as institutions such as the World Bank. These resolution models have rules and regulations related to how grant and loan resources can be used, and how they must be accounted for.

Furthermore, regional and international human rights treaties often have quasi-judicial dispute settlement systems for states that accept to be bound by them, which are available once domestic avenues have been exhausted—for example, the Committee on the Elimination of Discrimination Against Women (CEDAW), a treaty body tasked with monitoring state party compliance with the international Convention on the Elimination of All Forms of Discrimination against Women.<sup>80</sup> Unlike a court, a treaty body does not pass judgments, but monitors compliance and issues recommendations. In 2011, CEDAW heard the matter of *Alyne da Silva Pimental Teixeira versus Brazil*, which concerned human rights violations in the context of maternal mortality. CEDAW recommended reparations for the individual harmed, also recommending that Brazil reduce maternal mortality risks and discrimination against pregnant women. Brazil complied with both aspects of the decision.<sup>81</sup>

**Panel 5: Checks and balances and the rule of law**

The rule of law is central to achieving health with justice, and systems of checks and balances are central to the rule of law. Although checks and balances are often codified, this is not always the case. The World Justice Project notes: “governmental checks take many forms; they do not operate solely in systems marked by a formal separation of powers, nor are they necessarily codified in law. What is essential, however, is that authority is distributed, whether by formal rules or by convention, in a manner that ensures that no single organ of government has the practical ability to exercise unchecked power”.<sup>84</sup>

*Governing public and private institutions*

Finally, law can be used to establish, structure, and oversee public and private institutions. This function overlaps with the first two functions (establishing norms and resolving disputes) primarily with respect to scope and process. Law governs the operations of government institutions that are involved in setting standards (eg, parliaments, administrative agencies, and courts), as well as corporations and non-governmental organisations. We briefly explain how law works to establish, structure, and oversee the key players and organisations in global health.

Laws can establish institutions and define the reach of their activities by setting out institutional mandates. A mandate refers to the explicit, implied, and customary powers and responsibilities of an organisation.<sup>82</sup> A state’s constitution defines the government’s obligations to safeguard the public’s health and to protect personal freedoms and rights. Constitutions often establish branches of government, allocating power among them (and setting limits on those powers), and delineating responsibilities. Statutes establish a country’s key agencies, such as the Ministry of Health, defining its mandate and powers, while allocating funds for its operations. Treaties establish and govern international institutions, such as WHO. The WHO constitution is a legally binding treaty that defines the organisation’s mission, scope of its organisational activities, and the responsibilities of its organs (assembly, executive board, regional and country offices, and secretariat). A corporation’s mandate—that is, the purpose for which the corporation has been established—is set out in its charter or founding documents, such as a Memorandum of Association. Corporations are formed under provincial or federal laws that specify their fiduciary duties, duties to report and pay tax, and other responsibilities. Statutes and regulations can define the activities, structure, and limitations of a not-for-profit organisation with a global health mission. Non-governmental organisations must abide by the legal parameters set for their operation. The proliferation of institutions working in global health has added a new level of complexity, which includes the

overlapping mandates of public, private, and non-governmental organisations, and public–private partnerships. We elaborate on these issues in section 3.

Law also governs processes and institutions by providing systems of checks and balances. The classic example is the checks and balances between the legislative, executive, and the judicial branches of government, which help prevent one branch from dominating. Under this principle of government, “separate branches are empowered to prevent actions by other branches and are induced to share power.”<sup>83</sup> The law specifies the powers of each branch and the ways in which each branch can limit the powers of the others. The actions of legislatures and agencies are often subject to judicial review, but the legislature can override decisions of judges (other than with constitutional rulings). Checks and balances are crucial to the rule of law (panel 5).<sup>84</sup>

However, their robustness depends on institutional design, as well as the legal system and political culture within the jurisdiction.

Although governmental checks and balances provide the classic example, a similar framework can operate within and between public and private institutions, and between institutions making decisions at different levels—eg, national governments can modify the effect of decisions made at the international level. WTO members are required to implement the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) through national legislation recognising and enforcing pharmaceutical patents.<sup>54</sup> However, in many jurisdictions, these intellectual property protections have limited individuals’ access to medicines. In response, governments have devised mechanisms to balance intellectual property protection with greater access to medicines.<sup>85</sup> Therefore, national legislation on medicines procurement or patentability criteria, as well as TRIPS flexibilities, have sought to expand social goals, while recognising private rights.<sup>86</sup> Yet further scope remains for countries to use the flexibilities that TRIPS provides to enable greater access to medicines.<sup>87</sup>

Non-state actors can also provide a check on unreasonable exercise of government power. Civil society organisations are instrumental in demanding transparency and accountability from governing institutions. Non-state actors have a powerful voice in pushing governments and international institutions to use their legal tools in a manner that promotes justice and human rights, such as by protecting marginalised or disadvantaged populations. For example, advocacy on HIV has spurred government action around the world, ranging from research funding through to expanded treatment access.<sup>88</sup> Whether at the grassroots level or internationally, participation by non-state actors and civil society organisations in governing processes increases the legitimacy, transparency, justice, and democracy of such processes.

### Key players in global health

National public health agencies and intergovernmental institutions dominated the global health landscape for decades. Although these actors remain central, the landscape is changing rapidly: new institutions are proliferating, and traditional structures of power and control are evolving (see section 3). Many of these key players do not have the power to make law, but all are subjects of law. They are parties to contracts, disputes, or rules of various kinds, and they can use their influence to either encourage or impede legal reforms.

#### Nation states

Nation states remain the major force in the global governance system. The nation state is “the fundamental building block of the global polity ... [and] the primary authority for the negotiation of global rules.”<sup>84</sup> Compared with other actors, nation states have the broadest range of powers, with the sovereign power to directly govern and regulate health. While health ministries continue to oversee most public health policy making, laws made by multiple different agencies—across sectors such as agriculture, commerce, transport, and the environment—can profoundly affect health outcomes.

Moreover, nation states make up the membership of intergovernmental organisations, with a seat at the decision-making table. The major intergovernmental institutions include UN agencies and programmes, regional organisations, and economic policy forums such as the G7 and G20. Nation states also have a high degree of influence through their overseas development aid programmes, and through bilateral or multilateral cooperation.

#### International organisations

The UN is the primary international organisation. The UN system is charged with ensuring international cooperation, including promotion of health and human rights. UN organs and agencies have historically engaged in global health work. The WHO, formed in 1948, was the first specialised UN agency, and, under its constitution, has the primary mandate for governing global public health. For many decades, WHO remained the preeminent, if not the sole, institution in the global health space. The WHO has robust legal powers to govern global health and to encourage action among countries, including powers to make international treaties in the form of conventions and health regulations. However, many other UN bodies operate in the arena of global health, including the Food and Agriculture Organization (FAO, which has treaty-making powers)<sup>89</sup> the UNDP, UNICEF, the UN Population Fund (UNFPA), and UNAIDS,<sup>90</sup> all of which can influence both national and global health law.

Other multilateral organisations exert a substantial indirect influence on the legal and economic dimensions of global health. Of importance are the WTO and the

Bretton Woods institutions. The WTO’s mission is to “open trade for the benefit of all”.<sup>91</sup> WTO members must commit to certain legal obligations in fulfilling this mission, such as enacting strong protection for intellectual property. This may create access barriers for health services or impede public health policy by increasing the cost of essential medicines.<sup>92</sup>

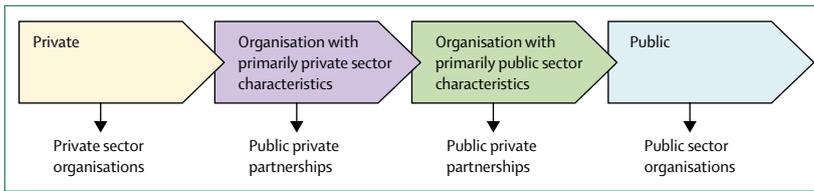
Established in 1944 with an initial mission of post-World War II reconstruction, the Bretton Woods institutions are the World Bank and the International Monetary Fund (IMF). They shape the global health landscape through their financial and economic support for global health and development. The World Bank provides financial and technical assistance to developing countries to foster income growth and end extreme poverty.<sup>93</sup> Since the 1970s, its loans and grants have supported a range of development priorities, including health. During 2000–16, the World Bank invested US\$35 billion in health, nutrition, and population.<sup>94</sup> In the aftermath of the Ebola epidemic in west Africa, the Bank has focused on global health security.

The IMF is an intergovernmental institution comprising 189 member countries, with a mission “to ensure the stability of the international monetary system”.<sup>95</sup> Their work includes lending and capacity development, and when providing support (or bail-outs) to countries in financial difficulties, the IMF’s assistance might be accompanied with conditions such as deregulation or reduced health spending.<sup>4,96</sup>

#### Non-state actors

Just as public health at the national level is no longer the sole purview of health ministries, WHO has now been joined by an “explosion of actors in the global health arena”.<sup>97</sup> Non-state actors—notably philanthropies, hybrid PPPs, and civil society organisations—have become crucial to the development, influence, and funding of global health initiatives. Through financial resources as well as social mobilisation and advocacy, these organisations wield considerable influence and can use that influence to drive legal change. Corporations, including in the tobacco, alcohol, food, and beverages sectors, can have negative effects on health. The private sector also works to improve health outcomes, providing funds but also expertise and personnel in response to specific needs such as health emergencies. For example, during the 2013–14 Ebola outbreak, companies provided logistics, communications, and transportation, as well as operating treatment units.<sup>98,99</sup>

Private philanthropic organisations are non-state actors that have become major funders of global health. The Bill & Melinda Gates Foundation is the single largest donor of discretionary funds to WHO.<sup>100</sup> This Foundation has a strong focus on technical solutions to global health challenges, investing in vaccines (eg, HIV, polio, and malaria) as well as family planning, nutrition, and maternal and child health.<sup>101</sup> The Rockefeller Foundation



**Figure 2: The public-private partnership continuum**  
Adapted from National Academy of Sciences, Engineering, and Medicine,<sup>105</sup> by permission of The National Academies Press.

is an older, more established philanthropic foundation with a long history in public and global health, which champions UHC. Other examples of philanthropic foundations include the Clinton Foundation working on HIV and AIDS, Bloomberg Philanthropies working on tobacco control and liveable cities, Mundo Sano working on neglected tropical diseases, the Children’s Investment Fund Foundation working on child health and poverty, and the Fundación Carlos Slim, working for health, justice, and community development.<sup>7,102–104</sup> Other prominent philanthropies include The Arab Gulf Programme for Development, working on poverty alleviation, human development, and human rights; the Aga Khan Foundation, addressing human development and strengthening civil society organisations; and the Sasakawa Memorial Health Foundation, working on leprosy, and rights of people with disabilities.

A defining feature of the global health governance landscape is the rise of PPPs: hybrid structures made up of non-state actors (eg, businesses, philanthropies, and civil society organisations) working jointly with governments and health agencies. These partnerships have both economic and legal dimensions. PPPs respond to the desire of funders to exercise greater control over the use of their resources, and to bypass bureaucratic and governance barriers in the UN system. Institutions established as PPPs often have a specific mandate, with control and influence shared by the public and private partners. They exist on a continuum, in which some are more public in nature (eg, largely financed funding agencies that include private actors on their boards), whereas others are closer to private institutions—eg, entities working closely with the private sector to accelerate research and development (figure 2).<sup>105</sup>

The largest PPPs operating in global health include the Global Fund to Fight AIDS, Tuberculosis and Malaria; and Gavi, the Vaccine Alliance. Unitaid is a PPP that invests in innovations to prevent, diagnose, and treat HIV, tuberculosis, and malaria. The Coalition for Epidemic Preparedness Innovations is among the newer PPPs, working to galvanise the development of new vaccines against diseases with pandemic potential. In 2016, the US National Academy of Sciences found that PPPs could deliver “improved responsiveness and accountability to society and...better outcomes in shorter timeframes.”<sup>105</sup>

Civil society organisations—primarily non-governmental organisations—have long been influential in

global health as advocates for research and treatment, and for human rights. Among the most well known non-governmental organisations are Médecins Sans Frontières, CARE International, the International Red Cross and Red Crescent, Oxfam International, Save the Children, Rotary, and Caritas. Many of these civil society organisations work primarily in the humanitarian and development sectors, and as first responders to health emergencies (eg, in natural disasters, epidemics, and war zones).

Other civil society organisations, such as the Center for Reproductive Rights, focus their efforts (including leveraging the law) on advancing international health and human rights. There are also civil society organisations at the country level undertaking grassroots social mobilisation and advocacy, such as the Treatment Action Campaign (HIV) and Section 27 (the right to health) in South Africa, and the Center for Health, Human Rights and Development in Uganda. Patient rights groups have also been powerful advocates for government policy, legal change, and funding, including in relation to HIV, tuberculosis, and Alzheimer’s disease, as have professional and scientific associations and networks such as the American Heart Association and the International Council of Nurses. Although these rights groups are often left out of formal global diplomacy, civil society organisations can be an influential voice for human rights and the right to health, especially domestically, as well as in multi-partner alliances such as the Framework Convention Alliance on Tobacco Control.<sup>106</sup>

Section 1 provided an introduction to the legal system for global health, including explanations of three key functions of law and the key players. We now turn to the substantive ways in which law can affect health and justice, which we characterise as the legal determinants of health.

### Section 2: legal determinant 1

The first legal determinant can be used to translate vision into action on sustainable development. This determinant relates to the power of law to channel the SDGs’ unifying vision for global health into concrete action. We first briefly describe the SDGs’ agenda for global health. Because UHC is so crucial to the future of global health, we present a case study showing how law can advance the SDGs’ bold vision of health and justice. We examine the legal foundations of UHC, as well as legal mechanisms for its implementation.

### The SDGs and global health

Adopting the 2030 Agenda for Sustainable Development in September, 2015, the UN General Assembly articulated a transformational vision: “We envisage a world free of poverty, hunger, disease and want, where all life can thrive. We envisage a world free of fear and violence. A world with universal literacy. A world with equitable and universal access to quality education at all levels, to

health care and social protection, where physical, mental and social well-being are assured. A world where we reaffirm our commitments regarding the human right to safe drinking water and sanitation and where there is improved hygiene; and where food is sufficient, safe, affordable and nutritious.<sup>114</sup>

Member states promised to rigorously implement this agenda, which comprises 17 goals (the SDGs) and 169 targets, by 2030. They replace the Millennium Development Goals (MDGs), while building on their success, expanding their scope, and highlighting unfinished business. Committing to “leave no one behind”, the SDGs articulate an equity agenda, developed through a crosscutting multisectoral strategy involving a consultative, grass-roots process.<sup>107</sup>

#### *Health in the SDGs*

Although the MDGs included several health-specific goals,<sup>108</sup> the SDGs have a single unifying health goal. Goal 3, supported by 13 targets, aims to “ensure healthy lives and promote well-being for all at all ages”.<sup>109</sup> Referencing the millions of preventable deaths, including deaths of children and childbearing women, goal 3 states: “these deaths can be avoided through prevention and treatment, education, immunization campaigns, and sexual and reproductive healthcare. The Sustainable Development Goals make a bold commitment to end the epidemics of AIDS, tuberculosis, malaria and other communicable diseases by 2030. The aim is to achieve UHC, and provide access to safe and affordable medicines and vaccines for all. Supporting research and development for vaccines is an essential part of this process as well”.<sup>109</sup>

Several other SDGs directly relate to the conditions needed for healthy people and healthy communities. For example, goal 2: “end hunger, achieve food security and improved nutrition and promote sustainable agriculture”;<sup>110</sup> goal 5: “achieve gender equality and empower all women and girls”;<sup>111</sup> and goal 6: “ensure access to water and sanitation for all”.<sup>112</sup>

Virtually all other goals include targets that relate directly or indirectly to health, such as: targets 4·2 (access to early childhood development and care); 7·1 (affordable modern energy services); 11·6 (adverse environmental impact of cities, with special emphasis on air pollution); 13·1 (climate related hazards and natural disasters, and related mortality); 16·1 (reducing violence-related deaths); 16·9 (legal identity for all, including birth registration); and 17·19 (measuring statistical capacity-building, including the registration of births and deaths).<sup>14</sup>

#### *Justice in the SDGs*

At the core of the SDGs’ vision is equal and universal access to health care and justice, with an emphasis on their interrelationship. For example, goal 3 aims to “ensure healthy lives and promote well-being for all at all ages”,<sup>109</sup> and includes targets such as achieving UHC

(target 3·8).<sup>109</sup> Goal 3 also relies on the concept of justice in its targets. Target 3·b focuses on building support for “research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries”.<sup>109</sup> This goal relies in part on concepts of justice embodied in transnational legal agreements, such as the Doha Declaration and the Agreement on Trade Related Aspects of Intellectual Property Rights.<sup>113</sup> Furthermore, goal 16 aims to “promote just, peaceful and inclusive societies”, and calls for “access to justice for all, and building effective, accountable institutions at all levels”.<sup>113</sup> A goal 16 target promotes “the rule of law at the national and international levels”, ensuring “equal access to justice for all”.<sup>114</sup> This formalises a longstanding understanding that the pursuit of justice is an essential ingredient of sustainable development.<sup>115</sup>

#### *The role of law in realising the SDGs*

With health linkages throughout the SDGs, the potential to advance health through realising the SDGs is vast. However, the ability of law to achieve this remains largely untapped and requires an enhanced understanding and recognition of how best to use law in different SDG areas. For example, climate change—which threatens the health SDGs and many others—is directly addressed in SDG 13, and is an area where the use of law is robust (eg, UN Framework Convention on Climate Change, the Paris Agreement, carbon taxes, and renewable energy incentives). However, the use of law specifically to address the interaction between health and climate change is less well developed and is an important agenda item for the future.

The SDGs and their targets give greater specificity to the broad principles expressed in the right to health. Going well beyond health-care services, they encompass the multiple conditions needed for health and safety throughout the lifespan. In turn, law can help give these goals tangible effect, moving the question from “what is sustainable development?” to “how can sustainable development be achieved?”<sup>116</sup> Governments use all three functions of law to establish the frameworks of authority needed to move from principles to actions. In relation to the SDGs, laws are essential to enshrine the right to health in national policy and to oversee the quality of health professionals and hospitals through licensing and accreditation (eg, establishing norms and standards); to adjudicate disputes between individuals, health providers, and the State (eg, resolving disputes); and to establish new institutions with a specific or broad health mandate (eg, governing institutions).

Regarding a broad, aspirational statement like SDG 3 (“ensure healthy lives and promote well-being for all at all ages”), law can provide detail and accountability. What does the concept of healthy lives mean? Who is obligated to ensure the conditions for health and safety? Through what mechanisms will they do so? To what standards will they be held? How will they be held accountable for good

performance? UHC offers a good illustration of the way in which law can translate vision into action on sustainable development. In the next section, we use UHC as a case study to identify the ways in which law functions both to lay the foundations for, and to implement, health for all.

#### Case study: law as a tool to achieve UHC

##### *UHC as a crucial component of sustainable development*

Nationally and globally, there exist profound differences in health outcomes, the socioeconomic determinants of health, and the availability and affordability of quality health services. The WHO and the World Bank both estimate that at least half of the world's population cannot obtain essential health services.<sup>117</sup> The most glaring inequities in health outcomes often correlate directly with unequal access to health services: service coverage is often poorest where needs are greatest.<sup>118</sup> These inequities occur both between countries (healthy life expectancy is 44·4 years in Sierra Leone, compared with 74·9 in Japan)<sup>119</sup> and within countries (ethnicity, geography, and socioeconomic status can greatly reduce the accessibility and quality of health care).<sup>120</sup> For example, in Australia, life expectancy for Aboriginal and Torres Strait Islander men born from 2010 to 2012, was 10·6 years lower than that of non-Indigenous men. The discrepancy for women was nearly as wide at 9·5 years.<sup>121</sup> The WHO views UHC as among its highest priorities.<sup>8,117,122–125</sup> In 2005, the 58th World Health Assembly (WHA) adopted a resolution for sustainable health financing, universal coverage, and social health insurance, calling on countries to plan for the transition to UHC.<sup>126</sup> Since then, UHC has become a global priority and a central element of WHO's efforts to strengthen health systems and improve the quality and distribution of health and health services.<sup>127–129</sup> With the UN General Assembly adopting the SDGs in September, 2015, UHC became a global target, which will be reinforced by the UN high-level meeting on UHC in 2019.<sup>130</sup> SDG 3.8 views UHC as “financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”.<sup>113</sup> SDG 3.8, if fully implemented, would help realise the universal right to health.

##### *Definition and basic principles*

UHC does not have a uniform definition and its variable meanings have created uncertainty. The World Bank offers a broad, conceptual framing: “UHC is about people having access to the health care they need without suffering financial hardship.”<sup>131</sup> WHO gives a more detailed definition, noting: “UHC means that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.”<sup>132</sup>

WHO emphasises equity in access to health services (everyone who needs services should get them, not only those who can pay for them); the quality of health services; and protection against financial risk—ensuring that the cost of using services does not put people at risk of financial harm, so that people's ability to pay is not linked to their ability to access health services.

UHC has been defined as a practical expression of the right to health,<sup>133</sup> drawing together all the health-related SDGs. However, it focuses primarily on access to and provision of health care, whereas the right to health is considerably broader, embracing multiple conditions for healthy and safe lives, such as potable water, nutritious and safe food, adequate housing, and clean air.

Health systems range from national health systems with single or multiple payers, to government subsidised access, to public or private insurance; therefore, no single path exists to UHC.<sup>134</sup> However, countries embracing UHC tend to consider health a basic human right, often enshrined in their national constitutions or laws. Since 2010, over 100 countries have sought technical guidance from WHO and the World Bank to move towards UHC.<sup>135</sup> Countries representing half of the world's population (Brazil, China, India, Russian Federation, and South Africa) are engaged in health system reforms to extend service coverage and increase financial protection.<sup>135</sup>

Although UHC often faces political resistance because of cost, the World Bank regards it as high value for money.<sup>134</sup> UHC brings direct benefits such as improved population health and more productive societies.<sup>136</sup> Health coverage also contributes indirectly to development, as healthy children learn better,<sup>137,138</sup> and healthy populations facilitate economic growth.<sup>139,140</sup> Furthermore, studies show that for every dollar spent on key health services, the direct and indirect benefits would exceed costs by a factor of between 9 and 20, further showing the benefits that arise from investing in health.<sup>3</sup>

##### *Legal foundations of UHC*

The duty to provide UHC derives from two sources of law: national and international.

Regardless of a government's motivation for pursuing UHC, the legal foundations remain the same in that a state has the sovereign duty and authority to safeguard the public's health and safety.<sup>15</sup> The State's duty and power to implement UHC derives from its constitution or legislation. For example, Thailand's constitution, promises that “health is considered as an entitlement of Thai citizens and equal access to basic health services should be guaranteed.”<sup>141,142</sup> Brazil's Constitution likewise recognises health as a social right.<sup>86,143</sup> In other jurisdictions, national public health legislation provides the mandate for UHC.

A legal right to health services is important but not sufficient. Governments must abide by the rule of law to develop, implement, and adjudicate a UHC framework. If the rule of law is weak, it will be difficult to engage

other legal mechanisms to achieve not only UHC, but also more basic tasks of governance. If public officials or health professionals are corrupt, it will be difficult to garner the resources and ensure the equity and functionality of UHC.

International law creates robust obligations to safeguard the right to health, strengthening states' domestic duty. The ICESCR (Article 2.1) requires states parties to: "take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures"<sup>26,144</sup>

Specifically, under Article 12, states parties "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", and undertake to take steps on concrete health goals, including the "prevention, treatment and control of epidemic, endemic, occupational and other diseases".<sup>26,144</sup>

As described above, the UN Committee on Economic, Social and Cultural Rights offered an authoritative interpretation of "the right to the highest attainable standard of health" in General Comment 14.<sup>29</sup> Beyond the ICESCR, many treaties safeguard health rights, including non-discrimination in access—for example, the UN Convention on the Rights of the Child, the Convention on the Elimination of all Forms of Discrimination Against Women, and the Convention on the Rights of Persons with Disabilities. Even though states may be parties to different treaties, the overwhelming majority of countries are party to at least one treaty that embodies the right to health, making it a virtually universal standard.

Human rights treaties place the primary responsibility for ensuring the right to health on governments. Yet, governments are also obligated to provide international assistance to protect and promote the right to health, for example under article 2(1) of the ICESCR. The concept of shared responsibilities for health has a "solid textual foundation".<sup>42</sup> The Office of the UN High Commissioner for Human Rights (OHCHR) guidelines on maternal morbidity and mortality and human rights, the UNAIDS and OHCHR guidelines on HIV and AIDS and human rights, and the Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights all confirm the international obligation to provide assistance on UHC. Furthermore, the UN Special Rapporteurs on the Right to Health have been clear on the obligations of states in so-called hard law and soft rules.<sup>145</sup>

Because states hold the primary responsibility to create and maintain UHC, many argue that gaping inequalities between countries are beyond legal remedy. We reject this proposition. The international community holds a responsibility to reduce health disparities, and international health assistance will remain an important funding source. Low-income and middle-income countries do need to

devote a higher percentage of their gross domestic product (GDP) into health systems, but still might be unable to afford the estimated US\$86 per capita (2012) required for UHC, and \$112 per capita (2014) to achieve the health SDG.<sup>146,147</sup> The first Special Rapporteur on the Right to Health, Paul Hunt, observed that "if there is no legal obligation underpinning the human rights responsibility of international assistance and cooperation, inescapably all international assistance and cooperation is based fundamentally upon charity. While such a position might have been tenable 100 years ago, it is unacceptable in the twenty-first century."<sup>148</sup>

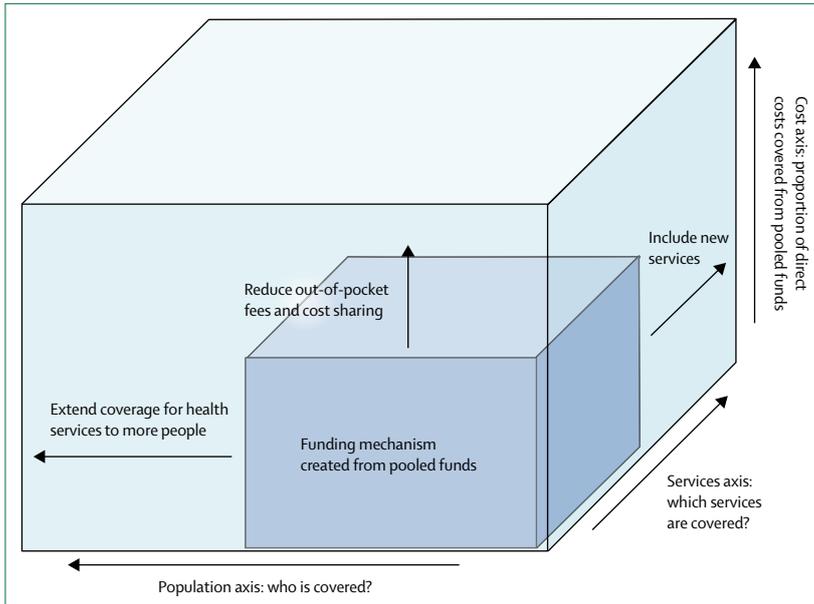
Although there is a strong ethos of charitable discretion in international health assistance, sustainable funding requires a mutual sense of responsibility between those providing and those receiving assistance.<sup>149</sup> Otherwise, the international system creates a situation in which governments can blame each other for not doing enough.<sup>150</sup> Moreover, in low-income countries, or those with unstable governments, weak health systems can exacerbate vulnerabilities leading to extremism and violence.

Development assistance for UHC is essential to global security—both health security and human security. In this regard, countries have existing commitments: under the UN Charter (to cooperate in achieving the universal observance of human rights) and the ICESCR (to provide international assistance and cooperation). Therefore, establishing an international legal or regulatory framework to clarify the obligations of international health assistance would be appropriate. Under such a framework, countries could, for example, agree to devote a percentage of their GDP towards national UHC, while higher-income countries agree to fill financing gaps through international development assistance for health.

#### *The role of law in achieving UHC*

Law provides both the mandate for UHC and the tools to achieve it. However, although the mandate is universal (based on the right to health) the means of realising UHC differ from country to country, depending on the legislative and regulatory mechanisms available, as well as policy choices. These mechanisms and choices will affect each of the crucial measures of UHC: access, equity, quality, cost, and choice. All these measures are important, but they also entail subtle or overt political choices or trade-offs. For example, universal access to high quality services, equitably distributed, has substantial economic costs. If governments place a high value on individual choice in the private market, this will affect measures such as access, equity, quality, and cost.<sup>151</sup> States, of course, are not entirely restricted in the ability to make trade-offs: their actions are constrained, at the very least, by their human rights obligations—especially the right to health.

In its report about health systems financing, WHO noted, "all countries must make choices and trade-offs, particularly in the way that pooled funds are used".<sup>152</sup> The trade-offs inherent in realising UHC are often depicted as



**Figure 3: Universal Health Coverage cube**  
Adapted from WHO,<sup>152</sup> by permission of World Health Organization.

a cube (figure 3), in which the X-axis depicts the population (who is covered?), the Y-axis depicts the cost (the proportion of direct costs that are covered from pooled funds, that is, prepaid funds from different sources that are accumulated and used to cover everyone who is part of the pool, such as the entire population), and the Z-axis depicts the services covered. Moving closer to universal coverage means expanding the cube: extending coverage to more people, including the marginalised and vulnerable; offering more services to meet essential health needs; and paying a greater part of the cost, thereby protecting citizens from impoverishment.<sup>152</sup>

Increasing coverage also requires good governance, and an understanding of both the documented and practical gaps in UHC: the possible “bottlenecks and weaknesses that prevent health systems from serving the entire population and from providing the full suite of priority services at a cost that is affordable and sustainable.”<sup>786</sup> Crucially, UHC must be understood as effective, affordable access to quality health services (UHC in practice)—and not merely covering everyone with some form of insurance, regardless of whether they can in fact access quality health services (UHC on paper). Effective access, particularly for those with the least means, will not only depend on how health systems are designed (eg, strengthening primary health services), but also on how health insurance systems are designed. Legal strategies relating to each axis of the cube (figure 3), in addition to good governance, are further discussed.

The X-axis, or, the population axis, describes who is covered. The term “universal” in UHC relates to a state’s duty to provide health services to all people under its jurisdiction. Without adequate legal frameworks to

support it, so-called universality might be no more than an aspiration, doing little to change “policies under which many governments either deliberately or passively refuse to grant access to health services to some people living within their national borders”.<sup>153</sup>

Governments often exclude a wide swath of vulnerable people from high quality services, including asylum seekers, refugees, undocumented immigrants, expatriate workers, indigenous peoples, nomadic people, or groups that are historically marginalised because of sexual orientation, gender identity, sex characteristics, disability, political beliefs, or religious affiliation.<sup>153,154</sup> These populations are often already vulnerable, and least able to afford out-of-pocket health care expenditures; they are precisely the groups a UHC system should aim to cover. For example, in Rwanda, households are means-tested on their assets and revenue and stratified accordingly. The government then pays premiums for the 25% of the population who have been classified as the most vulnerable.<sup>155</sup>

The law should inclusively define the meaning of the term universal in a country’s UHC scheme, as well as providing redress in cases of discrimination or service denial. This can be achieved by enshrining the right to health in a country’s constitution or legislation;<sup>152</sup> establishing a patient charter of rights that defines the right of access to the scheme, along with a dispute resolution system to deal with complaints by those who are denied health services to which they are entitled;<sup>86</sup> empowering a health-care ombudsman or health-care commission with powers to investigate breaches of the State’s duty to provide health services; decentralising or devolving health systems management, so that people can access services (including dispute resolution) at the local level, without having to travel; regulating the way in which health insurance schemes (public and private) deal with membership and coverage, such as banning insurers from discriminating against individuals with pre-existing conditions and requiring coverage of essential services such as vaccines, primary care, nutrition services, and child and maternal health; and ensuring statutory protection for the security, privacy, and confidentiality of health information.<sup>86</sup>

The Y-axis, or, the cost axis, describes financing in UHC. Governments express genuine concerns about financing UHC.<sup>152</sup> Full funding entails developing health systems that can deliver all required health services that are of good quality and readily accessible to the whole population. Sustainable financing can involve one of two strategies. Governments can allocate more of their overall budget to health—for example, at least 5% of GDP.<sup>156,157</sup> Alternatively or in addition, they can find new ways to raise revenue, whether by improving general tax administration and collection, increasing existing taxes, or introducing new taxes.<sup>152</sup>

States can raise revenue for UHC in a variety of ways. In countries with a longer history of UHC, funds are

traditionally raised through compulsory pre-payment schemes, such as taxation, compulsory insurance contributions, or a combination of both.<sup>86</sup> Conversely, low-income and lower-middle-income countries that have moved towards UHC are using novel mixes of funding mechanisms for their national health insurance models.<sup>158</sup> These include general taxes, earmarked taxes (eg, raised from taxing unhealthy products such as tobacco, alcohol, sugary beverages, or from airline taxes—a key source of financing for Unitaid), payroll deductions, household premium contributions, and in some cases, foreign assistance (eg, about half of the financing for South Africa's UHC programme comes from the US President's Emergency Plan for AIDS Relief).<sup>134,158,159</sup> However, countries should not overly rely on international health assistance because it can be inconsistent and unreliable, impeding the government's ability to plan for and finance its health system over the long term. Additionally, donors often give preference to their own special areas of health need, which might not match what the host population needs.

Moreover, countries should generally avoid voluntary schemes (those in which people are not required to purchase insurance) as these schemes are not effective ways to achieve UHC. Increasing—or, particularly in the case of sugary beverages or other categories of unhealthy foods, initiating—taxes on unhealthy products is a particularly promising route, which creates a direct, positive health effect while also raising revenue (panel 6).

Each of these mechanisms can raise legal issues. For instance, donor funding is often underpinned by international agreements with donor countries or organisations—eg, World Bank or Global Fund payments come with clear contractual conditions. Moreover, UHC programmes that combine public and private funding for health raise governance challenges, underlining the need for appropriate and robust oversight and regulation of coverage plans. For example, the Insurance Regulatory Authority in Kenya regulates insurers, including licensure, quality assurance, and consumer protection and education.<sup>161</sup> Earmarking (also known as hypothecation) can be a useful way to raise revenue and target behavioural health risks, as in the case of tobacco taxes that are earmarked for health spending. However, existing laws may prohibit the use of earmarking, and the practice is seen as contentious because it constrains fiscal policy making.

Furthermore, at each stage of the financing process (from revenue raising, to pooling, to the purchasing of services by providers and governments) regulation plays an important role in ensuring funds are allocated fairly and transparently.<sup>86</sup> Regulatory agencies are often empowered to require full disclosure of finances, and can oversee the efficiency and honesty of funding flows.

The Z-axis, termed the services axis, determines which services are covered in UHC. Health financing also concerns “the efficiency, equity, and effectiveness of the ways in which resources are raised, pooled, allocated, and

#### Panel 6: Policy options that involve the use of law and regulation, from WHO's menu of policy options on non-communicable diseases<sup>160</sup>

##### Tobacco use

- Increase excise taxes and prices on tobacco products
- Implement plain or standardised packaging and large graphic health warnings on all tobacco packages
- Enact and enforce comprehensive bans on tobacco advertising, promotion, and sponsorship, including cross-border advertising and using modern means of communication
- Eliminate exposure to second-hand tobacco smoke in all indoor workplaces, public places, public transport, and in all outdoor mass-gathering areas
- Provide cost-covered, effective, and population-wide support (including brief advice, national toll-free quit line services, and treatment for addiction) for tobacco cessation to all those who want to quit smoking
- Implement measures to minimise illicit trade in tobacco products

##### Harmful use of alcohol

- Increase excise taxes on alcoholic beverages
- Enact and enforce bans or comprehensive restrictions on exposure to alcohol advertising (across multiple types of media)
- Enact and enforce restrictions on the physical availability of retail alcohol (via reduced density of retail outlets and reduced hours of sale)
- Enact and enforce drink-driving laws and blood alcohol concentration limits via sobriety checkpoints
- Establish minimum prices for alcohol if applicable
- Enact and enforce an appropriate minimum age for purchase or consumption of alcoholic beverages
- Restrict or ban promotions of alcoholic beverages in connection with sponsorships and activities targeting young people

##### Unhealthy diet

- Reduce salt intake through the implementation of front-of-pack labelling
- Eliminate industrial trans fats through the development of legislation to ban their use in the food chain
- Reduce sugar consumption through effective taxation on sugar-sweetened beverages
- Implement subsidies to increase the intake of fruits and vegetables
- Replace trans fats and saturated fats with unsaturated fats through reformulation, labelling, fiscal policies, or agricultural policies
- Limit portion and package size to reduce energy intake and the risk of becoming overweight or obese
- Implement nutrition labelling to reduce total energy intake (kcal), sugars, sodium, and fats

##### Physical inactivity

- Ensure that macro-level urban design incorporates the core elements of residential density, such as connected street networks that include sidewalks, easy access to a diversity of destinations, and access to public transport
- Provide convenient and safe access to quality public open space and adequate infrastructure to support walking and cycling

used to achieve desired health systems outcomes”.<sup>134</sup> As WHO has warned, “pooled funds will never be able to cover 100% of the population for 100% of the costs and 100% of needed services. Countries will still have to make hard choices about how best to use these funds”.<sup>152</sup> This statement is in relation to the third axis of the UHC cube which describes the services that are covered. When

deciding what is covered and what is not, the central challenge is to achieve the right balance between preventive, health promotion, and treatment services, in a way that is equitable and does not entrench inequities within populations.<sup>162</sup> Prioritisation and selection of health services are driven by national disease burden and priorities, which in turn should be determined by evidence of cost-effectiveness, affordability, and health impact. A country's essential medicines list, for example, ought to be based on population needs, evidence of effectiveness, and cost.

Law and regulation are integral to making difficult choices, because they establish processes and institutions to guide transparent decision making. States use legal processes to express national health priorities, and legal frameworks define and delineate that which is possible for a state to achieve. In determining what is and is not covered, states use a variety of legal mechanisms and institutions, including the following four examples. First, independent statutory authorities are tasked with reviewing clinical and epidemiological evidence and providing advice to governments about the effectiveness and cost-effectiveness of treatments and technologies—for example, the UK's National Institute for Health and Care Excellence. Second, administrative agencies are tasked with determining which medications are placed on formularies, and the amount or extent of any government subsidy. Third, legislation can specify which services, or categories of services should be provided under a UHC scheme. Finally, courts and tribunals can make de-facto decisions on service prioritisation. In South Africa, the Constitutional Court required access to antiretroviral medication for pregnant women,<sup>60</sup> while in Brazil the judiciary has ruled on numerous claims of denial of access to medicines. Conversely, Colombia's Constitution Court required priorities to be decided through a participatory, evidence-based process (panel 4). Litigation can raise its own problems, including the concern that it could favour wealthy litigants and thus entrench health inequalities.<sup>163</sup>

Finally, good governance is an important role of the law in achieving UHC. An effective UHC programme requires a process of monitoring, evaluation, and accountability, including independent review, dispute resolution, and a compensatory process in the event of adverse outcomes, as well as other administrative, political, legal, and social remedies.<sup>164</sup> Again, law plays a vital role. Because health sector corruption drains scarce resources, eliminating corruption is an essential component of good governance.

The World Bank and WHO have developed a UHC monitoring framework that focuses on three key components: quality, essential health services, and financial protection.<sup>165</sup> In December, 2017, these two agencies launched the global monitoring report on tracking UHC.<sup>117</sup> The report uses a set of indicators to monitor service coverage and financial protection. It

indicated that about 800 million people around the world spend more than 10% of their household budget on health care, and almost 100 million people are pushed into extreme poverty each year because of out-of-pocket health expenses.

Monitoring and evaluation provide crucial information on health system performance, which assists countries in making further progress towards UHC.<sup>118</sup> Data could assist governments in selecting services, making wise investments, and evaluating progress, particularly for marginalised populations or those with special disease burdens. UHC requires a legal framework that adequately protects patient privacy while retaining information integrity and security.

Law can also promote good governance in UHC adoption and implementation, including transparency and inclusive participation. Although public participation in law making varies from country to country, transparency and participation are widely agreed cornerstones of effective governance.<sup>166</sup> For example, civil society participation in health policy can improve decision making and secure grassroots support for UHC. Robust public accountability and participation are more likely to result in reasonable and legitimate decisions, and fair, effective implementation. Such mechanisms are essential when deciding on the overall strategy, the specific pathways, and the appropriateness of central trade-offs, for UHC.<sup>118</sup>

Finally, a functional UHC programme requires a framework for dispute resolution, with explicit rules to guide those seeking relief. Different mechanisms for review and dispute resolution exist, including litigation and alternative dispute resolution. Considering the many public and private claims that arise under UHC, a country could establish a separate adjudication process for individual claims, similar to the Colombian *tutela* example (panel 5). Other models include a childhood vaccine compensation system to cover rare adverse events caused by immunisation, as is present in the USA.

### Law gives tangible form to the SDGs' goal of good health and wellbeing

Law provides mechanisms through which the vision and aspirations of the SDGs can be realised. Through this UHC case study, we have discussed multiple entry points by which law can influence UHC, from its legal foundations, to the establishment of fair and effective monitoring systems. The vital role of law and regulation is often overlooked; this case study makes visible the ways in which bad, or non-existent, laws might undermine UHC. Conversely, it shows where well-designed and well-implemented laws can support its achievement, and in so doing, give tangible form to the SDG promise of good health and wellbeing for all.

Recommendations 1 and 2 relate to national and international regulatory frameworks to strengthen national health systems, consistent with the SDG target of UHC. Recommendation 1 calls on the UN and WHO,

along with international partners, to support the achievement of SDG 3.8 by setting standards on implementation and compliance. Recommendation 2 gives greater detail at the national level: we urge governments to strengthen or create a legal framework to ensure rights-based UHC, and we set out key functions of such a framework.

### Section 3: legal determinant 2

#### Governance challenges and the role of law

The second legal determinant states that law can be used to strengthen the governance of national and global health institutions. The field of global health is complex, comprising a web of institutions, norms, and processes at the global, national, and subnational levels, in which activities might overlap, come into conflict, or leave gaps. Institutional fragmentation undermines the effective functioning of the global health system. Our second legal determinant of health relates to institutions and governance.

Although governing is what states do, governance is a more diffuse concept, encompassing a broad range of actors, processes, and forces.<sup>167</sup> Law is central to governance, but governance goes beyond law. We follow the *Lancet-Oslo* Commission's definition of global governance: "The complex of formal and informal institutions, mechanisms, relationships, and processes between and among states, markets, citizens, and organisations, both intergovernmental and non-governmental, through which collective interests on the global plane are articulated, rights and obligations are established, and differences are mediated."<sup>168</sup>

The *Lancet-Oslo* Commission gave sustained attention to systemic weaknesses in global governance for health, emphasising that norms, policies, and practices arising from transnational interaction serve as political determinants of health that cause and perpetuate health inequities.<sup>4</sup> The Commission noted that global governance for health requires a global economic and political system that is rooted in commitments to global solidarity and shared responsibility.<sup>4</sup> Here, we build on those findings by specifying areas where law can be used as a tool to strengthen governance for health. We identify three key governance challenges and propose ways in which law can strengthen and improve global governance for health.

Achieving good governance remains a work in progress. Failures of governance, including the WHO's response to the west Africa Ebola epidemic, or national scandals relating to food poisoning, or tainted milk or medicines, highlight institutional and systemic weaknesses. Yet, institutions can also be remarkably effective, for instance in preventing or quickly containing outbreaks, in empowering marginalised and disadvantaged populations, or in catalysing funding for neglected health priorities. The law offers tools, some of which are still evolving, which can build upon these successes and help strengthen the institutional landscape.

#### Challenge 1: fragmented and overlapping mandates of actors and institutions

The mandates of national and global health actors frequently overlap, which can impede the effective use of law to set norms and standards, and to resolve disputes.

At the national level, multiple ministries can have profound and sometimes conflicting effects on health, resulting in policy incoherence. A country's agriculture and health ministries, for example, often both have a mandate to regulate the safety and quality of the food supply. Ministerial mandates might overlap (eg, with regard to responsibility for food safety at various points in the supply chain) or might conflict. For example, agricultural policies could be inconsistent with health and nutrition policies: the Ministry of Health's (public health) aim of reducing sugar consumption could conflict with the Ministry of Agriculture's (economic) aim of increasing sugar production.<sup>169</sup> A further example might be evident within countries, for example China, which supports a state tobacco industry in which economic growth and health might be in conflict.

Similar overlaps occur at the international level, in which non-health actors can have a profound effect on global health outcomes. However, the mandates, rules and decision-making processes of these entities rarely take population health into account. International organisations that deal with trade, investment, intellectual property, security, and the environment are among the non-health regimes that can have major impacts on human health (appendix).

Given the broad definition and remit of global health, multiple institutions can claim a mandate on particular issues. States, international organisations, and private funders, each deriving their mandate from a different legal source, could be involved jointly or separately in the same project or problem. For example, in relation to reproductive health, and maternal and child health, the activities of WHO, UNFPA, UNICEF, agencies like the United States Agency for International Development, and non-governmental organisations might overlap, conflict, or be hampered by poor coordination. Similarly, multiple institutions operate in the HIV and AIDS space, including WHO, UNAIDS, the Global Fund, and Unitaid (a WHO hosted partnership). Accomplishing results on complex problems requires organisations to act in a well coordinated manner—for example, WHO, FAO, and the World Organisation for Animal Health must work in conjunction to prevent the spread of antimicrobial resistant organisms.

In theory, the potential for overlap, gaps, inadequate coordination and fragmentation could be minimised by recourse to a sovereign decision-making authority or an authoritative dispute resolution body. The International Court of Justice (ICJ) is the UN's judicial organ, with the power to determine whether certain activities are within the mandate of UN organs and specialised agencies. The ICJ decided in 1996 that WHO did not have a mandate to

deal with the legality of nuclear weapons.<sup>170</sup> However, global health governance involves multiple institutions beyond UN organs and agencies. The ICJ has no jurisdiction over these institutions and cannot determine whether activities fall within their mandate. Even within the sphere of the UN, the ICJ's role as an arbiter is quite limited in practice.

Fragmentation also exists in the international legal system governing global health. International law lacks a normative or institutional hierarchy,<sup>171</sup> meaning that multiple venues could have jurisdiction over similar issues. This fragmentation affects the way in which law functions to set standards and resolve disputes. For example, the WTO, WHO, and the UN Human Rights Council (UNHRC) each have a mandate to set norms that affect access to pharmaceutical drugs. However, their mandates require the institutions to examine problems arising in trade, public health, and human rights through different legal lenses. This approach leads to conflicting outcomes: the WTO will continue to prioritise international trade and intellectual property, while WHO and the UNHRC will prioritise affordable access to medicines and the right to health. With limited avenues and no global sovereign entity, global health continues to rely on the traditional tools of international diplomacy to resolve conflicting decisions across international organisations—with mixed results.

In dispute resolution, parties may seek to use the fragmentation of international law to their advantage. States and other actors engage in so-called forum shopping (choosing the venue based on the outcome sought), leading to inconsistent standards.<sup>171–173</sup> Tobacco giant Philip Morris reorganised its corporate structure in order to use the most favourable investment treaty to challenge Australia's plain packaging legislation (a 2015 arbitration panel found this to be an abuse of process).<sup>174</sup> Meanwhile, the tobacco industry apparently funded a few WTO member states in order to access the WTO dispute resolution system and challenge Australia's plain packaging law.

*Addressing the challenge of fragmented institutional mandates*

Law can be an effective tool to harmonise mandates, clarify functions, and promote multiagency cooperation. Law can be used to designate the responsible agency to resolve a particular issue, or to create new entities to coordinate activities across multiple agencies. General legal principles can inform and direct all institutions to abide by and promote the rule of law, with particular attention to social justice. SDG 16 on the rule of law includes target 16.3: “promote the rule of law at the national and international levels and ensure equal access to justice for all.”<sup>114</sup>

UNAIDS offers a prime example of an institution that spans multiple UN agencies operating to prevent and treat HIV and AIDS. Established by the UN Economic and Social Council in 1994, UNAIDS is a Joint Program

bringing together 11 UN agencies with different mandates, to promote interagency dialogue and cooperation, while mobilising resources and political will.<sup>175</sup> UNAIDS has a more modern governance system than other UN bodies, with civil society members represented on its governing board in a non-voting capacity.<sup>176</sup>

Because of the strong normative effect of non-binding instruments, soft rules can also fill gaps and clarify mandates. WHO's PIP Framework (adopted in 2011) governs the ways in which countries are expected to share virus samples to facilitate research, while enhancing equitable sharing of the fruits of that research.<sup>39</sup> As of 2018, WHO is working with states parties of the Nagoya Protocol to the Convention on Biological Diversity (2010) to resolve a mission conflict between the PIP Framework and the Nagoya Protocol. The former is designed to foster global sharing of virus samples, while the latter purports to grant states sovereign ownership of viruses, and naturally, the right not to share. Finding synergies between these two international instruments to enable WHO to develop a legal resolution that fosters the global common good requires good faith negotiations between international institutions representing different interests and governance systems.

Since establishing a supreme dispute-resolution body is a remote, and perhaps undesirable possibility, several actors can work together to reduce fragmentation. WHO and WTO have had ongoing discussions about resolving conflicts in areas such as access to medicines and tobacco control. WHO's IHR formally recognise the importance of international trade. In turn, the WTO has recognised FCTC guidelines as legitimate standards in WTO dispute resolution decisions.<sup>177</sup> The WTO's Agreement on the Application of Sanitary and Phytosanitary Measures explicitly recognises the sanitary and phytosanitary standards of the Codex Alimentarius Commission as the relevant food safety standard-setting entity.<sup>178</sup> Under this commission, WHO and FAO work together. In these examples, and others, international regimes are beginning to recognise and act to harmonise decision-making processes, and, in so doing, improve the public's health.

**Challenge 2: weak monitoring, compliance, and enforcement**

International law can be an important tool for global health because of its power to create norms that are binding on states parties. However, even though treaties are binding legal instruments, their implementation can be suboptimal because of weak enforcement and inadequate compliance. Typically, international law is built on a foundation of interstate cooperation and shared responsibility. The norms of international law guide behaviour, but often, treaty oversight bodies have few means by which to compel, or even incentivise, compliance. In extreme circumstances, UN organs can authorise economic sanctions, but these tend to be limited to the arenas of global security, eg, counterterrorism, cybersecurity, and non-proliferation

of nuclear weapons.<sup>179</sup> The WTO can also authorise sanctions through its dispute resolution process.<sup>180</sup> The inability to enforce and ensure compliance with international law has stymied the international community's ability to fully use human rights law to prevent or ameliorate gross inequalities.

In global health, the options to incentivise or coerce behaviour in the face of non-compliance are even more limited.<sup>181</sup> The FCTC and IHR—the two major international legal instruments under the direct authority of WHO—have been plagued by incomplete state compliance.<sup>39</sup> This poor compliance has resulted, in part, from external and political forces, and partly from limited technical, legal, and financial capacity.

The IHR seeks to prevent the spread of public health threats from any source (including biological or even radio-nuclear), but primarily aims to prevent the spread of infectious diseases. The IHR covers areas such as state surveillance requirements and obligations to notify WHO regarding potential public health threats of international concern and establishes WHO procedures for when the organisation has been notified. Furthermore, states parties are required to have, or develop, eight minimum core public health capacities to prevent, detect, and respond to specified health hazards: legislation and policy, coordination, surveillance, response, preparedness, risk communication, human resources, and laboratory.<sup>182</sup> Each of these core capacities requires substantial resources and investment from national governments. These activities are largely unsupported by WHO or through other forms of international assistance.<sup>183</sup> Although the IHR encourage international assistance to build capacity in lower-income states, higher-income states—with notable exceptions, such as the US-led Global Health Security Agenda (GHSa)—have largely ignored the treaty's norms of international financial and technical cooperation.

Weak monitoring, assessment, and follow-up capacity can also present a challenge to the effectiveness of international instruments like the IHR. Before 2016, countries were required to self-assess their IHR compliance and competencies. In 2016, WHO worked with the GHSa to introduce a new process and tool, the Joint External Evaluation (JEE).<sup>184,185</sup> Under the JEE, independent experts work alongside national officials to ensure transparent reporting. However, JEE is voluntary and some countries remain reluctant to adopt it, in some cases because of concerns about national sovereignty. Furthermore, regarding the points at which JEE does identify gaps in IHR competencies, no comprehensive global mechanism exists to assist low-income countries to finance required reforms. As observed during the Ebola crisis, this absence of a global mechanism presents a potential threat to global security.<sup>39,99</sup>

Additionally, states could withhold cooperation for political or economic reasons. For example, the IHR require rapid state identification and reporting of novel

infections to WHO. However, if states parties do report novel infections they could face travel and trade restrictions or loss of tourism and prestige. Consequently, states might be reluctant to comply in a timely manner with the IHR's reporting obligations. States parties in west Africa were late in reporting Ebola in 2014. When an epidemic did engulf these countries, governments widely ignored WHO recommendations not to impose travel and trade restrictions. Airlines also unilaterally suspended flights to the region.<sup>186</sup>

#### *Addressing the challenge of weak treaty compliance*

There are creative ways to foster state compliance, even if it is extraordinarily difficult to assure that compliance. Treaty oversight bodies need to work with states and other stakeholders to find innovative ways to promote treaty implementation. This is also true for soft rules, which are often amenable to similar compliance-enhancing incentives and methods. The following are examples of tools that could facilitate compliance, and many already exist in most compliance-enhancing international instruments.

Setting targets and monitoring progress are important tools. Oversight bodies should set clear targets and benchmarks based on norms set in the treaty or soft rule. Having set clear, transparent targets, in collaboration with stakeholders, the oversight body should monitor progress through objective and transparent mechanisms and make its findings publicly available. For instance, WHO's Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–20 is supported by a monitoring framework, which includes voluntary targets and indicators. Countries' progress in taking actions to achieve the targets is now also being regularly monitored through the WHO Progress Monitor.<sup>187,188</sup>

Another tool is state reporting. Both hard law and soft rules could require or encourage states to self-report their progress. Fully transparent reporting is vital, and the oversight authority (such as WHO's Director-General) publicly holds states accountable for abiding, or failing to abide by the relevant norms. For example, the public should know if states fail to rapidly report novel infections as required under the IHR. Greater transparency encourages states to abide by global norms.

Working under a mandate from the UNHRC, UN Special Rapporteurs are independent experts who examine, monitor, advise, and publicly report on human rights from a thematic or country-specific perspective.<sup>189</sup> As of 2018, 43 thematic and 13 country mandates are present. The Special Rapporteur on the Right to Health is Dainius Pūras. Other health-related thematic mandates, for which Special Rapporteurs exist, include access to safe drinking water and sanitation, extreme poverty and human rights, and the right to food.

Treaty monitoring bodies can also receive so-called shadow reports, which supplement the reports provided by states. Shadow reports can come from

non-governmental organisations, UN organisations, and academic institutions, and can be presented to all the human rights treaty monitoring bodies, including CEDAW and the Committee on Economic, Social and Cultural Rights, as well as the UNHRC. Because states might not report fairly, completely, or truthfully, shadow reporting provides a mechanism for civil society organisations to provide their own public reports on states' compliance with their treaty obligations.

External evaluations can also be used as tools that could facilitate compliance. As mentioned previously, many states do not have the capacity or political incentives to properly assess their own compliance with global health norms. The majority of states have either not reported or under-reported their compliance with IHR core health system capacities. In the wake of Ebola, several global commissions criticised WHO for failing to ensure more independent assessments.<sup>186</sup> The JEE was developed in response to these criticisms, but, as mentioned above, faces challenges for implementation.

Lower-income states often require financial and technical assistance to comply with treaty obligations. This assistance both incentivises and aids governments in fulfilling their responsibilities. The Global Health Security Agenda (a partnership between nations, international organisations and non-governmental organisations) provides financial and technical assistance in exchange for full cooperation with independent health system preparedness evaluations, which in turn strengthens compliance with the IHR.<sup>190</sup>

A further tool that can be used to assist compliance is transparency and public disclosure. State performance can often be hidden, or partially hidden from public scrutiny. Indeed, there is a subtle norm within certain international organisations not to publicly name or criticise member states. Yet, good governance requires openness and public accountability. Civil society and oversight bodies can push for compliance with international health norms by emphasising state actions.

As mentioned in section 1, WHO treaties have weak dispute resolution systems. These treaties could be amended to model more rigorous dispute resolution. Alternatively, WHO should work with states to emphasise the importance of routinely submitting to such resolution mechanisms for the common (public) global good.

The final tool that can be used to assist compliance is private law dispute resolution. As previously described, under the WHO's PIP Framework, parties can be subject to private contracts that are binding, to strengthen compliance with the non-binding PIP Framework. Understandably, many observers will continue to lament the absence of strong enforcement mechanisms in international law. Unfortunately, most international legal obligations are hard to enforce, for example, in relation to human rights, climate change, or arms control. However, the above examples describe ways in which the innovative use of legal and governance tools can enhance compliance

with international rules, ultimately strengthening the governance of global health.

### Challenge 3: new legal entities, old governance regimes

In the aftermath of World War II, WHO stood unrivalled in the global health space. As of 2019, the same space is occupied by more than 200 international agencies and initiatives.<sup>191</sup> New institutions bring a host of benefits—more funding, an enhanced voice for civil society, and innovative ideas—but also new challenges in leadership, oversight, and accountability. In many cases, old regimes have not fully adapted to the emergence of these new players, raising concerns relating to finding the appropriate level and means of participation by new institutions in governance processes such as those of WHO, and improving the internal governance arrangements of both old and new institutions.

Traditional actors in global health (states and inter-governmental organisations) are governed by established domestic and international legal frameworks. Frameworks originally established many decades ago can fail to take account of new actors and values. Member states, for example, have almost exclusive governance powers under the WHO constitution. By contrast, valuable voices, such as those in civil society, are often not fully heard. Although non-state actors can informally contribute to the Organization's work and attend governing body meetings, they are not permitted to engage in actual decision-making processes.<sup>192</sup> This raises questions of equity, transparency, and accountability. At the same time, although civil society organisations often bring considerable practical and technical expertise, assessing their legitimacy or their sources of finance can be difficult.

As reported by the *Lancet-Oslo* Commission, global health is characterised by imbalances in political power, leading to inequities in health.<sup>4</sup> Powerful, entrenched actors might influence international institutions to advance their private interests, rather than the health of the public. For example, civil society has criticised WTO for diminishing access to essential medicines in favour of private commercial interests in intellectual property (eg, patent protection for pharmaceuticals).<sup>193</sup>

WHO itself suffers from so-called capture by its powerful member states and non-state actors, who fund almost 80% of its annual operating budget.<sup>194</sup> The Gates Foundation has considerable influence on WHO's agenda. At the same time, WHO has been struggling to find an appropriate way to engage with the private sector. Health and human rights advocates have expressed concern about an overly close relationship between WHO and vested corporate interests.

Although WHO and other post-World War II inter-governmental agencies often have clear governance arrangements, oversight of new players and new legal entities (eg, civil society organisations, foundations, and PPPs) presents a greater challenge. Large PPPs often

have limited transparency and accountability because of participation of private actors.<sup>195</sup> At the national level, private entities such as corporations and charitable foundations are subject to government oversight, especially to protect private shareholders and the general public.<sup>196</sup> However, no single state can fully control the activities of large, transnational corporations that operate in multiple countries and regions. States' oversight of major non-profits such as the Gates Foundation is also inadequate.

This limited transparency can pose governance concerns: some PPPs have been criticised as vehicles for market penetration (increasing a product's market share through strategies such as bundling, advertising, lower prices, or volume discounts), or as a means for private actors to wield influence over international law-making and policy-making processes.<sup>197</sup> In the fast-changing arena of global health, the potential efficiency of newer actors should not be traded against "good governance, transparency, participation and engagement; clear accountability for success and failure; coordination and coherence; and a new eye on priority setting to achieve ambitious global goals while balancing equity and efficiency".<sup>195</sup> Good governance should both facilitate efficiency, while still ensuring effective oversight and accountability.

#### *Addressing the challenge of new and old governance regimes*

To some extent, governance regimes are evolving in response to these new players. In 2016, WHO member states negotiated a Framework for Engagement with Non-State Actors,<sup>192</sup> which includes non-governmental organisations, private sector entities, philanthropic foundations, and academic institutions. The Framework guides and strengthens the ways in which WHO interacts and works with these entities, seeking to ensure "transparency, openness, inclusiveness, accountability, integrity and mutual respect", while "protecting its work from potential risks such as conflict of interest, reputational risks, and undue influence".<sup>192</sup> The Framework could assist WHO to strike a better balance between active engagement with outside actors, and maintaining the integrity of its own governance arrangements. Yet, many in civil society continue to campaign for more participatory decision making.

Overcoming the problem of limited participation in WHO governance will require innovative thinking. The WHO's Executive Board has granted a small number of non-governmental organisations, international business associations, and philanthropic foundations an official relations status on the basis that they "have a sustained and systematic engagement in the interest of the Organization...and contribute significantly to the advancement of public health".<sup>192</sup> This criteria has excluded smaller non-governmental organisations working in the health space, separating them from WHO. The Organization should find a way to better harness the creativity and energy of civil society organisations.

Innovative governance arrangements in newer entities could help improve inclusiveness and transparency. For example, The Global Fund has implemented innovative governance for greater civil society participation, described as follows.<sup>7</sup> The first implementation was non-governmental organisation representation—including from developed and developing countries, as well as from communities living with the Fund's targeted diseases—on its Board, alongside representatives of the private sector, national governments, and philanthropies. Additionally, local, multi-sector, multi-stakeholder committees, known as Country Coordinating Mechanisms (CCMs) were introduced to oversee grant implementation at the local level. CCMs must include members of communities living with the Fund's target diseases and must document the involvement of marginalised or vulnerable populations in their work. The Global Fund has also adopted standards to manage conflicts of interest with CCMs.<sup>198</sup> Dual-track financing, whereby the CCMs nominate both a governmental and non-governmental principal recipient for financing was introduced;<sup>198</sup> and finally, community systems strengthening through activities such as partnerships, capacity building, service delivery, as well as planning, monitoring, and evaluation.

The Global Polio Eradication Initiative is another example of a PPP that has adopted innovative governance arrangements to foster greater transparency. The Initiative—a partnership between WHO, Rotary International, the US Centers for Disease Control and Prevention, UNICEF, and the Gates Foundation—is overseen by an Independent Monitoring Board of global experts. The Board evaluates the Initiative's work against key milestones. If milestones are deemed to be at risk, off track, or missed, the Board reports to the partners, and makes its reports public.<sup>199</sup>

Independent and civil society voices are crucial for holding global health actors accountable. Arrangements such as these provide legal and governance mechanisms for those voices to be heard, leading to more robust processes, and ultimately, outcomes that achieve health with justice.

#### **Legal reforms could greatly enhance the governance of global health**

Law can shape the governance of global health in various ways. Law defines the mandates, powers, and structures of, and the interactions between, key players in global health. However, the potential to deliver health with justice is weakened by multiple governance challenges: fragmentation and overlap, poor compliance and enforcement, and disjunctions between actors with great influence over global health and the regimes intended to govern them. In this section, we have built on the work of the *Lancet*-Oslo Commission, specifically identifying ways in which law could strengthen good governance for global health. We have identified measures to harmonise institutional mandates, mechanisms for review of

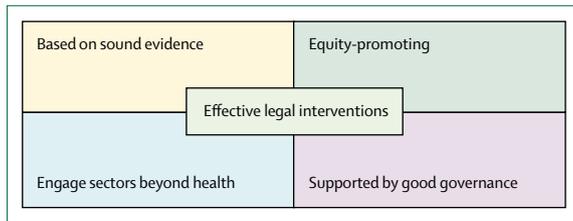


Figure 4: Core characteristics of legal interventions that advance health with justice

decisions, forums for ensuring international policy coherence on health, and innovative compliance-enhancing arrangements. In each of these ways, law can address vital governance challenges in global health. Specifically, recommendation 3 proposes that the UN set good governance standards for UN specialised agencies and programmes, including WHO. This proposal is supported at the national level by recommendation 4, which states that governments should develop legal frameworks establishing principles of good governance throughout national health systems and policy making.

### Section 4: legal determinant 3

Law can be used to implement fair, evidence-based health interventions, and can be a powerful tool for global health.<sup>3</sup> Statutes and regulations can be used to implement interventions that lower the exposure to risk factors across entire populations. As a result, law has been integral to many of the great public health successes of the past century, including motor vehicle safety, tobacco control, infectious diseases control, a safer food supply, workplace safety, and childhood vaccinations.<sup>200</sup> Many public health interventions require enactment and enforcement of laws and regulations, such as taxes on tobacco, alcohol, or sugar-sweetened beverages; marketing or sponsorship bans; and minimum age of purchase requirements. In other cases, laws facilitate effective health interventions, such as immunisation requirements for school entry or creation of safe injection sites for drug users.

However, law is only a tool. When used without sufficient evidence, or without regard for justice and human rights, statutes and regulations may be ineffective—or worse, could undermine health. Law could also perpetuate injustice, such as by establishing a multi-tier UHC health insurance system that provides real benefit to some people (eg, civil servants, formal sector employers) but only limited benefits to others (eg, informal sector workers). Our third legal determinant of health is the effective, fair, and evidence-based enactment and implementation of legal interventions.

In this section, we first offer a framework for evaluating health laws, and propose four characteristics of effective laws that advance health with justice. We then provide key examples of effective laws, across three risk factor domains: infectious diseases, non-communicable

diseases, and injuries. In each domain, we describe ways in which international and domestic laws interrelate and inform one another. Sharing of experiences and research regarding the effectiveness of public health laws among jurisdictions, and with international organisations, will be crucial to the global dissemination of just, evidence-based legal interventions. Finally, we explain how laws that are not informed by evidence and human rights principles could undermine health, while entrenching inequality and discrimination.

### Evaluating health laws: does this intervention advance health with justice?

The Commission concluded that across the spectrum of global health hazards, legal interventions will be most effective when they are based on sound science, and guided by the values of justice, transparency, and inclusion. The most just and effective public health laws share the following four core characteristics: they are evidence based, equity promoting, multisectoral, and supported by good governance (figure 4). Laws that share all these characteristics will best advance health with justice.

#### Health laws must be evidence-based

Sound scientific evidence is the most important characteristic of effective public health laws.<sup>201</sup> Laws should be informed by scientific evidence, rigorously answering the question: do they improve the health and safety of the population, while not posing undue burdens on individual rights? Although we emphasise the important role of innovation and well considered novel approaches in public health law and regulation, this should always be implemented in conjunction with well designed evidence gathering and rapid evaluation. In section 5, we suggest ways to expand and strengthen the evidence base for, and the legal capacity to, implement legal interventions.

Policy makers sometimes—perhaps often—must act on incomplete evidence or scientific uncertainty. A classic example of the need to act without complete information is when a major health hazard or emerging health risk demands an urgent response, and perhaps an innovative approach. For example, the Democratic Republic of Congo deployed investigational new vaccines and therapies in response to Ebola in 2018–19, even though regulatory agencies had not yet found the vaccine and drugs to be safe and effective.

The absence of full information to thwart legal innovations should not be allowed. If policy makers always had to wait for an exhaustive research study, many substantial threats to the public's health would persist. Evidence might come from analogy to other areas of law, such as the effectiveness of taxes on reducing sugary beverages, based on effectiveness of taxes in reducing tobacco use. Similarly, evidence of effectiveness for portion controls on sugary beverages might come from studies

showing increased portion size, and its relationship to overweight or obesity. In such cases, policy makers need to make informed choices for law reform, in the absence of complete evidence.

While using the best available (albeit incomplete) evidence at the time, evaluating the law's effect to ensure continuous quality improvement in health legislation is imperative. Even then, though, law makers might need to accept some uncertainty, such as where there is clear evidence that a suite of legal measures is effective at addressing a complex health threat (eg, obesity, or gun violence), but it is difficult to determine the specific contribution of any single intervention. For example, in tobacco control, a comprehensive approach using a host of demand and supply reduction measures has, in combination, substantially reduced smoking rates over time.

#### *Health laws must promote equity*

Poor and disadvantaged communities often have a disproportionate burden of morbidity and premature mortality, as well as the social and economic consequences of disease and injury. These populations include people with mental or physical disabilities; racial, ethnic, or sexual minorities; and women and children. Poor health outcomes, in turn, further entrench disadvantage. Poor and marginalised populations—whether living in low-income and middle-income countries, or in wealthier countries—often live, work, recreate, travel, and go to school in unsafe or unhealthy environments. They also benefit less from prevention services and have less access to high-quality treatment and rehabilitation services.<sup>202</sup> Interventions that target inequalities are thus fundamentally linked to those that address ill health.<sup>203</sup>

Achieving health with justice requires non-discrimination; equitable distribution of benefits and resources within and across communities, within countries, and globally; and protecting underserved communities. At a national level, law makers should pay particular attention to the needs of the poorest, the most vulnerable, and those who are marginalised. At the global level, it is important to translate international norms to the national and local levels to reduce health disparities among and within states. If the world is to achieve the SDG's pledge of "leaving no one behind", public health laws must target areas of deep inequity.

#### *Health laws must engage sectors beyond health*

Laws far beyond the health sector influence the conditions for achieving population health and reducing inequalities. The criminal justice system, taxes and transfers, urban planning and development, trade, agriculture, housing, and the environment are incidental to, but deeply affect population health.<sup>10</sup> If not conceived with due consideration for health objectives, laws in these sectors could have powerful adverse effects on health. For example, agricultural subsidies for corn, sugar, or meat can exacerbate major health and environmental threats.

Conversely, multiple sectors have the potential to improve population health and justice. Urban planning, education, social services and other portfolios can have major health-enhancing features. Yet, public health researchers and officials often neglect agencies outside of health ministries. Achieving health with justice requires an all-of-government approach, supported by the head of government.

Health Impact Assessments (HIAs) measure the health effects of proposed initiatives in diverse sectors (criminal justice, education, housing, nutrition, education, and revenue) using quantitative, qualitative, and participatory techniques, with particular regard for health equity. HIAs adopt an all-of-government or health-in-all-policies (healthy policies) approach to governance. HIAs dynamically improve health and wellbeing across sectors. Several countries and sub-national jurisdictions, such as Thailand, Slovakia, and several US states, have laws requiring HIAs for policies substantially affecting public health or for policies or programmes in certain sectors. Other laws empower public health authorities, or even the public, to request an HIA,<sup>204</sup> as evidence shows that HIAs can have a substantial positive effect on public policy.<sup>205,206</sup>

In 2008, the WHO Commission on the Social Determinants of Health recognised the importance of reform in multiple sectors. Despite this, international institutions (including WHO itself) and governments have not devoted the attention and resources needed to address the social determinants of health. We argue that law can be highly effective in defining and operationalising government action. By creating and implementing social norms and redistributing resources, law can create the conditions for the public's health. Examples of the power of law to affect the social determinants of health include social welfare and income support programmes; market regulations that enhance income and agency for workers (minimum wages, paid sick leave or family leave); protection of union and labour rights; redistribution policies, such as pre-tax limits on compensation levels, progressive taxation, and negative income taxes; nutrition policies, such as subsidising healthy foods and restricting unhealthy foods in school lunches; consumer protection; and occupational health and safety regulations.

#### *Health laws must be supported by good governance*

Finally, health with justice can only be delivered against a backdrop of good governance, sound regulatory principles, and the rule of law. These include transparency and openness; civil society or community engagement and inclusive participation; monitoring and evaluation systems; honesty, non-corruption, and stewardship; and accountability at all levels, from legislating, through implementation, to enforcement. We have addressed these concepts in detail elsewhere in this report, in sections 3 and 5.

	Purpose of intervention	Actions necessary for success of intervention
Legal interventions related to testing, screening, reporting, contact tracing, and partner notification can improve surveillance data, while protecting confidentiality and privacy	Improving essential data through early warning, identify individuals at risk, reduce transmission, monitor incidence, facilitate response	Improve public health infrastructure: labs, workforce, data systems
Legal interventions related to occupational health and safety, so-called wet markets, animal quarantines, and culls can decrease animal-human interchange	Protecting animal health, and preventing so-called species jumps to humans	Improve hygiene and infection control in animal farming, and meat and poultry markets
Legal interventions related to hand-washing, disinfection, respiratory hygiene, potable water, and sanitation can improve community hygiene	Reducing transmission in families and the community	Public education grounded in risk communication science, clean water and sanitation systems
Legal interventions related to disinfection, hand hygiene, personal protective equipment, and health-care worker vaccinations can help control hospital infections	Reducing transmission among patients, health workers, and families and communities	Training and monitoring in infection control, greater acceptance of vaccination by health professionals
Legal interventions related to the closing of public places, cancelling public events, and restricting mass transit can help decrease social mixing in the event of an outbreak	Slowing the spread of infection in public settings	Target closures to high-risk settings based on evidence
Legal interventions related to screening (entry and exit), reporting, health alerts, passenger data, travel advisories, hygiene (inspection, disinfection, and pest extermination) can help improve border controls	Preventing cross-border spread of infectious diseases	Adequate resources for surveillance, treatment, and response in affected areas and national borders
The law can prevent spread of infectious diseases through isolation and quarantine, and ensuring respect for human rights. Laws should ensure that in the event of an outbreak, any isolation or quarantine strategies, including so-called shelter in place policies, are safe and humane, evidence-based, and no more restrictive than necessary to protect public health	Separating the infected or exposed from the healthy	Safe and humane settings, assure necessities of life, logistics, modern laws with due process
Legal interventions related to vaccines and antivirals can help improve medical countermeasures	Implementing prophylaxis, and reducing infectiousness	Stable, viable supplies: incentives, public-private partnerships, tort reform, compensation
Legal interventions related to antibiotic use in humans and animals, and falsified or substandard medications can help in preventing drug-resistant infections	Reducing spread of drug-resistant infections in animals and humans and developing new antimicrobial medications	Appropriate medical prescribing, reduced use of antimicrobials in farmed animals, curbing the trade in falsified and substandard medications, incentivising research and development of new antimicrobials

Table: National public health laws to control infectious diseases

### Effective legal interventions

Despite past successes, law remains underutilised as a tool for population health.<sup>207</sup> In this section, we discuss legal and regulatory interventions across three broad health domains: infectious diseases, non-communicable diseases, and injuries. These interventions have been effective because they share the characteristics previously discussed. For each, we provide key illustrations, complementing the other examples and case studies found throughout this report. A comprehensive list of domains and interventions from around the world can be found in the report from WHO, International Development Law Organization, O’Neill Institute, Sydney University: *Advancing the right to health—the vital role of law*.<sup>86</sup>

In keeping with our global health lens, we also focus on the ways in which national and global health law intertwine, showing the potentially far-reaching effects of law. Legal interventions that successfully advance health with justice at the local and national levels have been adopted (and adapted) in other jurisdictions, as well as translated into international norms. At the same time, international norms have been codified in national and local laws. This interaction shows the multidimensional nature of creating and diffusing highly effective health laws from the global level to the local and national levels, and vice versa (figure 1).

#### Infectious diseases

During the 20th century, improvements in sanitation and hygiene, vector abatement, and surveillance ushered in substantial advances in infectious disease control.<sup>208</sup>

Previously devastating infections are now treatable, even as the global health community wrestles with the frightening prospect of antimicrobial resistance. The advent of vaccination laws vastly reduced deadly childhood diseases such as measles, mumps, and rubella. Smallpox was a major killer before mass immunisation led to its eradication. Before the Salk vaccine, people feared the paralysing effects of polio. WHO, along with international partners, is now aiming to eliminate polio around the world.

Throughout modern history, law has played a major role in reducing infectious diseases through national public health laws and regulatory frameworks, international legal agreements, and governance reforms. As of 2019, the international community faces new challenges and must undertake health system and animal husbandry reforms, while also incentivising development of new medicines to combat antimicrobial resistance.

National legal frameworks in the form of laws and regulations give public health agencies wide-ranging powers to control infectious diseases. These regulations include powers to identify individuals (testing) or populations (screening) who can potentially transmit infections; require health providers and others to notify public health agencies of cases of infectious disease; trace contacts of infected individuals or notify partners; vaccinate exposed persons, their contacts, and broader populations; directly observe individuals to ensure they take the full course of their medications such as directly observed therapy for tuberculosis; and separate people who are infected (isolation) or have been exposed

(quarantine) from healthy populations. Law can also require rigorous community and hospital infection control, such as disinfection, hand hygiene, and personal protective equipment. It can limit animal–human interchange to prevent pathogens jumping from animals to humans (table). When public health officials exercise compulsory powers, they should provide due process or natural justice, such as a fair hearing. Procedural safeguards are often necessary to prevent health officials from acting in an arbitrary or discriminatory manner.

In addition to the IHR and PIP Framework, which relate to human pandemic illness, countries should prepare for, and evaluate preparedness for, zoonotic diseases (animal diseases that can be transmitted to humans). Even diseases that infect only animals can damage economies by curtailing meat exports, or driving up domestic food prices. As of April, 2017, only six countries worldwide had undergone two external evaluations of their ability to withstand a global pandemic. One evaluation is for human diseases (the JEE, in cooperation with WHO) and the other relates to animal diseases (in cooperation with the World Organization for Animal Health).<sup>209,210</sup>

Law can also be used to help limit the spread of organisms that are resistant to antimicrobial medications. For example, regulation can operate to better ensure appropriate prescribing of antimicrobials. Law can also be used to ban the prophylactic use of antibiotics in animal populations or to promote growth, thus reducing the reservoir of drug resistant organisms in farmed animals. Similarly, regulations can require surveillance of drug resistant infections in both human and animal populations.

Law plays a particularly important role in limiting the manufacture of, and trade in, falsified and substandard medicines. When patients take antimicrobials that have sub-optimal doses of active pharmaceutical ingredients, they can develop drug resistant infections. Countries should update legislation to provide clarity on what qualifies as falsified and substandard medicines according to the definitions that the WHA approved in 2017,<sup>211</sup> strengthen criminal penalties to deter manufacture and sale of these products, ensure adequate registration and quality surveillance systems, and sufficiently resource public health regulatory and customs agencies for increased surveillance and enforcement. Legislation could require that pharmacists are trained in detecting falsified and substandard medicines. The WHA should adopt a code of practice on falsified and substandard medicines that sets standards on surveillance and international reporting and provides guidelines for and coordinates regulation and law enforcement.<sup>212</sup>

Because infectious diseases do not respect national borders, global health law and governance are just as important as national legislation. WHO has adopted two major legal instruments to safeguard global health security, but both face major problems, as does WHO governance itself.

The 2014–15 Ebola virus epidemic in west Africa revealed “deep inadequacies in the national and international institutions responsible for protecting the public from the far-reaching human, social, economic, and political consequences of infectious disease outbreaks.”<sup>99</sup> A review of four global commissions in the wake of the epidemic drew together recommendations and suggested reforms for future global health pandemic preparedness.<sup>186</sup> Many proposed reforms involved law and regulation, including surveillance, disease notification, infection control, and strengthening national health systems. Good governance for health was another major aspect of the required reforms, both at the national and global levels—for example, transparency, monitoring, risk communication, community engagement, and accountability.

Crucial to this last function is strengthening and scaling up WHO’s IHR and PIP Framework, and building capacity at WHO itself.<sup>39</sup> Implementation of the IHR during the Ebola epidemic was deeply flawed: WHO delayed its declaration of a Public Health Emergency of International Concern (PHEIC) for over 4 months after the first international spread.<sup>213</sup> Declaration of a PHEIC under the IHR carries normative weight under international law, and allows WHO to alert and engage the international community.<sup>214</sup> At the same time, only 30% of states parties had reported meeting the IHR requirements to develop core health system capacities,<sup>215</sup> and states widely ignored WHO travel recommendations. During the Ebola epidemic, the PIP Framework was not even applicable, as its narrow scope is limited to pandemic influenza strains.

The post-Ebola commission reports urged research and development of vaccines and anti-microbial medications to be better funded and expedited. Yet, regulatory frameworks such as intellectual property, so-called ownership of viruses, inconsistent regulatory approval pathways, legal liability for pharmaceutical companies, and divergent clinical trial standards can hinder rapid development of medical technologies to respond to public health emergencies. These regulatory frameworks need to be reformed, or made more flexible, to support the development, procurement, approval, and deployment of effective therapeutic countermeasures. Legal obstacles to the effective deployment of countermeasures should be addressed and resolved in advance of future pandemics.

The law can also offer a protective function, helping to ensure that patients and human participants in research are treated with dignity and respect, while safeguarding them against unethical research and unsafe products. Liability reform can incentivise manufacturers to more rapidly develop and deploy products. Additionally, the formation of multi-disciplinary partnerships that include patients, health care providers, experts, industry partners, ethicists, lawyers, and others would promote a clearer understanding of regulatory rules and ethical practices, as well as better sharing of research information.

Despite considerable progress, the burden of infectious diseases remains unacceptably high, particularly in low-income and middle-income countries, and among poor and rural populations.<sup>3</sup> Each year, millions of people die from diseases such as HIV and AIDS, tuberculosis, malaria, hepatitis, influenza, and neglected tropical diseases (although WHO is making substantial progress in controlling neglected tropical diseases).<sup>119</sup> The unprecedented movement of people and goods around the globe is amplifying the spread of infectious diseases, as is climate change.<sup>216,217</sup> In settings where health systems are weak, populations are all the more vulnerable to emerging or re-emerging infectious diseases. Since 2000, the world has experienced major outbreaks of novel infections such as Severe Acute Respiratory Syndrome, Middle East Respiratory Syndrome, new strains of pandemic Influenza (H1N1), Ebola, and ongoing Zika virus transmission.<sup>186</sup> Outbreaks of cholera, plague, and yellow fever have caused considerable illness and death.

Infectious disease laws are crucially important, but must respect human rights, promote equity, and reflect international norms such as the Siracusa Principles.

#### *Non-communicable diseases*

WHO estimates that non-communicable diseases cause 40 million deaths annually, amounting to 70% of all deaths globally.<sup>218</sup> People die too young from these diseases, with negative consequences on productivity and socioeconomic development. In 2015, 16·9 million deaths were estimated to occur before age 70 years and 9·2 million before age 60 years. Moreover, the huge toll of death and disability from non-communicable diseases does not affect all populations equally; 31 million (or three quarters of the total) of global non-communicable disease deaths occur in low-income and middle-income countries. The main non-communicable diseases—cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes mellitus—share four main behavioural risk factors: tobacco use, physical inactivity, the harmful use of alcohol, and unhealthy diets.<sup>160</sup> Evidence shows that social and economic circumstances can significantly increase the risk of non-communicable diseases.<sup>219</sup>

An increasingly strong evidence base exists regarding how population-level interventions can be used to prevent and control non-communicable diseases. WHO's Global Action Plan for the prevention and control of non-communicable diseases 2013–20, including the updated appendix 3, represents the most important normative instrument on non-communicable diseases at the global level.<sup>160</sup> Many of its policy recommendations, some of which are so-called best buys for public health (highly cost-effective, evidence-based interventions), include the use of law and regulation (panel 6). Building on the strong evidence of success in Denmark, New York City and other settings, WHO now recommends that countries use legislation to eliminate industrial trans fats in the food supply.

Tobacco control is important in containing the spread of non-communicable diseases. WHO's non-communicable diseases Global Action Plan incorporates the FCTC's provisions in its recommended actions. Updated appendix 3 calls on states parties to “strengthen the effective implementation of the WHO FCTC and its protocols”, including by establishing “national mechanisms for coordination of the WHO FCTC implementation as part of national strategy with specific mandate, responsibilities and resources”.<sup>160</sup> The action plan also invites member states that are not parties to the FCTC to “consider implementing the measures set out in the WHO FCTC and its protocols, as the foundational instrument in global tobacco control”.<sup>160</sup>

The FCTC provides a prime example of the inter-relationship between international and domestic law, providing a precedent for future global health governance. The WHA in 1995 urged member states that had already successfully implemented all or most of a comprehensive strategy for tobacco control to provide assistance to WHO.<sup>220</sup> This aid would allow WHO to provide advice and support to other member states seeking to improve their tobacco control strategies. The following year, the WHA voted to begin work on developing a framework convention. A decade later, the FCTC entered into force.<sup>221</sup>

The FCTC has had a substantial effect on global tobacco control, with its norms widely implemented at national and local levels. Particularly in high-income countries, a so-called suite of national and local laws and regulations has resulted in large declines in tobacco use. A combination of legal interventions all operate to reduce smoking in youth and adults, including lowering the legal age for buying tobacco products, marketing bans or restrictions, bans on smoking in public places, high taxation, and graphic packet warnings. For example, 111 of 181 FCTC states parties require pictorial warnings on cigarette packages, as recommended under Article 11.<sup>222</sup> Governments are now implementing major so-called endgame strategies, such as gradually increasing the legal smoking age, and vast reductions in the nicotine levels in cigarettes, which addict virtually all smokers.<sup>223</sup>

However, the FCTC faces substantial compliance challenges, particularly in low-income and middle-income countries. For instance, Article 14 encourages countries to put in place tobacco cessation infrastructure but does not provide the resources to allow low-income and middle-income countries to do so. As of 2013, only a minority of countries had in place the infrastructure necessary to offer cessation support to tobacco users.<sup>224</sup> Furthermore, compliance and enforcement challenges are only made more difficult in the presence of aggressive opposition from vested commercial interests.<sup>225</sup> Ongoing monitoring, and strategies to strengthen the capacity of states to comply with their FCTC obligations, are two important ways to bolster the effect of this instrument.

Dietary salt reduction provides another good illustration of countries incorporating WHO guidance on non-communicable disease prevention, fitting global norms into their social, political, and regulatory contexts. High salt intake is estimated to be associated with nearly half of the disease burden ascribed to hypertension, a major contributor to global morbidity and mortality.<sup>226–228</sup> The physiological requirement for salt is less than 1 gram per day,<sup>229</sup> and WHO recommends less than 5 grams per day for adults.<sup>230</sup> Yet, in 2010, the global mean salt intake was twice this level, or 10 grams per person per day.<sup>231</sup> WHO's Global Action Plan has set a target of a 30% reduction of population-level salt intake by 2025.<sup>232</sup>

Population salt reduction is among WHO's so-called best-buys to reduce chronic disease—an intervention that could lead to substantial health benefits as well as cost savings.<sup>233,234</sup> In the USA, it has been estimated that a regulatory intervention designed to achieve a reduction in salt intake of 3 grams per day would save 194 000 to 392 000 quality-adjusted life-years and US\$10–24 billion in health-care costs annually, and would be more cost-effective than using medications to lower blood pressure in all people with hypertension.<sup>235</sup> From a population perspective, the most effective and equitable means of reducing salt consumption is to reduce the salt content of manufactured foods.<sup>236,237</sup> In many countries, processed foods substantially contribute to salt intake,<sup>238</sup> regardless of any action individuals might take to reduce the salt they add to food.

Countries are adopting population-level salt reduction strategies to achieve WHO's 30% reduction target by 2025. Many of these focus on reductions at the manufacturing level (reformulation), complemented by public information campaigns and nutrition labelling. The strategies also use diverse regulatory forms. In 2006, the UK became the first country to set salt targets for food composition. Using a voluntary approach, but with strong government leadership and oversight, UK manufacturers agreed to progressive reduction targets for around 80 categories of processed foods. Their reformulation efforts were supported by consumer education and improved food labelling. The approach was highly successful, resulting in a 15% decrease in salt intake across the population.<sup>239</sup> South Africa was the first country to set legislatively mandated salt reduction requirements across a wide range of processed foods. In March 2013, the South African Minister of Health issued the Regulations Relating to the Reduction of Sodium in Certain Foodstuffs and Related Matters.<sup>240</sup> The requirements took effect on June 30, 2016, with more stringent maximum levels coming into force on June 30, 2019.<sup>240</sup> Argentina has used a combination of voluntary and mandatory salt reduction techniques. Initially, the Ministry of Health and large food companies signed a voluntary agreement in 2011 to gradually and progressively reduce sodium in processed foods.<sup>241</sup> Voluntary targets were set according to the category of food, with reductions ranging between 5–18% over a 2-year

period, and a government campaign supporting and encouraging behaviour change. In 2013, to build on the success achieved through the voluntary scheme, Argentina enacted a national law regulating the sodium content of processed foods. As of 2019, 83 countries have salt reduction strategies in place or planned, including 35 countries with voluntary targets and nine with mandatory, legislated targets. Almost all countries use a multifaceted regulatory approach, with 70 countries implementing, or planning to implement more than one type of strategy, and 33 countries incorporating legislative initiatives such as taxes, maximum limits, or warning labels.<sup>242</sup> Programmes are now being implemented in countries across all WHO regions and across countries with a broad range of income levels.<sup>242</sup> An example of these changes is described in the case study of the regulation of sugar-sweetened beverages (panel 7).

Physical inactivity is the fourth leading risk factor for global mortality and was associated with an estimated 55.3 million deaths globally in 2008.<sup>255,256</sup> A European prospective investigation of over 334 000 men and women found that twice as many deaths could be attributed to lack of physical activity, compared with the number of deaths attributable to obesity. Even a modest increase in physical activity could have significant health benefits: a brisk 20 minute walk each day could be enough to reduce an individual's risk of early death.<sup>257</sup> WHO recommendations go further, recommending that adults undertake 150 minutes of moderate-intensity physical activity, or 75 minutes of vigorous-intensity physical activity, throughout the week.<sup>258</sup> Building on these findings and recommendations, an emerging body of evidence on legal and regulatory interventions is aimed at increasing physical activity.

Features of the built environment, including the so-called walkability of a city, are strongly associated with the prevalence of obesity. A gender equity dimension is also present, as women tend to be further disadvantaged in their opportunities for physical activity where cities are not walkable.<sup>259</sup> This is another area in which laws and regulations that affect population health might lie well outside the usual reach of health ministries, thus requiring intersectoral cooperation. In a 2009 review of the evidence, WHO found that modifying the built environment, policies that reduce barriers to physical activity (such as walking, biking, and recreation), transport policies, and increased space for recreational activity were all effective interventions.<sup>260</sup>

Examples of effective laws and regulations to increase physical activity include urban planning, land use management and zoning, transport policy (including taxes on car use, availability and accessibility of public transport, and bicycle and walking paths), and road and traffic control.<sup>261</sup> Local governments can play an important role because land use and zoning frequently fall under their remit. Local governments can implement building, zoning, and development regulations that encourage

**Panel 7: Regulation of sugar-sweetened beverages**

Sugar-sweetened beverages (SSBs), generally defined as liquids with added sugars (soft drinks, sports beverages, energy drinks, sweetened waters) are a known contributor to a variety of non-communicable diseases such as obesity, type 2 diabetes, heart disease, kidney disease, non-alcoholic liver disease, tooth decay and cavities, and gout.<sup>243</sup> In response to the non-communicable disease epidemic, countries have begun to regulate SSBs, primarily through excise taxes, which add a per ounce fee to the SSB sales price, although traditional sales taxes have sometimes been employed.<sup>244,245</sup> The trend toward taxation has increased substantially over the past decade, and particularly during the past 5 years. As of 2019, more than a dozen countries, including France, the UK, Norway, Portugal, Chile, Saudi Arabia, South Africa, Thailand, and Mexico, along with numerous localities, have adopted sugar taxes of varying scope and size.<sup>246</sup>

Two of the most studied tax cases were in Mexico and Berkeley, California. Mexico was among the first countries to implement a substantial tax on SSBs, in 2014, levying a 10% excise tax on all SSBs except milk. Researchers found an immediate reduction in SSB consumption during the following years, with sales of SSBs falling by 5.3% in 2014 and 9.7% in 2015, while sales of untaxed beverages increased in 2014 and fell by only 1% in 2015.<sup>247</sup> In Berkeley, which adopted a 1 cent per ounce tax on SSBs, researchers found that SSB sales decreased by 9.6% while untaxed beverage sales increased by 3.5%, driven primarily by a 15.6% increase in sales of bottled water.<sup>248</sup> Importantly, the tax did not seem to meaningfully affect overall consumer shopping habits, as average grocery bills did not increase, and Berkeley store revenue did not decrease compared with control cities. Multiple studies (in addition to those in Mexico and Berkeley) found that SSB taxes lead to moderate reductions in consumption, which could support positive downstream health outcomes.<sup>249</sup>

WHO supports adoption of SSB taxes as a strategy to help combat non-communicable diseases, particularly obesity and diabetes, citing evidence that an SSB tax that increases consumer prices by 20% can lead to an approximate 20% reduction in consumption.<sup>249</sup> Crucially, researchers have cautioned that SSB taxes must be relatively high to reduce consumption; at lower levels retailers could elect to absorb the cost of the tax in order to retain customer business, particularly if customers are readily able to purchase comparable goods from a nearby retailer in a location without such a tax.<sup>250</sup>

Supporters of SSB taxes often argue that improved population health resulting from SSB taxes will eventually reduce health-care costs. WHO cites estimates that, over 10 years, a tax on sugary drinks of 1 cent per ounce in the USA would result in more than US\$17 billion in health-care cost savings.<sup>249</sup> Supporters argue that the revenue generated by SSB taxes can offset health-care expenses. For example, WHO cites estimates that an SSB tax of ¥1 (US\$0.16) per litre in China would generate an estimated ¥73.6 billion (US\$11.8 billion) in revenue.<sup>249</sup>

As policy makers have become more interested in taxation and other regulation of SSBs, so too has the beverage industry, adopting creative techniques to forestall new regulation. For example, in response to local efforts to implement SSB taxes within California (the largest state in the USA, with over 39 million residents), the beverage industry engaged in an aggressive and ultimately successful strategy to preempt local taxation authority. In California, the generally liberal state government would normally be unlikely to adopt a state wide ban on new soda taxes. However, in 2018, the beverage industry deployed a two-pronged effort to curb local SSB taxing authority, first, by financing a ballot initiative in support of a sweeping preemptive tax law<sup>251,252</sup> that would have been devastating to localities, and later, by agreeing to withdraw the proposed initiative if a more narrow food and beverage tax ban bill passed, a move that was characterised by some legislators as “blackmail” and “being held hostage”.<sup>253</sup>

The industry’s forceful techniques were effective. In June, 2018, the California legislature passed a bill preempting any new local food or beverage taxes for 12 years,<sup>254</sup> joining Michigan and Arizona in adopting state wide bans on new soda taxes. Several other states in the USA have considered such bills, and the industry appears likely to continue to lobby in support of their passage in the USA and globally.

The California example is emblematic of the challenges facing policy makers and health advocates. Although research shows that SSB taxes are an effective legal tool to help combat the non-communicable disease epidemic, the industry has mobilised to defeat any important new regulation. With industry willing to spend heavily in support of its objectives, public health advocates must be prepared for a more difficult path toward adoption of future SSB taxes.

more physically active lifestyles: streets that are welcoming and safe for pedestrians and cyclists, facilities for public recreation (parks and playgrounds), and traffic calming measures.<sup>15</sup>

The common theme among legal and regulatory interventions to prevent non-communicable diseases is that they promote small changes, across entire populations, for a mass impact. By simply changing a default option (eg, reducing salt in processed food,

forbidding smoking in certain areas, or making public transport easier than car use), law has the power to facilitate profound changes in behaviour. Good laws can make healthier and safer behaviours the easier or normal choice. In conjunction with health promotion and awareness campaigns, countries can use law to support and encourage communities to resolve the problems arising from the shared risk factors of non-communicable diseases.

### Injuries

WHO estimates that more than 5 million people (equivalent to 9% of global mortality) die each year as a result of injuries, and many more endure temporary or permanent disability, along with great social and economic hardship.<sup>262</sup> Leading causes of injuries include road traffic crashes, drowning, poisoning, falls, burns, and violence.<sup>262</sup> Again, the burden falls disproportionately on the poor, and more than 90% of injury-related deaths occur in low-income and middle-income countries. Unsafe workplaces or dwellings expose people to high levels of injury risk: prominent incidents include the 2012 Tazreen Fashion factory fire on the outskirts of Dhaka, Bangladesh, and the 2017 Grenfell Tower fire in London, UK. In both episodes, fire safety laws were substandard, poorly enforced, or both. In lower-income countries, countless women sustain debilitating injuries or death from unsafe cooking stoves. Around the world, injuries from the mining and extractive industries disproportionately affect men, and young men bear a disproportionate burden of motor vehicle injuries. Yet, a strong evidence base exists for legal interventions in injury prevention, with road safety being the most prominent example.

The UN General Assembly declared 2011–20 as the Decade of Action for Global Road Safety,<sup>263</sup> and road safety is integrated into SDGs 3 and 11. Each year, 1·24 million people die as a result of road traffic injuries, and a further 20 million to 50 million sustain non-fatal injuries.<sup>263</sup> Road traffic injuries are the leading cause of death among people aged 15–29 years.<sup>264,265</sup> Evidence shows that legislating on five key behavioural risk factors—speeding, drink driving, helmet use, seat belt use, and child restraint use—could significantly reduce this toll.<sup>266</sup> The regulation of environmental and design factors, such as safer vehicles and roads, has also proved highly effective in preventing road crashes. Such interventions include energy-absorbing crumple zones on cars, passive restraints, visible roads with clear lane markings, traffic separation (eg, oncoming vehicles or bicyclists), and traffic calming (eg, roundabouts and speed bumps). However, few countries have systematically implemented laws that target behavioural risk factors and design features, or laws that implement best practices. In particular, low-income and middle-income countries often have substandard laws, and poor compliance and enforcement.<sup>267</sup>

Global health institutions can establish norms that promote the uptake of such laws. Efforts to define technical standards for safety and to conduct policy surveillance of national road safety laws can be effective in helping to spread better laws. For example, seatbelts are a proven way to reduce road traffic injuries and have been mandatory in northern Europe and the USA since the 1970s.<sup>268,269</sup> In 2004, the WHA adopted resolution WHA57.10, recommending that member states implement mandatory seatbelt laws. The following year, the UN

General Assembly adopted its own resolution, A/60/5, similarly calling for mandatory seatbelt legislation. Since then, there has been a significant increase in the number of states that have legislated for national mandatory seatbelt use.<sup>270</sup> Botswana, Cuba, and Kyrgyzstan had a notable drop in road fatalities after mandating seatbelt use for all vehicle occupants.

Wearing helmets can substantially reduce road traffic injuries, and laws mandating helmets for motorcycle drivers and passengers are making an impact around the world. The UK and many US states have had such laws in place since the late 1960s and early 1970s; however, many states in the USA have since repealed their helmet laws, which has significantly increased head injuries. Helmet laws have been proven to be highly effective, reducing the risk of head injuries by 69% and the risk of death by 37%.<sup>271</sup> In 1997, Taiwan introduced legislation making it compulsory to wear a motorcycle helmet. The government supported this legislation with, on one hand, a public information campaign, and on the other, strict fines for both riders and passengers.<sup>272</sup> The results have been powerful: between 1991 and 2008, motorcycle-related deaths almost halved (from 7322 to 3646), despite an increase in both motorcycle use and crashes during the same period. In 2007, Vietnam introduced a similar law,<sup>273</sup> supported by large fines for non-compliance. The Ministry of Health in Vietnam and WHO reported that road traffic head injuries and deaths had decreased by 16% and 18%, respectively, 3 years after the law was introduced.<sup>274</sup>

### When laws do not advance health with justice

When used effectively, law can be the foundation for sustainable, transformational social change. However, when used inappropriately, law can cause grievous harm—sanctioning discrimination and inequality, imposing barriers to access, creating intentional obfuscation, and increasing complexity. As we have reiterated throughout this report, law is only a tool, and its effectiveness depends on how this tool is used. Emphasising the risks that arise when laws do not have the characteristics set out above is important.

The criminal justice system has had a particularly tenuous relationship with public health. Criminal laws can provide a powerful incentive for behaviour change that improves public health, as in the case of road safety. However, too often, the criminal law is used in ways that cause harm to health and to dignity. The history of laws relating to mental health, substance abuse, sexual and reproductive health, sexually transmitted infections, and poverty are often particularly harmful.

Even with an ostensible public health objective, laws can institutionalise inequality, discriminate against already vulnerable populations, and remove opportunities for stigmatised populations to access testing and treatment. We see this most often where criminal laws are enacted to promote a moral norm, rather than to punish a harmful act. For example, numerous

**Panel 8: Effects of the criminalisation of drug use on health and justice worldwide**

Control of the cultivation, trafficking, and use of illicit drugs is an issue of global concern. The international legal drug control system is comprised of three treaties: the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances of 1971, and the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. Countries have a two-pronged obligation: to ensure adequate availability of drugs for medical and scientific purposes, while also preventing illicit production, trafficking, and use of such drugs.<sup>278</sup> Although the drug conventions require governments to take steps to reduce supply and demand for controlled drugs, these efforts must be balanced with countries' human rights obligations,<sup>279</sup> including their citizens' rights to health, dignity, and freedom from arbitrary detention.

The UN Office on Drugs and Crime has stated that the UN drug conventions do not require penalisation of drug use or drug possession for personal use,<sup>280,281</sup> and the system is grounded in a health framework explicitly stating that the "health and welfare of mankind" is its overarching concern.<sup>282</sup> Despite this, countries across the globe use criminal law measures to try and address the reduction of demand prong of their obligations—including 33 countries that maintain the death penalty for drug-related offences.<sup>283</sup> In many countries, sentences for minor drug dealing are longer than sentences for serious acts of violence such as murder, rape, or armed robbery,<sup>284</sup> and people imprisoned on drug-related charges make up a substantial proportion of prison populations worldwide.<sup>282</sup> In many countries, punitive drug control efforts have resulted in serious human rights abuse, including torture and ill treatment by police, mass incarceration, extrajudicial killings, arbitrary detention, and denial of essential medicines and basic health services.<sup>282</sup>

The criminalisation of drug use has facilitated the spread of blood-borne viruses, particularly HIV, among drug users. Some of the most severe drug-related harms are associated with injecting drug use. Outside of sub-Saharan Africa, up to 30% of all new HIV infections occur among people who inject drugs with unsafe injecting practices.<sup>285</sup> In fact, HIV prevalence in countries that rely on punitive approaches is substantially higher (37–42% vs less than 5%) than countries that use public health approaches to drug use.<sup>275</sup> Furthermore, criminalisation has also been used to limit access to treatment options. Drug control efforts often have a disproportionate effect on vulnerable groups and marginalised communities, including indigenous populations, the poor, and racial or ethnic minorities.<sup>286</sup> In some countries, including the USA, treatment for hepatitis C has been restricted on the basis of a person's active injecting status. Criminalisation has also resulted in reduced access to disease prevention interventions, and proliferation of high-risk drug use behaviours in the absence of accessible harm reduction technologies.

international commissions have called for the decriminalisation of HIV exposure or transmission.<sup>275</sup> The overly broad criminalisation of HIV non-disclosure, exposure, or transmission are not only contrary to established public health evidence, but have also been shown to negatively affect health outcomes.<sup>275,276</sup> In many countries it is a crime for a person with HIV infection to have sex without disclosing his or her HIV status. In these settings, such laws are inequitably enforced, fail to meet any tangible public health objective —ie, reduce rates of HIV transmission<sup>277</sup>—and additionally, embed stigma and punish people for engaging in common behaviours such as sexual activity. The result is that individuals are driven underground, preventing them from accessing treatment, and potentially placing the broader community at risk.<sup>275</sup>

Similarly, criminal laws have also posed barriers to the treatment and rehabilitation of people who use drugs (panel 8).

Criminalisation can lead to people avoiding health (and potentially other needed) services for fear of arrest, and because of concerns about discrimination. Consequently, their health and wellbeing are harmed.

Another pertinent example involves people with mental disabilities incarcerated in the criminal justice system, rather than treated in a therapeutic environment. Studies of the US prison system show that "about 20 per cent of inmates have a serious mental illness, 30 to 60 per cent have substance abuse problems and, when including broad-based mental illnesses, the percentages increase significantly."<sup>287</sup> Most inmates placed in seclusion have a mental health disorder. Beyond lack of any therapeutic intent, incarcerating people with a mental health disorder results in further marginalisation and discrimination of an already vulnerable group (panel 9).

The criminal justice system can be especially unfair to women, particularly with regards to sex work and reproductive health. Laws criminalising sex work are globally ubiquitous. Sex workers are a highly marginalised group, and the illegality of their work often results in scant protection against abuse, violence, and financial extortion.<sup>300</sup> The criminalisation of sex work virtually eliminates the negotiating power of people engaged in sex work. Criminalisation makes it harder for sex workers to negotiate safe sex with their clients, and it increases the risk of violence, because sex workers are deterred from reporting violence to police. Some jurisdictions, such as New Zealand, have legalised sex work, but both legalisation and decriminalisation are controversial and politically difficult.

In many jurisdictions, reproductive choice and health, including access to safe contraception and abortion, are threatened. Despite WHO guidance, many countries have criminalised abortion and restricted family planning, and in some countries, women are imprisoned for involuntary miscarriage.<sup>301</sup> A 2016 study found that "abortion rates are not substantially different across groups of countries classified according to the grounds under which abortion is legally allowed."<sup>302</sup> However, the study did find "the level of unmet need for contraception is higher in countries with the most restrictive abortion laws than in countries with the most liberal laws, and this contributes to the incidence of abortion in countries with restrictive laws."<sup>302</sup>

Laws that restrict or penalise reproductive health programmes and family planning not only cause stigma, but can also undermine public health messages. Several Latin American countries restrict reproductive rights. These restrictions caused major concern during the Zika epidemic, given fears about neurological disorders and neonatal malformations.<sup>303</sup> Countries in the Americas have observed an increase in babies born with microcephaly, with a clear association between microcephaly

**Panel 9: Law as a tool to support improvement of mental health disorders**

WHO defines mental health as “a state of well-being in which every individual realises his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community”.<sup>288</sup>

The WHO and Institute for Health Metrics and Evaluation category of mental health and substance use disorders encompasses several conditions including depression, anxiety, bipolar disorder, eating disorders, schizophrenia, intellectual developmental disability, and alcohol and drug use disorders.

Globally, the burden of mental health disease is substantial. Approximately 15–20% of the world’s population have one or more mental or substance use disorders;<sup>289</sup> in 2016, approximately 1.1 billion individuals had a mental or substance use disorder. Some argue that the true burden of mental health and substance use disorder is even higher because of factors such as difficulties in accurate measurement and reporting, along with challenges in categorisation of overlapping conditions.<sup>290</sup>

Mental health is neglected in most countries, particularly in relation to physical health conditions. Individuals with mental health disorders face pervasive stigma and discrimination, resulting in considerable disparities between the services available for physical and mental health, with decreased availability, accessibility, and quality of mental health services.<sup>290</sup>

Although countries vary widely in access to mental health services, even the best performing systems have yet to meet the need, leaving a wide treatment gap between the need for treatment and actual service delivery. Estimates range from 76% to 85% of people with mental disorders not receiving treatment in low-income and middle-income countries, compared with 50% of comparable individuals in high-income countries.<sup>291</sup>

WHO has identified the development of mental health policies and laws that promote human rights as crucial to the protection of people with mental health disorders, observing that such policies and laws are inadequate in most countries.<sup>292</sup> WHO’s Mental Health Action Plan 2013–20 set a target that 50% of countries should have developed or updated their mental health laws in line with international and regional human rights instruments by 2020.<sup>293</sup>

Although successful mental health policy involves myriad components, a foundational issue is access to affordable, quality mental health services, which requires laws supporting

such access along with adequate funding for services.

Historically, countries devoted their scarce mental health resources almost exclusively to high-cost inpatient services for relatively few acute cases, which has contributed to the treatment gap. As evidence has shown the effectiveness of community-based outpatient treatment and integration of mental and physical health services, countries are slowly transitioning their laws and policies accordingly.

A notable example is the UK’s Improving Access to Psychological Therapies (IAPT) programme. Initiated in 2008, the IAPT programme provides evidence-based outpatient services to people with anxiety or depressive diagnoses. The programme has several unique features, including mandatory use of standardised evidence-based protocols with intensive clinical supervision and, crucially, providing the services free of charge at the point of care.<sup>294</sup> The UK invested £400 million in the programme from 2011 to 2015, and data indicate that about 950 000 people per year access IAPT for an initial assessment, of whom more than 537 000 receive therapy.<sup>295</sup> This increase in access has helped narrow the treatment gap by improving treatment rates for adults with anxiety or depression from 24% in 2007 to 37% in 2014.<sup>294, 296</sup>

Another example of a law designed to improve mental health is India’s Mental Healthcare Act of 2017, a broad bill that seeks explicitly to comply with the UN Convention on the Rights of Persons with Disabilities. India has traditionally underfunded its mental health services, spending only 0.06% of its total health expenditures on outpatient mental health care,<sup>297</sup> and has a severe shortage of mental health providers, even when compared with other low-income and middle-income countries.<sup>298, 299</sup> Among the new law’s provisions is a requirement that insurers cover mental and physical health services in parity, which supporters hope will help combat the stigma surrounding treatment and lead to improved mental health outcomes.

The ongoing stigma surrounding mental health conditions and continued shortfalls in funding mean that change will come slowly, but the actions of countries such as the UK and India show that targeted laws can help speed progress toward improved mental health outcomes, particularly when coupled with adequate resources.

and exposure of the mother to Zika virus during pregnancy.<sup>304</sup> In 2016, WHO recommended that women in countries where Zika virus infection is a threat should delay pregnancy for several months to several years.<sup>305</sup> However, at the same time, several affected countries have strict barriers to accessing abortion, including laws that criminalise abortion for any purpose.<sup>306</sup> Women are consequently placed in an untenable position and can face a violation of their human rights. Such laws endanger the health of women, especially those who seek

unsafe abortions because of the lack of access to legal abortion services.

Laws in other realms can also adversely affect the public’s health. Many countries ban or restrict access to health services for non-nationals—particularly, but not only, undocumented immigrants. The law can also undermine the health of migrants in other ways. For example, immigration laws often require deportation of non-citizens infected with tuberculosis, which drives the population underground (panel 10).

**Panel 10: The effect of international law on the health of refugees—the case of tuberculosis**

Nowadays, the world is facing the highest levels of displacement on record.<sup>307</sup> With an unprecedented 68.5 million people around the world forced from their homes—of whom, nearly 25.4 million are refugees and 10 million are stateless people—the origins and consequences of the displacement crisis remain some of the most formidable challenges of our modern time.<sup>307</sup> Attempting to address the myriad challenges that face refugees and asylum seekers across the world, the international community, by way of international law and treaties, has sought to foster norms on how countries treat refugees. The core instruments of international refugee law—the 1951 Convention relating to the Status of Refugees, and the 1967 Protocol<sup>308</sup>—provide protection for refugees by prohibiting refoulement of refugees, or forcible returning of refugees to places where they fear for their lives or freedom.<sup>309</sup>

Although the law has taken important steps to protect the wellbeing of refugees, profound gaps persist and negatively affect the rights and experiences of refugees, particularly with respect to health. Yet even more troublingly, laws and policies themselves can hinder health outcomes and contravene well established public health principles. This twin dynamic of unmet need and avoidable harm is exemplified in national laws and policies surrounding refugees and tuberculosis.<sup>310</sup>

From the start of the journey, through to arrival at the country of asylum, refugees and others who are subject to forced migration are susceptible to contracting tuberculosis. This vulnerability begins with refugees' experiences in their home country, where health-care infrastructure might be lacking or have broken down because of war. For example, before the 2011 crisis began, Syria had a relatively low burden of tuberculosis.<sup>311</sup> Although data regarding tuberculosis in Syria remains elusive, reports show a rapid rise of the disease in the country, which is still believed to only be a fraction of the actual burden.<sup>311,312</sup>

After refugees leave their home country, the journey exacerbates their susceptibility to tuberculosis. Economic, social, and legal barriers increase the likelihood that tuberculosis will spread along the way and block access to care for those who contract it. These barriers, in turn, can lead to increases in the prevalence of tuberculosis in countries of asylum. Lebanon has

been a country of asylum for Syrian refugees from the start of the conflict in 2011.<sup>313</sup> In the first year of receiving Syrian refugees, Lebanon saw a 27% increase in tuberculosis cases.<sup>311</sup>

Reflecting this dynamic, countries enact national laws and policies regarding migrants and tuberculosis. For instance, some countries will not provide essential medical services to migrants with tuberculosis, some have legal requirements that individuals with tuberculosis undergo treatment as a condition of attaining legal status, and many detain and deport individuals who have or develop tuberculosis, frequently without providing necessary treatment.<sup>310</sup> In the USA, active tuberculosis is still one of the communicable diseases that trigger inadmissibility under the Immigration and Nationality Act, though a waiver may be possible.<sup>314</sup> These national restrictions based on tuberculosis claim public health as a justification, but directly contravene established public health principles and violate international law.

The WHO emphasises that screening of migrants, including refugees, for active or latent tuberculosis “should always be done with the intention to provide appropriate medical care, and never to exclude or preclude entry”.<sup>315</sup> Because tuberculosis is preventable, treatable, and curable, public health principles guide the international community towards identifying and treating every individual with active tuberculosis, regardless of location, immigration status, or socioeconomic status.<sup>310</sup> This approach builds on the experience of countries' HIV and AIDS responses and the International Health Regulations, which call for any measure to prevent the spread of an infectious disease to use the least restrictive means possible.<sup>316</sup>

With respect to international law, countries have a right to exercise their sovereignty in imposing immigration restrictions.<sup>317</sup> However, international law requires that states only undertake measures that are consistent with human rights and other international obligations. These obligations include non-discrimination on the basis of other status, which includes health status. If states do indeed opt to limit rights, states must show that the limitations are necessary to achieve a legitimate aim, that the means achieve the stated aim, and that they are the least restrictive means.<sup>318</sup>

People who fear deportation are unlikely to seek testing and treatment, placing infected individuals and the wider public at risk. Moreover, by interrupting continuity of care, deportation can jeopardise tuberculosis treatment for those who have already started it, which risks resistance developing to first-line tuberculosis medications.<sup>310</sup>

**Healthy people in healthy communities**

A substantial body of evidence and learned experience shows that legal interventions can advance global health with justice. Around the world, law has been used to reduce health risks, examples of which include vector control and immunisation for infectious diseases, tobacco

control, food reformulation, healthy built environments for non-communicable diseases, vehicle and road design, and increased road safety measures.

But the lessons of evidence and practice also run in the opposite direction. Too often, governments have used law for improper purposes, or with little consideration for the values of health with justice. In such cases, law can raise risks and create stigma. Inappropriate use of the criminal law has been deeply harmful in multiple spheres. For these reasons, policy makers should monitor and evaluate the effects of law on health and on justice. Legal determinant 3 encapsulates the need for ongoing evaluation of public health laws, ensuring that laws and

their implementation are evidence-based, fair, intersectoral, and transparent. Laws that promote human rights, particularly the right to health, can be transformative; however, those that violate human rights can be deeply harmful.

Despite the firm foundation of the right to health in international law, the persistence of unconscionable health inequities and the lack of accountability to health commitments have led to calls for a new treaty on the right to health. The Framework Convention on Global Health (FCGH), an idea first suggested a decade ago, is a major proposal for a treaty based on the right to health.<sup>319</sup> The FCGH has since been supported by a growing number of civil society organisations, as well as national and global health leaders,<sup>320,321</sup> with this movement now crystallised through the FCGH Alliance. The FCGH would reinforce norms of equity, justice, and human rights; create mechanisms for inclusive participation, cross-sector cooperation, and accountability; and delineate national and global responsibilities for sustainable financing.<sup>322</sup> Rather than a piecemeal approach to discrete global health challenges, the FCGH would function as an overarching, rights-based framework under which all the vital components of the right to health could be realised, with additional protocols where needed to fill gaps. The FCGH would respond to the SDGs call for governments and international institutions to “leave no one behind.”

When research tells us that an intervention works, and when governments operate on the basis of sound scientific evidence and the rule of law, it becomes possible to create the conditions in which people can achieve health with dignity and human rights. Healthy populations and healthy communities start with the enactment and implementation of effective and just public health laws. Recommendation 4 urges governments to form country-appropriate mechanisms to advise on legal interventions that will impact the public’s health and safety. These might take the form of national health law commissions, task forces, or other structures, with the aim of developing a systematic plan to identify and propose effective legislation. As part of this process, we also recommend that governments adopt legislation requiring HIAs for policies, programmes, and projects that might seriously affect health.

At the international level, recommendation 4 proposes that WHO use its constitutional law-making powers to adopt further international legal instruments to safeguard the public’s health and safety. This approach would build on the successes of existing instruments, while also addressing deficiencies, and aim to understand and improve underserved areas such as mental health.

## Section 5: legal determinant 4

Our final legal determinant of health underpins all the others: building and strengthening legal capacities for health. Robust legal architecture and resources for

enacting, implementing, and monitoring public health legislation can bring to fruition all the legal determinants of health. Law and health should be mutually reinforcing, but the two fields often do not work synergistically, whether in research, practice, or philosophical orientation. In this section we make the case for, and set out the key features of, the legal capacities required to achieve health with justice.

### Why build capacity?

Strong legal capacity for health will be a key determinant of progress towards global health and sustainable development. Yet, too often, countries lack the basic legal infrastructure or the capacity to build it. The WHO report, *Advancing the right to health: the vital role of law*,<sup>86</sup> put forward several reasons why legal capacity building is essential.

First, the report states that over time, laws have become outdated, fragmented, ambiguous, or incoherent. Therefore, health officials might lack the mandate and legal powers to implement new, evidence-based interventions. Outdated laws and existing interventions might stigmatise or penalise vulnerable individuals and communities, driving epidemics underground. Secondly, new and emerging health hazards might require new legislative frameworks. Public health laws are often introduced reactively, and then stay on the books for decades. In the face of emerging threats—whether novel pandemics, or new paradigms such as non-communicable diseases—these laws might not be fit for purpose. Conversely, an ambitious goal like achieving UHC calls for forward planning and proactive regulation. The WHO capacity building report also stated that governments might lack the legislative and regulatory tools to discharge their public health and human rights responsibilities effectively. Public health officials need a wide-ranging set of powers to carry out their responsibilities to safeguard the population. At the same time, the law must protect the civil and political rights of individuals, as well as their social, economic, and cultural rights, including non-discrimination and equal protection under the law. Protecting such rights is particularly relevant to achieving the SDGs, in which health, development, and human rights are closely intertwined.

In settings where regulatory and governance capacity is lacking, laws intended to protect the public’s health might be poorly drafted or ineffectively implemented. In the absence of a sound legal infrastructure, the law might even undermine health goals.

### How do we define legal capacity?

The term capacity building (or capacity development) originally comes from the lexicon of sustainable development.<sup>323</sup> Capacity can include “infrastructure, institutions, human knowledge and skills, and collective attributes such as social relationships, leadership and management.”<sup>324</sup> The UN Economic and Social Council

For more on the FCGH Alliance  
see <https://www.fcghalliance.org>

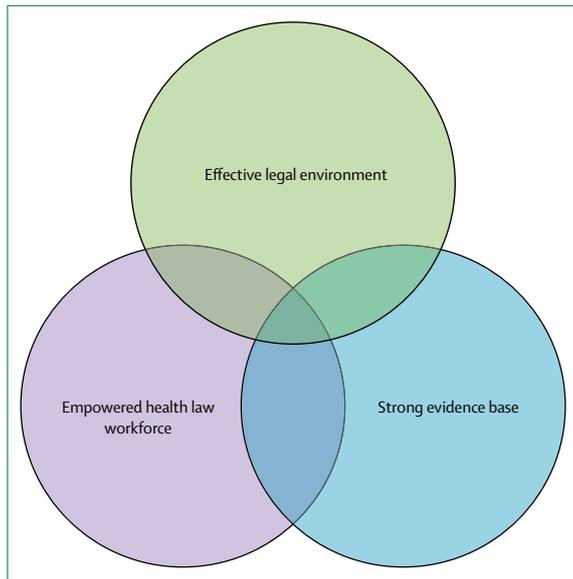


Figure 5: The overlapping dimensions of legal capacity building for health

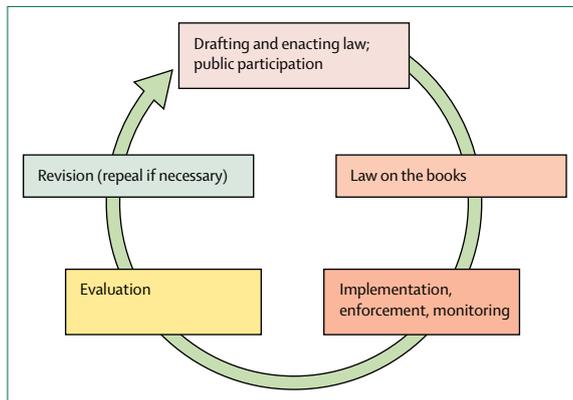


Figure 6: Features of an effective legal environment

defines capacity development as “the process by which individuals, organizations, institutions and societies develop abilities to perform functions, solve problems and set and achieve objectives.”<sup>325</sup>

Just as public health requires governments to invest in health systems, it also requires investment in regulatory capacity and effective legal environments.<sup>36</sup> Legal capacity for health refers to three interlinked dimensions: effective legal environments (which include the infrastructure for drafting, implementing, and enforcing laws that promote health with justice, as well as fairly resolving grievances that arise); a strong and growing evidence base, built on the rigorous monitoring and evaluation of existing laws; and an empowered, transdisciplinary health law workforce. The latter includes connected networks of well trained professionals—legal and non-legal—who share information and strategies, and who provide technical legal assistance.<sup>16</sup> Building capacity means attending to each of these dimensions (figure 5).

### An effective legal environment: a process, not an endpoint

Enacting a good health law is only the first step towards building an effective legal environment. Laws that are defined as on the books must be supported by effective processes for their drafting (including public participation), implementation, enforcement, monitoring, evaluation, and ultimately their revision or repeal where necessary (figure 6). Ongoing evaluation and continuous quality improvement lead to legislation and regulations that demonstrably improve the public’s health and safety.

#### Drafting and enacting public health law

The most visible aspect of an effective legal environment for health is so-called law on the books—the group of enacted laws and regulations that makes up public health law. Traditionally, the focus of public health law was on the management of unsanitary environmental conditions (eg, drains, water, food, and housing), and the control of infectious diseases.<sup>17</sup> Nowadays we recognise that public health law encompasses a far wider range of topics. Specific public health laws include “laws that are intended as health interventions, laws that define the powers, duties and boundaries of health agencies and systems, and laws that have an impact on health but were not enacted primarily with population health in mind”.<sup>3</sup> Examples for each of these categories are provided (panel 11).

From pandemic responses to the prevention of non-communicable diseases, law on the books is a crucial determinant of what is achievable: empowering and obligating agencies to safeguard the public’s health, but also protecting individual rights by placing limits on government and private action.

Governments first need capacity to write and enact laws and regulations. Such drafting should ensure that laws are comprehensible and systematic; adhere to principles of good governance and sound regulation, such as being developed through transparent processes with public participation; are evidence-based; are transparent and clearly communicated to the public, setting out health officials’ powers and responsibilities, as well as their limits; are consistent with, and supportive of human rights; and promote equity. Many of these features are addressed in sections of this report.

Effective legal environments, like effective health environments, require transparency and accountability. Effective legal environments give affected populations and civil society organisations meaningful opportunities to participate in the decision-making process. Translating the goals and processes of health laws from the immediate context of policy makers and legal or health practitioners, to the wider public and the organisations that represent their interests, is crucial. This idea goes far beyond education or health promotion: rather, it means that affected communities should be genuine partners in, rather than targets of, health policy.

**Panel 11: Public health laws****Laws intended as health interventions**

- Standards: food safety; consumer protection; air quality; drinking water; drugs, cosmetics and medical devices; pesticides; occupational health and safety; road safety; hygiene and sanitation; vector control
- Regulation and licensing of tradespersons and professionals: health workers; social workers; hair and nail stylists; tattoo artists
- Regulation and inspection of premises: hospitals and nursing homes; bars and restaurants; food markets; docks; swimming pools; tattooing and tanning establishments
- Pest and animal control: vector abatement (eg, mosquitoes, fleas, and rodents); dangerous or exotic animals
- Infectious disease response: vaccinations; testing and screening; isolation and quarantine; contact tracing and partner notification; directly observed therapy
- Tobacco control: age limits, smoking bans in public places; taxation; advertising and marketing bans and restrictions; packet labelling (or warnings) and plain packaging; bans on cigarette flavouring; nicotine reduction
- Alcohol control: age limits; restrictions on marketing and advertising, package warning labels; prohibiting driving while intoxicated
- Mental health laws: guardianship and civil commitment; mandatory or community treatment; rights protections
- Promoting healthy diets: nutrition labelling on food products and restaurant menus; regulation of junk food advertising aimed at children; regulating food ingredients (eg, limits on trans fatty acids, added sugars or sodium); portion size limits; taxes on unhealthy foods (eg, sugar-sweetened beverages)

**Laws that define the powers, duties, and boundaries of health agencies and systems**

- Laws establishing and governing public health agencies, including mission, powers, limits
- Laws establishing and governing health-care agencies, including quality assurance, eligibility for services, essential medicines list, reimbursement for services
- Laws protecting patients' and service users' rights and privileges
- Privacy laws governing data held by health agencies and health-care providers, including data protection and confidentiality

**Laws that have an effect on health, but were not enacted primarily with population health in mind**

- Planning and zoning laws: walking and biking paths; parks, playgrounds, and recreation; pedestrian zones and congestion taxes; limiting fast food outlets and encouraging supermarkets
- Firearms regulation: weapons bans (eg, automatic discharge firearms); smart firearms (eg, discharge only with owner's fingerprints); safe gun storage; firearms training; background checks prior to purchasing
- Social, welfare, and housing services and programmes: child protection and benefits; community centres (for the elderly or vulnerable) and support groups (for drug or alcohol dependency); pensions and disability benefits; income supports; nutrition programmes; public and subsidised housing
- General taxation: progressive tax structures; negative income taxes; deductions for health care, child care, and public transportation expenses; eliminating tax havens or loopholes; fair and efficient tax collection

The global response to HIV and AIDS provides the most powerful illustration of community mobilisation. In the face of stigma, discrimination, and neglect, advocates raised social and political awareness, which ultimately generated the political will to take action. They demanded high quality research into the prevention and treatment of HIV infection. When interventions were developed, they advocated for the right to affordable access throughout the world. The response to HIV and AIDS is, of course, an ongoing struggle, and is only one major health hazard among the many that urgently require social mobilisation.

In areas where civil society voices are not yet sufficiently empowered—for instance, for non-communicable diseases,<sup>326</sup> injuries, or mental health—governments should actively seek public involvement in policy making, using public announcements, open forums, and public comment sessions. Consumers and health advocates should be invited to attend important meetings as partners alongside public officials, health professionals, and

scientists. These governance mechanisms can incentivise public participation and help “dispel potential concerns of suspicion or mystification that might surround the development of public health laws”.<sup>327</sup>

Public participation and open forums also enable civil society to understand the purpose of health law and engage more effectively in the policy process. In turn, this can support adherence to the norms and standards established by health laws. For example, in Denmark, public health groups worked with the government, industry bodies, and civil society organisations, to raise public awareness of the cardiovascular risks of consuming artificial trans fats.<sup>328,329</sup> This type of public engagement meant that when regulation limiting these harmful fats was introduced in 2003, it already had a high level of public confidence and support, and strong industry compliance—ultimately leading to a successful public health legal intervention.

Public participation can also mean opening the door to powerful vested interests. New York City's regulation

limiting the portion size of sugary drinks (known popularly as the soda ban) received a great deal of community opposition. However, research subsequently showed that much of this opposition was led by organisations supported by the sweetened beverage industry.<sup>330</sup> The American Beverage Association (with Coca-Cola and PepsiCo as members) spent millions of dollars swaying public opinion against the soda ban, and ultimately succeeded in having the courts strike down the measure. Elsewhere, the food industry has spent lavishly to influence legislative processes on issues ranging from menu labelling to taxes on sweetened beverages.<sup>331</sup>

Furthermore, as sales of unhealthy foods in higher-income countries have begun to lag, food companies are expanding their markets in developing countries by targeting community networks. An exposé in *The New York Times*,<sup>332</sup> describes the use of direct marketing by multinational Nestlé to sell sugary foods to poor people in Brazil, under the guise of nutrition and community empowerment. These grassroots efforts take place while food and beverage conglomerates enjoy an enormous amount of political and economic power in Brazil.

Policy makers must be alert to the risk that genuine community voices are likely to be weaker, less organised, and less well-funded than commercial players with substantial interests to defend. As such, governments should empower civil society organisations to meaningfully participate in the development of health laws. Health advocates also need to anticipate industry opposition and build broad-based community coalitions for health.<sup>333</sup>

*Implementation: inspections, monitoring, and enforcement*

Effective legal environments are supported by systems of monitoring, inspections, and tools for enhancing compliance with public health laws and regulations. A range of different professions—including public health, food and drug, and environmental health officers; medical and nursing practitioners; scientists; and even police in certain contexts<sup>17</sup>—will have responsibility for monitoring and enforcing public health laws. These professionals exercise statutory powers as health officials, officers, or inspectors. For the purposes of enforcement, these powers usually include a range of responsibilities, described as follows: inspect and search premises or goods—eg, to ensure safe workplace environments, purity of food and drugs, or sanitary conditions of farms or restaurants;<sup>327</sup> issue orders to cease and desist unsafe conditions or activities, such as pest or animal abatement; issue formal notices of failure to comply; levy and collect fines; confiscate unsound goods; shut down unsafe businesses or premises; sanction professionals for poor quality or safety lapses, including the loss of a licence, permit, or accreditation needed to legally operate; publicly disclose instances in which there has been a failure to adhere to public health standards, such as by issuing prominent notices on restaurants of their sanitation and hygiene rating; and finally, engage in dispute resolution,

when there is a legitimate disagreement between regulators and the regulated party.<sup>327</sup>

Where disputes arise, the court system or other means of redress must be empowered to impartially adjudicate disputes, ensuring fair application of the regulations, and allowing regulated professionals or industries to contest decisions.

*Research and evaluation*

Ongoing monitoring and evaluation of the effects of laws and regulations are crucial steps in the process of ensuring effective legal environments for health, but are often overlooked. Because law has the power to affect diverse populations in different ways, it is crucial that policy makers rely on evidence, whenever possible, to distinguish between laws that work, laws that do not work, and laws that cause harm. Yet, nowhere else in the realm of public health are interventions used to treat so many people with so little evaluation of the effects.<sup>201</sup> A few exception areas, including alcohol and tobacco control, have showed the importance of evaluation in developing and spreading highly effective legal solutions. In the following section, we focus on a second dimension of legal capacity for health: a strong evidence base.

**A strong evidence base, informed by the values of justice and equity**

Health laws and regulations should be informed by a robust body of evidence regarding their effectiveness in reducing risks of injury and disease. In this section, we make the case for strengthening the evidence base in relation to the design and use of health law research. At the same time, we acknowledge the important role of values in health policy innovation. As we have noted throughout this report, public health is not simply the application of technical solutions to health problems. Rather, it is unabashedly infused with the values of social justice and grounded in the language and practice of human rights. Although we recognise that the law-making process is embedded in politics, we urge policy makers to critically evaluate existing evidence, support ongoing health law research, and prioritise the right to health and other human rights.

*Health laws must be based on robust evidence*

Since the turn of the 21st century, public health law as a field of scholarship has undergone a renaissance: its philosophical orientations, conceptual frameworks, and core debates have been well articulated.<sup>15</sup> Building on this, researchers and policy makers are now recognising the growing need for empirical research. Empirical research can relate to any of the stages in figure 6—from the design of laws, to their monitoring and enforcement—and aims to answer the questions: which laws or practices are associated with better health outcomes? Which laws or practices are associated with worse health outcomes? Which laws impose undue burdens, particularly on

disadvantaged populations? How can these laws or practices be improved, for population health and the protection of human rights?

Law is rarely amenable to what scientists regard as the so-called gold standard of evaluation, which is the randomised clinical trial. Nevertheless, the impact of law can be studied scientifically, the study of which leading scholars describe as legal epidemiology.<sup>334</sup> Legal epidemiology aims to study law as a variable that can affect health outcomes. For example, it might rigorously examine whether a law is correlated with a particular health outcome, or compare outcomes in jurisdictions that have implemented similar or different laws—noting that contextual factors will mean that success in one jurisdiction will not necessarily predict success in a neighbouring jurisdiction. Comparison of health effects before and after implementation of a law is also a useful research tool. Health law research can also survey those who implement laws, and those affected by them, to ascertain their effects on the ground.

Empirical health law research employs scientific, quantitative methods to assess the effect of laws and to improve their design. Such empirical research methods include evaluating the policy-making process, so-called mapping particular categories of laws or regulations, examining how laws are implemented and enforced in practice, intervention studies, and close analysis of the legal mechanisms of particular interventions.<sup>334</sup> Beyond strengthening the evidence base, this type of research can have far-reaching social and political effects. Research findings can strengthen political and public support for the enactment of particular health laws (by giving an evidence-based rationale for their implementation) and, at a deeper level, can also help strengthen the philosophical and practical linkages between law, health, development, and related disciplines.

A persistent reason for public opposition to health laws lies in the claim that they are paternalistic: an intrusion by the so-called nanny state onto individuals' freedom to choose what to eat or how to behave. Opponents argue that certain public health laws force individuals to act in ways they would not otherwise choose—such as compelling them to wear a motorcycle helmet or raising the price of sugary drinks. Health advocates can use normative reasoning to address claims of paternalism—arguing, for example, that these laws increase wellbeing and reduce health-care costs. However, objective evidence of positive behaviour changes that improve health can be a more powerful counter to such so-called nanny state arguments.

Well designed studies often require access to large datasets, medium-to-long-term funding and perhaps most importantly, a workforce of interdisciplinary researchers.<sup>335</sup> Universities, which have played an important role in the expansion of global health as a discipline,<sup>6</sup> can help to build such a workforce by offering health training to legal graduates, and legal training to health professionals. As a

global health community, we need to set, and drive forward, a clear and ambitious research agenda. We need to build consensus on the key questions that require answers and the laws in most urgent need of evaluation, and to prioritise resources accordingly.<sup>336</sup> Given that society invests substantial political and economic capital in enacting and enforcing public health laws, devoting resources to enable high-quality research into their effects would be worth the investment.

#### *But evidence is not the only consideration*

Even as we advocate for high-quality empirical research on the relationship between law and health, we recognise that evidence is only one important aspect of a well regulated society. Policy makers often must act on the basis of incomplete scientific information, taking social values into account. In some cases, the call for full objective evidence before enacting any public health intervention can stifle innovation. If a new law represents a sharp turn from accepted practice, the case for reform will often require building an evidence base over time.

In settings where law makers have good grounds for believing that legislation will have positive effects, and have a plan for ongoing evaluation, they should have the leeway to introduce novel ideas. For example, following the first case of HIV transmission via drug-injecting equipment in 1985, Australia quickly introduced a Needle and Syringe Programme (NSP). The NSP provided sterile drug injection equipment and facilities for the safe disposal of used equipment. The programme also became a first point of contact between injecting drug users and health services, providing education, information, and onward referrals to drug treatment, medical care, and legal and social services.<sup>337</sup>

Evaluations of NSPs in Australia found them to be “the single most important and cost-effective strategy in reducing drug-related harms among [persons who inject drugs]”,<sup>338</sup> and the programme has been endorsed by WHO, UNAIDS, and the UN Office on Drugs and Crime. Yet initially, experts and policy makers faced intense opposition. The evidence was not watertight, but policy makers had to act decisively to stem a potential epidemic. In doing so, they were guided by human rights principles and the need to protect a susceptible community. Once adopted, programmes such as NSPs can and should be subject to rigorous empirical examination. As of 2019, we have robust evidence that NSPs help prevent the transmission of blood-borne diseases and save lives. As observed with so many public health successes, the lack of complete evidence did not act as a barrier to innovation. Therefore, governments should establish infrastructure to enable early, rapid, and systematic evaluation of innovative policy ideas.<sup>339</sup>

#### **An empowered, transdisciplinary health law workforce**

Finally, effective legal environments are only possible with a knowledgeable and capable health law workforce.

As the linkages between global health and the law become stronger, the need for an empowered, transdisciplinary health law workforce will become more pronounced. Recognition of the potential for legislative and regulatory interventions to improve population health is growing; however, this is not matched by the availability of skilled professionals who can implement and evaluate such interventions.<sup>340</sup> Although difficult to quantify numerically, in our assessment, the deficit is marked. We identify three aspects central to building the necessary workforce capacity: building disciplinary bridges, building knowledge and skills, and building networks.

### *Building disciplinary bridges*

Researchers and practitioners in law and in health have traditionally worked in quite distinct ways. In the medical profession, as in the wider public, understanding or recognition of the power of law to drive behavioural and social change is lacking. Health professionals might even have a negative view of the legal profession, perceiving lawyers as adversaries bringing malpractice litigation.<sup>340</sup> For their part, lawyers can be protective of their turf and unwilling to acknowledge the limits of their subject-matter expertise. This silo mentality leads to missed opportunities for teaching, research, practice, and problem-solving. Colleges and universities are uniquely positioned to address this problem, but these institutions alone are insufficient to foster the necessary health law ecosystem. Building the empirical evidence base for effective health laws first requires building disciplinary bridges: mutual understanding, collaboration, common terminologies, and an appreciation of how different skill sets can be applied to public health problems. It also requires genuine interdisciplinary (or even transdisciplinary)<sup>16</sup> research, drawing on the expertise of legal scholars, epidemiologists, clinical scientists, policy analysts, behaviour change experts, and anthropologists, amongst others, working together.

### *Building knowledge and skills*

The interdisciplinary or transdisciplinary nature of health law presents unique challenges for teaching and training. Nevertheless, equipping law graduates with health knowledge and epidemiological skills, and health graduates with an understanding of the role of law and governance in creating healthy environments, is crucial for building capacity. Both health graduates and law graduates should be introduced to the basics of international human rights law. Education in public health, law, and policy should include the range of skills needed in a transdisciplinary public health law practice, including policy development, basic principles of law and legal procedure, advocacy, ethics, implementation and enforcement, and legal epidemiology.<sup>16,201</sup> Schools of medicine, nursing, public health, and law can teach a broad

curriculum encompassing a variety of transdisciplinary skills. These schools can also collaborate to offer joint degrees, such as a Juris Doctor with Master of Public Health or Juris Doctor with Doctor of Medicine.

Academic institutions have the opportunity to successfully deliver training and teach skills to help resolve specific health challenges—for instance for non-communicable diseases, access to medicines, and injuries. Solutions to all of these complex health problems require a variety of scientific and legal skills. Progress in these areas can be achieved only if health advocates have access to the training and resources needed for deep understanding not only of the health hazard, but also of the legal rules and mechanisms that govern the particular field. Understanding the field of non-communicable diseases and the law requires a strong understanding of multiple other areas, including consumer law, marketing law, food law, tax law, and environment and planning law.<sup>341</sup> Similarly, the law surrounding access to medicines requires understanding the linkages between trade law, intellectual property law, and health.<sup>340</sup> Health advocates push for affordable access to medical technologies, but to be truly effective they need the acumen to understand the legal rules governing the pricing and regulation of vaccines and medicines.<sup>342</sup>

Health diplomacy is another crucial legal capacity. Whether at the national, regional, or global level, legal and health professionals must develop the skills and gain the experience needed to bridge often bitter ideological and political divisions to forge effective norms and standards. Health diplomacy requires the ability to genuinely listen to the concerns of stakeholders, while identifying common ground and finding fair and innovative ways to coax the parties toward consensus. WHO explains that global health diplomacy “brings together the disciplines of public health, international affairs, management, law, and economics, and focuses on negotiations that shape and manage the global policy environment for health”.<sup>343</sup> Effective health diplomacy can operate at the national level (eg, negotiations over new legislation or regulations, especially where health considerations need to be integrated in non-health legislation) and at the transnational level (eg, negotiations over new health treaties, global action plans, or codes of practice). The complex negotiations over the FCTC, the IHR, or the PIP Framework all provide good examples of the need for skilful health diplomacy. Academic institutions can partner with governments and international organisations to fill these gaps in knowledge and skills. For instance, academic institutions could help train the workforce charged with implementing health laws and international agreements.

### *Building networks*

Trained health law professionals must also have the opportunity to share knowledge, strategies, and expertise. This approach is of particular relevance in relation to

new and emerging areas of law, and in resource-constrained environments. Many low-income and middle-income countries do not have a cadre of trained health law professionals, and health lawyers are also scarce in many high-income countries. In such cases, networks of experienced health lawyers could collaborate with local health professionals, lawyers, and policy makers to strengthen local capacities.

Training in health law could strengthen the contribution of a variety of professions or groups to advancing health with justice. These include officials of international organisations such as WHO, the WTO, and the World Bank; officials in regional organisations such as WHO regional offices, regional alliances such as the Association of Southeast Asian Nations, the Organization of American States, or the European Union; policy makers and public officials in health or justice ministries who have responsibility for developing, implementing, or enforcing health laws and regulations; officials in other ministries, whose work could have an impact on public health (eg, agriculture, trade, urban planning, foreign affairs);<sup>36</sup> front-line government workers who might be involved in enforcing health laws (eg, customs or taxation officials);<sup>34</sup> personnel responsible for funding decisions, programmes, and policy making within health-related entities, such as non-governmental organisations, philanthropies and PPPs; lawyers who work closely with health agencies or programmes;<sup>36</sup> and lawyers tasked with defending new health laws from legal challenges.

Network-building and collaboration have been especially important in cases where health advocates face powerful, organised resistance from vested interests. The FTC explicitly calls for legal capacity building and knowledge sharing in litigating tobacco control cases, such as defending strong tobacco control laws or suing tobacco companies for deception or unfair marketing. These calls have been realised through the efforts of professional groups (eg, the so-called lawyer's circle for tobacco control, which connects legal expertise in high-income countries with that in low-income and middle-income countries), civil society (eg, the Framework Convention Alliance, made up of 500 member groups worldwide), and philanthropies (eg, the Bloomberg International Legal Consortium, which provides resources for legal capacities in tobacco control). Earlier we mentioned food industry opposition to new laws facilitating healthier population diets. Ensuring that the food industry does not undermine efforts to protect public health could be another area in which cross-jurisdictional networking would be particularly valuable. As multinational organisations expand their markets, a trained cadre of well-connected health lawyers can help guide health legislation, regulations, and litigation to ensure the public's health and safety.

Public interest law organisations can act as centres of excellence, sharing their knowledge and expertise gained from grassroots experience. In South Africa, Section 27

combines legal action with research and advocacy in its pursuit of human rights and social justice. Building on past success in mobilising legal and community action around HIV and AIDS, as of 2019, Section 27 focuses on access to health care, the right to food, and good governance. In India, the Lawyers' Collective works at the intersection of health, human rights, and the law; fighting for access to medicines; and the rights of women, the lesbian, gay, bisexual, transgender and intersex community, and those living with HIV and AIDS.

In the USA, the Network for Public Health Law lawyers connects public health practitioners; local, tribal, state and federal officials; policy makers; public health advocates and organisations; and provides training and technical assistance.<sup>345</sup> Its areas of legal expertise include overdose prevention, health data sharing, injury prevention, maternal and child health, and environmental health. In the USA, medical-legal partnerships bring together health, public health, and legal expertise for the benefit of patients, but also bring about systemic changes and improve population health.<sup>346</sup> Medical-legal partnerships guide patients through the complex terrain of the health-care system, enabling them to claim their rights and gain access to the services they need.

### Strong capacity for an effective legal environment

Throughout this report, we have identified multiple ways in which the law can be a powerful instrument for the public's health and justice, focusing on effective, coordinated, and strategic uses of law. Building legal capacity is the common denominator. Governments, international organisations, funders, non-governmental organisations, academic organisations, and other health institutions can take concrete, practical action to support states as they build legal capacity. Such measures fall under three interlinked dimensions: effective legal environments, which should be supported by a strong evidence base, and an empowered, transdisciplinary health law workforce.

Although all of our recommendations relate to capacity-building, we have made four targeted recommendations to a variety of institutional actors. In recommendation 5, we call on WHO to partner with governments, foundations, and civil society, to expand the evidence-base for public health laws (including research and information sharing), and support strategies to enact and implement national and global health laws that are effective and sustainable. Recommendation 6 is for governments to build national capacities to enact and effectively implement public health laws. This relates to leadership, planning, funding, and professional training. Finally, in recommendation 7, the Commission offers to partner with *The Lancet* to create a standing commission on global health and the law, building on the momentum of this Commission.

## Section 6: recommendations

In the following seven recommendations (summarised in panel 12), we propose a public health law action agenda

For more on the **Lawyers' Collective** see <https://www.lawyerscollective.org/>

For more on **Section 27** see <http://section27.org.za/>

**Panel 12: Commission recommendations for the legal determinants of health**

**Legal determinant 1: using law to translate vision into action on sustainable development**

Recommendation 1: the UN, WHO, and international partners should set standards to support the implementation of, and objectively evaluate compliance with SDG 3.8 Universal Health Coverage (UHC), as well as the upcoming UN political declaration on UHC in 2019  
Who must take actionable steps: the UN, WHO, and international partners

Recommendation 2: governments should strengthen or create a legal framework, such as a constitutional or statutory right to health, to ensure rights-based UHC on the basis of principles of equity and non-discrimination, including affordability, financial protection, transparency, accountability, participation, privacy, and sustainable financing  
Who must take actionable steps: national governments

**Legal determinant 2: using law to strengthen the governance of national and global health institutions**

Recommendation 3: the UN, WHO, and international partners should use their respective powers and influence to safeguard the public's health and safety through the creation or adoption of good governance standards, embracing the highest principles of equity, inclusive participation, transparency, and accountability  
Who must take actionable steps: UN, WHO, and international partners

Recommendation 4: governments should develop legal frameworks that establish principles of good governance throughout national health systems and policy making, form a

country-appropriate mechanism to advise on legal interventions with high health impact, and adopt legislation requiring health impact assessments for policies, programmes, and projects that might seriously affect health  
Who must take actionable steps: national governments

**Legal determinant 3: using law to implement fair, evidence-based health interventions**

Recommendation 5: WHO should increase its legal capacity to enable it to spearhead development of a global evidence base for public health laws and to support the enactment and implementation of national and global health laws that are effective and sustainable  
Who must take actionable steps: WHO, national governments, foundations, and civil society

**Legal determinant 4: building legal capacity for health**

Recommendation 6: governments should build national capacities to enact and effectively implement public health laws  
Who must take actionable steps: national governments  
Recommendation 7: WHO and *The Lancet* should partner with legal and health experts to create an independent standing commission on global health and the law that would advance the health-related SDGs by proposing evidence-based legal interventions for addressing major global health challenges, reforms of the global health architecture and international law, and strategies to build and strengthen global and national health law capacities  
Who must take actionable steps: *The Lancet* and WHO

consisting of legal instruments, legal capacities, and institutional reforms as tools for achieving global health with justice. Our programme of action is based on principles of human rights and good governance, founded on the right to health. Overarching the specific aims in each recommendation, we intend these recommendations to help foster conversations among policy makers and health workers, researchers, public health authorities, civil society, and others who work in global health.

**Legal determinant 1**

Recommendation 1 states that the UN, WHO, and international partners should set standards to support the implementation of, and objectively evaluate compliance with, SDG 3.8 (UHC), as well as the upcoming UN political declaration on UHC in 2019.

WHO should develop a joint external evaluation (modelled on the IHR's JEE) of country compliance with SDG 3.8 and the UHC political declaration. Under the JEE, national and peer country stakeholders and external experts would evaluate UHC laws, regulations, and programmes against rights-based benchmarks, make such evaluations publicly available, and issue recommendations.

WHO or the UN should establish an international legal framework to ensure that high-income countries and other development partners provide the funding and expertise necessary for all countries to implement UHC, in line with their right to health obligations.<sup>157</sup>

Recommendation 2 states that governments should strengthen or create a legal framework, such as a constitutional or statutory right to health, to ensure rights-based UHC on the basis of principles of equity and non-discrimination, including affordability, financial protection, transparency, accountability, participation, privacy, and sustainable financing.

Governments should promote sustainable financing and financial protection by allocating an adequate share of GDP to implement UHC. They should ensure quality through accreditation systems for public and private sector health facilities, pharmacies, and professionals; inspection of health facilities; and drug and medical device approvals based on safety and efficacy. They should also prevent health sector corruption and misappropriation of resources by establishing strong public financial management systems and anticorruption mechanisms, and avoiding conflicts of interest.

**Legal determinant 2**

Recommendation 3 advises that the UN, WHO, and international partners should use their respective powers and influence to safeguard the public's health and safety through the creation or adoption of good governance standards, embracing the highest principles of equity, inclusive participation, transparency, and accountability.

The UN General Assembly should adopt a set of good governance standards, reflecting best practices in governing complex public institutions for UN specialised agencies such as WHO, civil society organisations, and others. These standards should ensure the operations of the institutions are consistent with the highest principles of equity and transparency. WHO should additionally establish an independent unit tasked with ensuring effective implementation of such governance standards.

As a normative agency with law-making powers, WHO should use these powers to adopt international legal instruments to safeguard the public's health and safety, prioritising health threats in low-income and middle-income countries and developing compliance mechanisms. They should explore a global treaty focused on the right to health, equity, and accountability, such as the proposed FCGH.

Recommendation 4 suggests that governments should develop legal frameworks that establish principles of good governance throughout national health systems and policy making, form a country-appropriate mechanism to advise on legal interventions with high health impact, and adopt legislation requiring health impact assessments for policies, programmes, and projects that might seriously affect health.

Governments should develop national laws and regulations that safeguard inclusive participation in health-related decision making, from community to national levels, which require transparency. They should also establish mechanisms that ensure accountability, guarantee equitable distribution of health services, and require multi-sector action on health equity.

Governments should form a national health law commission, task force, or other structure to develop a systematic plan to identify and propose legislation with high impact on the public's health and safety. The commission or other mechanism should base its recommendations on the best available evidence, focus on equity, propose repealing or reforming existing laws that undermine the right to health, and address the broader socioeconomic determinants of health.

Governments should develop HIAs through inclusive participation, with compliance, and reinforced by independent oversight. These should analyse the anticipated impacts of health and non-health sector policies on health before implementation, should be regularly monitored, and where possible, should be enhanced with real-time assessments. HIAs should actively promote the public's health and guide decision makers'

choices about available options to prevent injury and diseases.

**Legal determinant 3**

Recommendation 5 suggests that WHO should increase its legal capacity to enable it to spearhead development of a global evidence-base for public health laws and to support the enactment and implementation of national and global health laws that are effective and sustainable.

The WHA should provide WHO with the resources and political backing to develop WHO's capacity to support member states in developing public health laws on the basis of evidence, equity, and human rights.

The WHO should increase its legal capacities to include a robust global network of well-trained experts, linking existing repositories and databases of national health legislation, and developing platforms and information systems. These changes would enable health lawyers, medical professionals, policy makers, and advocates to share information and strategies on laws and litigation, as well as increasing legal skill sets within the WHO Secretariat at headquarters, and at regional and country levels.

**Legal determinant 4**

Recommendation 6 states that governments should build national capacities to enact and effectively implement public health laws.

Ministries of health and justice should lead an inter-ministerial, multi-stakeholder process, which includes civil society, to develop a strategic plan to build health law capacities, working to strengthen or create institutions to lead and coordinate health law research and development, identifying priority areas for public health laws.

Governments and foundations should support research to build a high-quality empirical foundation for evidence-based, rights-based, equity-based laws that provide health coverage and safeguard the public's health and safety, expanding research on existing public health laws and developing open access databases to share public health law research.

Recommendation 7 suggests that WHO and *The Lancet* should partner with legal and health experts to create an independent standing commission on global health and the law that would advance the health-related SDGs by proposing evidence-based legal interventions for addressing major global health challenges, reforms of global health architecture and international law, and strategies to build and strengthen global and national health law capacities.

As an example, this standing commission could recommend a comprehensive and legal reform agenda for global health security that would examine issues such as potential improvements to the IHRs, incentives for bringing countries into full compliance with IHR obligations and the JEE process, better coordination of laws relating to animal and human health, greater

harmonisation of regulatory standards to accelerate development of vaccines and other countermeasures, and improvements to benefit-sharing frameworks. This potential legal reform agenda could feed into the work of the newly established Global Preparedness Monitoring Board, which will monitor progress, identify gaps, and advocate for efforts needed for global preparedness for outbreaks and other health emergencies, and help ensure it fully considers legal issues and possibilities.

**Contributors**

All authors contributed to the structure and concept of the report, the editing of drafts, revisions of key intellectual content, and the writing of the recommendations and key messages. The report was prepared under the direction of Commission co-chairs Lawrence O Gostin and John Monahan.

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We declare no competing interests.

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