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Advancing the right to health:

The vital role of law

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Preface

At its birth in 1948 as the United Nations' first specialized agency, the World Health Organization (WHO) enshrined the right to health as its foremost aspiration. Its constitution proclaims:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition…. The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.

What is less well understood is that progressively realizing the right to health is a legal obligation enshrined in the International Covenant on Economic, Social and Cultural Rights and other international treaties, as well as in constitutions and statutes in many countries around the world. Both at international and domestic levels, law is a powerful tool for safeguarding and promoting the public's health and safety. All sovereign states have the power, and the duty, to advance the right to health.

What are the most effective legal tools for advancing the right to health? This ground-breaking report – sponsored by WHO, the International Development Law Organization (IDLO), and its academic partners the University of Sydney and the O'Neill Institute for National and Global Health Law at Georgetown University – illustrates how countries have enacted and implemented a wide range of laws and regulations with a demonstrable impact on the health and safety of their populations. Public health laws should be evidence-based, fairly and effectively implemented, and for the good of the population.

Communicable disease control

The control of infectious diseases is perhaps the best understood, and most historically powerful, illustration of law's vital role in public health. From the earliest days, governments introduced measures to detect, report and respond to infectious diseases –from smallpox, malaria and tuberculosis, to the modern-day HIV/AIDS pandemic, and to fast moving novel infections such as SARS and new strains of influenza. The recent outbreaks of Ebola virus disease and Zika virus disease demonstrate the urgent need for all countries to fully implement the International Health Regulations. At the national level, public health laws in this area address matters including screening, reporting, contact tracing, isolation and quarantine.

Noncommunicable diseases

Beyond infectious diseases, the law plays a vital role in prevention and control of noncommunicable diseases (NCDs) such as cancer, cardiovascular disease, diabetes and respiratory disease. The world

has witnessed an epidemiological transition from infectious to noncommunicable diseases, which are now responsible for the greatest global burden of disease and early death. Most of this suffering takes place in low- and middle-income countries – which often face the twin burdens of under- and over-nutrition. It may be tempting for some to view NCDs as the product of behavioural risk factors for which individuals – rather than governments – are responsible. But innovative governments have demonstrated that public health laws can make a substantial difference to health outcomes in this area. For example, smoking rates have dropped sharply in countries that have taken steps to fully implement the WHO Framework Convention on Tobacco Control. Legal interventions such as taxation, marketing restrictions, graphic label warnings, plain packaging and bans on smoking in public places have transformed culture and behaviour.

With due regard to the differences between them, many tools that have proven to be successful in tobacco control can be applied to other NCD risk factors such as harmful use of alcoholic beverages, unhealthy foods and sugary drinks, and physical inactivity. Law can transform the economic, informational and built environments to reduce the morbidity and premature mortality caused by NCDs from current historic highs. The economic environment can incentivize healthy behaviours (e.g. subsidizing fruits and vegetables) and disincentivize unhealthy behaviours (e.g. taxes on sugary drinks). Changing the informational environment can empower consumers to make healthier choices, through laws regulating packaging and menu labelling (e.g. laws requiring disclosure of calories and unhealthy ingredients such as added sugars and saturated fats). Governments can also use law to improve the built environment, making walking, cycling, participation in sports, and other physical activities safer and more attractive.

Most legal interventions in this area simply "nudge" consumers in a healthier direction, making health the easier choice. But governments can also directly regulate businesses, and have done so with considerable impact on NCD risk factors. Examples include legal bans on trans-fatty acids, controls on sale and advertising of tobacco, and liquor licensing laws. In addition, governments can influence the actions of businesses through public/private partnerships; for example, food reformulation to reduce the salt content of high-sodium foods. Sodium and trans-fats contribute to cardiovascular and other diseases, and evidence-based regulation can reduce these risks.

Mental health

Although the major NCD risk factors (tobacco, unhealthy foods and physical inactivity) do not apply in the same way to mental illness, global mental health is a major goal. Historically, laws have been used to structure the response to mental illness, but not always consistently with human rights. People with mental illness, like those with physical illness, require a full range of medical and social services. Instead, law has sometimes been used to incarcerate mentally ill people in sterile institutions and without the protection required under the rule of law. WHO has published a resource book on *Mental health, human rights and legislation* intended to guide governments in reforming their mental health laws in accordance with human rights principles.

Injuries

Individuals may experience horrific injuries, particularly in low- and middle-income countries. These injuries occur on the roads, in homes and at workplaces. We often call these "accidents", which suggests they are not preventable. But laws and regulations can significantly reduce injuries – both

unintentional and intentional. Road traffic regulations have pushed injury rates considerably lower in many countries. Injuries would be significantly reduced if automobiles, motorcycles and bicycles were road worthy and safe; if roads were designed to separate traffic and slow vehicles; and safety equipment were standard and required (e.g. seat belts, passive restraints, helmets). It is also possible to regulate drivers, for example, by prohibiting driving while under the influence of alcohol and other drugs, and texting while driving.

In the home, women in particular face hazards such as unsafe, open stoves. Many people live and work in buildings that are unsafe, because, for example, they are prone to fire or unable to withstand natural disasters such as earthquakes or floods. At work, individuals face major risks, such as unsafe machines, exposure to asbestos, toxic chemicals or other environmental hazards, or by working in mining and other hazardous occupations.

Intentional injuries – assaults, murder and suicide – are also preventable. Consider gun control laws that restrict access to dangerous weapons and require safety devices such as trigger locks. Or think about laws that prevent intimate partner assaults, such as laws requiring the police to enforce restraining orders against domestic abuse. Laws that make it harder to obtain the means to harm oneself, such as barriers on bridges, or reducing carbon monoxide exhaust from petrol, can also reduce suicides.

Universal health coverage

Perhaps the most important policy to advance the right to health is universal health coverage (UHC) – a major WHO priority that is also a key health target in the United Nations Sustainable Development Goals (SDGs). Building robust health systems starts with advance planning and sustainable financing. It requires clinics, hospitals, and human resources (e.g. doctors, nurses and community health workers). Law also plays a role in UHC, regulating and ensuring universal access, equity, and quality at an affordable cost. For example, we now know that charging a fee for services, even if very small, can lower access, particularly for the poor, vulnerable, marginalized, and those in remote locations.

Fulfilling the SDG target for UHC will be of major importance in advancing the right to health, and law can expedite that process. It requires mutual responsibilities from international partners and national governments, together with “bottom-up” social mobilization.

Multisectoral engagement

Legal regimes, whether national or global, extend well beyond the health sector. A “health-in-all policies” or “all-of-government” strategy is needed. Ensuring the public’s health and safety requires more than effective health policies. It requires active engagement with finance, justice, housing, energy, transportation, and other ministries – with leadership at the highest levels of government. This is also true at the global level. Consider, for example, the role of trade and intellectual property in ensuring (or denying) access to essential medicines or vaccines. Or consider the role of agriculture in reducing the proliferation of antimicrobial resistance. Indeed, health requires an “all-of-society” strategy that fully engages civil society and businesses for the public good.

Stigma and discrimination

The law does not merely operate as a tool to advance the right to health. Equitable and fair treatment lies at the heart of human rights and the right to health itself. Law's role is to prohibit discrimination in the health sector and beyond. The greatest health burdens usually fall on the most vulnerable, marginalized and impoverished individuals. Law's goal is to protect them against discrimination and affirmatively improve their access to needed services. In many societies, women, LGBT (lesbian, gay, bisexual, and transgender) communities, certain religious/ethnic minorities, and the poor are routinely denied equal access to opportunities and services. The human rights of women are infringed in many societies as governments restrict their access to reproductive health services, including safe and effective contraception and abortion. The highest role for law is to ensure access to justice, particularly for the least powerful and most disadvantaged in society.

Law as an obstacle to health

Law is not always an unmitigated social good, but can actually stand in the way of progress in health and human rights. During major disease outbreaks, many countries put in place restrictions on travel and trade or enforced quarantine against WHO recommendations. Some countries punish people simply for their status (e.g. LGBT) or impede public health policies for harm reduction, such as the distribution or exchange of safe drug injection equipment. Consequently, to advance the right to health it may be necessary to dismantle harmful and stigmatizing laws that stand in the way of progress.

Good governance

Law is not only concerned with discrete interventions to safeguard and promote the public's health and safety. The rule of law also requires "good governance" that ensures the fair and efficient operation of public institutions and social structures. Good governance includes setting priorities, monitoring outcomes, transparency, civil society participation, anti-corruption and accountability. It requires a legal infrastructure with impartial courts and tribunals and the regulatory capacity to effectively implement legal rules. In short, good governance encompasses all the norms, processes and institutions of a just society that passes and enforces laws for the common good and with an equal hand.

There is a saying that goes to the heart of this report on *Advancing the Right to Health*: "Law is but the means, health and justice are the ends". We hope that our examination of what countries can do to protect the health and nurture the dignity of all peoples will contribute to a greater understanding, and effective use, of the law in advancing the right to health.

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Introduction

SUMMARY POINTS

· **This report aims to raise awareness about the role that the reform of public health laws can play in advancing the right to health and in creating the conditions for people to live healthy lives. By encouraging a better understanding of how public health law can be used to improve the health of the population, the report aims to encourage and assist governments to reform their public health laws in order to advance the right to health.**

· **The report highlights important issues that may arise during the process of public health law reform. It provides guidance about issues and requirements to be addressed during the process of developing public health laws. It also includes case studies and examples of legislation from a variety of countries to illustrate effective law reform practices and some features of effective public health legislation.**

Purpose and scope of this report

The right to health is a fundamental human right that is indispensable for human well-being, for well-functioning societies and economies, and for the ability to exercise all other human rights. Without a basic level of health, it may be difficult or impossible for people to work, to attend school and obtain an education, to enjoy recreation, to fully participate in society, and to enjoy other basic freedoms. Countries around the world face many challenges that threaten the health of their populations. These include endemic and emerging communicable diseases (e.g. HIV, tuberculosis, malaria, emerging strains of influenza), and noncommunicable diseases (e.g. cancer, cardiovascular disease, respiratory diseases and diabetes). Added to this are intentional and unintentional injuries, global environmental degradation, threats to food safety and security, and trade in harmful products.

Although these challenges have an impact on health in all countries, they disproportionately affect poorer countries, which not only lack the resources to manage them but may also lack the political and economic power to negotiate effective international agreements to achieve better health and justice for their populations. Within countries, poorer segments of the population are disproportionately affected by health risks, and by mortality and disability from disease.[1]

Law is increasingly being recognized and used as a tool for improving the health of populations at global, national and subnational levels. At the national level, governments need functioning health systems that are supported by strong legal frameworks. Public health legislation sets out the responsibilities and functions of governments to coordinate responses to public health risks, to create healthier environments, to promote healthier behaviours, to generate the information base

that is needed for effective action and policies, to manage a competent health workforce, and many other functions.

This report aims to raise awareness about the role that the reform of public health laws can play in advancing the right to health and in creating the conditions for people to live healthy lives. By encouraging a better understanding of how public health law can be used to improve the health of the population, the report aims to encourage and assist governments to reform their public health laws in order to advance the right to health.

Governments may choose to reform their public health laws for many reasons: for example, to modernize old and out-of-date laws, to address neglected issues and to respond to problems that have arisen as a result of the application or enforcement of other laws. The process of revising public health laws will vary significantly according to the historical and constitutional context and the legal tradition of each country. These legal traditions include common law, civil law, tribal laws and customs, and Sharia law. Public health law reform may occur in very different ways at national and subnational levels. For all these reasons, there is no single approach to the reform process, and this report is not intended to be prescriptive.

In order to achieve its aims, this report highlights important issues that may arise during the process of public health law reform. Secondly, it provides guidance about issues and requirements to be addressed during the process of developing public health laws on particular topics, such as access to essential medicines, tobacco control or the regulation of infectious diseases. Thirdly, it includes case studies and examples of legislation from a variety of countries, both large and small, to illustrate effective law reform practices and some features of effective public health legislation.

In this report, public health law refers to the formal set of laws – and to the legal processes for implementing and enforcing them – that seek to ensure the conditions for people to live healthy lives. At the international level, law includes global, regional and bilateral intergovernmental agreements, as well as the rules and regulations made by international bodies (e.g. WHO, the World Trade Organization). At the national level, law includes executive orders and decrees issued by the executive body or under the authority of the head of State or government; legislation passed by Parliaments at national, state and local levels; subsidiary legislation (issued by executive agencies in order to implement or give effect to principal legislation); the judgments and rulings of courts and tribunals, and customary and tribal laws. In addition to legally binding instruments, executive agencies and other government bodies may also issue non-binding guidelines and technical standards: these may have normative effects and may play an important subsidiary role in reducing health risks and creating healthier environments.

Who should read this report?

This report is intended to inform a wide audience, including:

- senior officials working within ministries of health;

- officials of other ministries within government who can significantly influence public health through their actions and policies, and through the laws they administer. The relevant ministries or departments may include: finance, foreign affairs, justice, agriculture, consumer affairs, education, housing, infrastructure, transport, energy, trade, environment, communications and social security;

- members of the legislative, executive and judicial branches of government (including parliamentarians, ministers, judicial officers, and their advisers); and

- other stakeholders, including members of health organizations, philanthropic organizations, the media, industry, academia, employer and labour organizations, and civil society organizations.

Individuals have a critical role to play in protecting their health and in minimizing risks to their health. Parents also play an important role in protecting their children's health and in creating a healthy home environment. At the same time, the State bears primary responsibility for realizing the right to health for the population as a whole. Collectively, through the legislature, courts and executive and statutory agencies, the State has the capacity to pass public health laws, to implement them and enforce them, and to balance health with other policy and social goals.

Typically, the health ministry serves as the steward of the health sector, with primary responsibility for health services and for protecting and promoting public health. On the other hand, responsibility for administering laws and for regulating matters that may directly affect the health of the population will be allocated between the health ministry and a range of other ministries, including law and justice, finance and revenue, agriculture, media and communications, housing and infrastructure, and transport. Officials from these sectors will be important stakeholders in the public health law reform process.

States will need to build appropriate executive and legislative structures to facilitate a cooperative approach to health protection spanning different ministries, agencies, and (where applicable) different tiers of government. For these reasons, the audience for this report will extend across a number of government ministries, and may include officials and elected representatives at regional and city levels of government.

In some countries, the impetus for reform of public health legislation may come from non-State actors, rather than from government. Civil society organizations, professional associations and community groups – including patient advocacy groups – make important contributions to public health by advocating for effective policies and laws within their areas of expertise and influence. Meaningful participation by affected communities in the design and implementation of public health laws will help to ensure support for the law within the community, thereby improving its effectiveness.

In summary, this report is intended to support the actions of both governments – as they lead the process of public health law reform – and non-government stakeholders who are involved in advocating for the reform of public health laws and supporting effective public health practices.

The structure of this report

This report aims to encourage a better understanding of how public health law can help governments to discharge their international obligations under the right to health. The structure of the report reflects the consensus reached at the second of two international consultations of experts in public health law, hosted by WHO and the International Development Law Organization, in collaboration with the O'Neill Institute for National and Global Health Law at Georgetown University, Washington (DC) and Sydney Law School, University of Sydney, Australia. The first consultation, held in Rome (27–29 April, 2009), called for the development of this report. The second consultation, held in Cairo (26–28 April, 2010), identified the key topics and issues that this report should include, and strategies for its dissemination.

Part 2 of this report discusses the process of public health law reform. The law reform process refers to the practical steps involved in advancing the political goal of law reform, and the kinds of issues and obstacles that may be encountered along the way. The context in which law reform occurs, and the specific scope of the law reform process, will vary significantly between countries. Nevertheless, there are a number of common reasons for reviewing and updating public health laws, and many of the most important risks to health are shared by most countries. Part 2 identifies some of the actors who may initiate or lead the public health law reform process, discusses principles of good governance during that process, and ways of building a consensus around the need for public health law reform.

As noted earlier, health is frequently shaped by factors and policies that lie outside the operational sphere of the health ministry. On the other hand, the right to health is an obligation of government as a whole. For this reason, Chapter 6 considers the law's role in achieving an intersectoral, whole-of-government approach to public health law reform.

Part 3 turns from the process of reforming public health laws to the substance or content of those laws. It identifies a number of core areas of public health practice where regulation is essential in order to ensure that governments (at different levels) discharge their basic public health functions. Traditionally, these core areas of public health practice have included: the provision of clean water and sanitation, monitoring and surveillance of public health threats, the management of communicable diseases, and emergency powers. Part 3 also considers the role of law in advancing universal access to quality health services for all members of the population.

Building on these core public health functions, Part 3 goes on to consider a range of other public health priorities where law has a critical role to play. These priorities include tobacco control, access to essential medicines, the migration of health care workers, nutrition, maternal, reproductive and child health, and the role of law in advancing universal access to quality health services for all members of the population. The report includes many examples that illustrate the ways in which different countries have used law to protect the health of their populations in ways that are consistent with their human rights obligations. Countries vary widely in terms of their constitutional structure, size, history and political culture. For these reasons, the examples given are not intended to be prescriptive, but to provide useful comparisons for countries involved in the process of legislative review.

REFERENCE

[1] Commission on the Social Determinants of Health. Closing the gap in a generation: health equity through action on the social determinants of health. Final Report of the Commission on Social Determinants of Health. Geneva: World Health Organization; 2008.

PART 1
ADVANCING THE RIGHT TO HEALTH THROUGH LAW REFORM

Chapter 1: Public health regulation and the right to health

SUMMARY POINTS

· **The human right to health, understood as the right to the highest attainable standard of health, provides an overarching and exacting standard to guide the actions of governments as they strengthen their health systems by reforming their public health laws.**

· **The principles of *availability*, *accessibility*, *acceptability* and *quality* are essential elements of the right to health. They serve a diagnostic function, drawing attention to what remains to be done as governments move towards universal health coverage. By increasing the capacity and quality of health care and public health services, by ensuring that the entire population is covered by these services, and by ensuring that these services remain affordable to everyone, governments can help to respect, protect and fulfil the right to health.**

· **The principles set out above provide guidance to governments as they make decisions about the goals, resources, focus and scale of public health law reform activities. Although the precise form that the law takes will vary significantly between countries, law has a flexible and enabling role in helping to realize the right to health. For example, the law has a role in: eliminating discriminatory barriers to the accessibility of health services, ensuring the accountability of health service providers, strengthening the components of an effective health system, creating a framework for the discharge of core public health functions, and reducing health inequalities.**

1.1 Justifications for public health regulation

A variety of theoretical justifications have been put forward to justify public health regulation. These include reducing externalities (such as protecting non-smokers from second-hand smoke or improving suboptimal vaccination rates), or increasing the production of public goods (by improving air quality, or vector control).[1] Regulation may also aim to provide consumers with better information about harmful goods (such as health warnings on tobacco and alcohol products), or seek to improve their capacity to make healthier choices, for example through front-of-pack food labelling that interprets the nutritional content of food.

Other theoretical justifications for regulation pay greater attention to the persistence of health inequalities, to the role that a healthy population plays in economic and social development, and to shared agreement around the goal of "health for all". These ideas, which were powerfully expressed in the Alma Ata Declaration (1978)[2] and in the Rio Declaration on Social Determinants of Health (2011)[3] continue to inspire health sector reform efforts, and provide a justification for the role that public health law reform plays in health development generally.

The approach to public health law reform taken in this report rests on two fundamental human rights concepts: the rule of law, and the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (hereafter the right to health). The rule of law refers to the principle that law-making processes should be transparent, laws should be enforced fairly, courts and tribunals should be independent, and the administration of law and its substantive content should be consistent with international human rights standards (**Box 1.1**).

Box 1.1: Public health and the "rule of law"

The rule of law is a fundamental concept within the United Nations system. It requires that "laws must be publicly promulgated, equally enforced and independently adjudicated and [must be] consistent with international human rights norms and standards".[4] Under the rule of law, "all persons, institutions and entities, public and private, including the State itself, are accountable to just, fair and equitable laws and are entitled without any discrimination to equal protection of the law".[5] The United Nations General Assembly has acknowledged that advancing the rule of law at national and international levels is "essential for sustained and inclusive economic growth, sustainable development, the eradication of poverty and hunger and the full realization of all human rights and freedoms, including the right to development".[6]

The right to health is a human right that is well-established in international law (**Box 1.2**). Most countries in the world have ratified at least one international agreement that imposes specific obligations on governments regarding the right to health.[7] The right to health is recognized in the Universal Declaration of Human Rights,[8] in the International Covenant on Economic, Social and Cultural Rights (ICESCR),[9] and in a number of other international human rights treaties including the Convention on the Rights of the Child.[10]

Box 1.2: What are human rights?

Human rights are legal guarantees protecting universal values of human dignity and freedom. Human rights define the entitlements of all human beings and the corresponding obligations of the State as the primary duty-bearer. Human rights have been negotiated by States and agreed upon in human rights treaties, such as conventions and covenants, which are legally binding on States that are parties to them.

Although this report focuses mainly on the right to health, as recognized in the ICESCR and a number of regional human rights treaties, there are a variety of other health-related rights in international law that support actions by government to improve the health of their populations. These include the right to adequate food, clothing and housing, the right to freedom from hunger, and the right to environmental and industrial hygiene in the ICESCR (Articles 11 and 12).[11] Other rights include the right to liberty and security of the person, freedom from coerced labour, liberty of movement, freedom of thought, conscience and religion and freedom from discrimination on grounds including race, colour, sex, language, religion and political opinion, as recognized in the International Covenant on Civil and Political Rights (Articles 4, 8, 9, 12, 18 and 26).[12]

The right to health has also been included in three major regional human rights agreements, in Africa,[13] Europe[14] and the Americas.[15] For example, Article 16 of the African Charter on Human and Peoples' Rights states:

> 1. Every individual shall have the right to enjoy the best attainable state of physical and mental health.
>
> 2. States Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.

In some countries, the right to health has been recognized in the national constitution. For example, in Article 6 of the Constitution of the Federal Republic of Brazil, health is designated as a social right. The right to health is further reinforced by Article 196, which states:

Health is the right of all persons and the duty of the State and is guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at universal and equal access to all actions and services for the promotion, protection and recovery of health.[16]

The Constitution of South Africa guarantees access to health services, including reproductive health and emergency services, basic health care for children, and medical services for detained persons and prisoners.[17]

Similarly, the Constitution of Mongolia declares that citizens shall enjoy the right to a healthy and safe environment, and the right to the protection of health and medical care.[18] In turn, citizens owe a duty to protect their own health.[19]

The substantive obligations embodied within the right to health were clarified by the United Nations Committee on Economic, Social and Cultural Rights (CESCR) in General Comment 14.[20] General Comment 14 explains that the right to health is an inclusive right that extends beyond health care to the underlying determinants of health, including access to safe and potable water, adequate sanitation, an adequate supply of safe food and nutrition, housing, healthy occupational and environmental conditions, access to health-related education and information, including on sexual and reproductive health, and freedom from discrimination.[21] States have an obligation to take immediate steps to progressively ensure that services, goods and facilities are available, accessible, acceptable and of good quality. These obligations are discussed further in Section 1.1.

The right to health imposes three distinct obligations on States that are parties to the ICESCR. States have an obligation to *respect*, to *protect*, and to *fulfil* the right to health:[22]

- *Respecting* the right to health means not interfering directly or indirectly with the enjoyment of the right. For example, States may breach this obligation by unlawfully polluting the air, water and soil, by unjustifiably denying or limiting access to health care services, by limiting access to contraceptives and by withholding or misrepresenting health information, including sexual health information.

- *Protecting* the right to health means taking the actions that are necessary to prevent third parties from interfering with the right. For example, this requires States to adopt legislative

or other measures to ensure that registered medical practitioners and other health professionals have achieved appropriate standards of education, professional skill and ethics. Protecting the right to health also requires States to take measures to protect marginalized and vulnerable groups in society from violence: this includes protecting women and children from being coerced into undergoing female genital mutilation and other harmful procedures.

- *Fulfilling* the right to health means taking actions to facilitate, provide and promote the conditions in which the right can be fully realized.[23] This requires States to adopt a national health policy and to implement legislative measures that seek to realize the right.[24] The obligation to fulfil the right to health requires States to ensure the provision of adequate health services, including immunization programmes, equal access to basic sanitation services, nutritious and safe food, and safe drinking water. It requires States to consider the infrastructure requirements for the provision of health services, including the provision of an adequately trained workforce, as well as hospitals and other health-related facilities that are culturally appropriate and respond to the needs of vulnerable and marginalized groups. It requires States to ensure the availability of a health insurance system (whether public, private, or mixed) that is affordable for all. States must promote medical research and health education, and disseminate information to meet the health needs of the population. Information campaigns should include information relating to healthy lifestyles and nutrition, the availability of health services, harmful traditional practices, HIV/AIDS, sexual and reproductive health, domestic violence, the harmful use of alcohol, and the use of tobacco and other drugs. States are required to take appropriate actions to respond to environmental and occupational health hazards, and other threats that have been demonstrated by epidemiological evidence, and to provide a coherent national policy on occupational accidents.[25]

(a) Obligations of immediate effect under the right to health

As explained in General Comment 14,[26] the right to health requires States to take concrete steps towards ensuring the availability and accessibility of quality public health and health care services, especially for socially disadvantaged and marginalized groups. Although the right to health acknowledges resource constraints and is subject to progressive realization, certain obligations are of immediate effect.[27]

For example, countries owe an immediate obligation to ensure that the right to access health services and other underlying determinants of health (e.g. sanitation and potable water) is not undermined by discrimination on grounds recognized in the Covenant. These grounds include discrimination on the basis of "race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation and civil, political, social or other status".[28] For example, in the case of children and adolescents, the principle of non-discrimination precludes preferential feeding or medical treatment for boys at the expense of girls.[29] In societies that are sharply divided between different ethnic groups, it requires health service providers to be blind to these differences and to treat everyone with dignity and respect. In some countries, HIV-related stigma and discrimination

are widespread: governments may need to take bold measures to confront and reduce this in order to overcome the disincentives that prevent people, including mothers and children, from being tested and accessing the treatments they need.[30]

Another important obligation of immediate effect is the obligation to take "deliberate, concrete and targeted" steps *towards* the full realization of the right to health. A useful starting-point is to adopt and implement a national public health strategy and plan of action, based on the specific health needs of the population. A national strategy and plan of action are identified elsewhere in General Comment 14 as one of a number of "core obligations" that arise from the right to health.[31] National public health strategies and plans of action should be developed through processes that facilitate community participation, with clear goals, targets, health indicators and time frames to enable monitoring of progress and evaluation.[32]

(b) Core obligations arising under the right to health

Separate from the obligations of immediate effect discussed above, General Comment 14 identifies a number of core obligations that arise under the right to health. These core obligations may be seen as priorities for action as States move as quickly as possible towards the full realization of the right to health. These core obligations are summarized in **Box 1.3**.

Box 1.3: Core obligations arising under the right to health[33]

The right to health in Article 12 of the ICESCR, as interpreted by the CESCR in its General Comment 14, imposes a number of core obligations. These include the obligations to:

- ensure the right of access to health services without discrimination;
- ensure access to food that is safe and nutritionally adequate and to ensure freedom from hunger;
- ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
- provide essential medicines, as defined by WHO from time to time;
- ensure equitable distribution of health facilities, goods and services;
- adopt and implement a national plan of action addressing the health concerns of the population.

In addition to the core obligations above, there are a number of obligations of "comparable priority". These include the obligations to:

- ensure reproductive, prenatal and postnatal maternal and child health care;
- provide immunization for priority diseases;
- prevent, treat and control epidemic and endemic diseases;
- provide education about the major health challenges facing the community;
- provide appropriate training for health personnel, including education on health and human rights.

(c) The right to health and health systems

In order to respect, protect and fulfil the right to health, States must invest in the components or building blocks of an effective health system. WHO's definition of a health system encompasses all the "organizations, people and actions whose primary intent is to promote, restore or maintain health".[34] This includes not only the provision of health services by government and the private sector, but public policies directed at the determinants of health, regulatory frameworks, health legislation and intersectoral efforts by government ministries to support the determinants of better health. **Table 1.1** summarizes the building blocks of WHO's health system framework. Laws, fiscal strategies and governance frameworks support each of the components of an effective health system, and are tools for further strengthening it.

Table 1.1: Building blocks of a well-functioning health system[35]

Leadership and governance: includes policies, strategies, laws, incentives, enforcement and accountability mechanisms. Includes governance structures to improve leadership and to facilitate intersectoral action to improve health.	**Health information systems**: includes the collection, production, management, analysis and sharing of information on health status, health determinants, and all aspects of health system performance (including progress in meeting health goals and targets, improving equity, and efficient use of resources).
Health financing: financing structures to raise sufficient funds and to share financial risks across the population. By removing financial barriers and by preventing catastrophic expenditure, an effective health financing system ensures that the full range of quality health services are available to the entire population, according to need.	**Human resources for health**: includes a competent health workforce that is available in sufficient numbers, comprises an appropriate mix of functions, is fairly distributed, competent, responsive and productive. Includes payment systems, incentives and regulatory mechanisms to ensure the effective and sustainable delivery of high-quality services.
Delivery of health services: both personal and population-level services covering disease prevention, health promotion, treatment, rehabilitation and palliative care. Includes standards to ensure access, safety, quality, effectiveness and accountability.	**Essential medicines and technologies**: universal access to health services is not possible without policies to assure affordable access to essential medicines, vaccines and health technologies. Includes a national list of essential medicines, an effective distribution system for essential medicines and health technologies, and a regulatory system for marketing authorization, and for the monitoring of medicines and therapeutic products.

The right to health, as explained in General Comment 14, does not create an entitlement to be healthy. Nor does it hold States responsible for all the potential causes of poor health, including genetic susceptibility or an individual's choice to adopt an unhealthy lifestyle. On the other hand, the

obligation to respect, protect, and fulfil the right to health places health on the agenda of every government, and provides a mandate for the legislative and administrative actions that are necessary, across all the relevant sectors of government, to create the conditions in which members of the population can realize the highest attainable standard of health. The right to health provides an over-arching and exacting standard to guide the actions of governments as they seek to strengthen their health systems, and to review the health impact of legislation and policies outside the health sector.

The right to health has inherent value for members of the population because it imposes on governments an obligation to help to create the conditions for a healthy, productive and flourishing life. However, in addition to its inherent value, there are at least two important reasons why the right to health – as a guiding value for the law reform process – is more likely to achieve the goal of longer and healthier lives.

Firstly, in some areas, including sexually transmissible infections, and contagious diseases (e.g. influenza), it is difficult if not impossible to effectively or efficiently monitor the behaviours that result in disease transmission. As a result, the extent of disease transmission will depend, to a significant degree, on the voluntary cooperation of individuals. In the case of pandemic or infectious diseases, people are more likely to trust the advice of governments, and to follow lawful directions, if they are confident that they will be treated fairly and in accordance with the rule of law. Laws that take account of the impact of government actions on all members of the population, including those who are marginalized and powerless, are likely to be most effective in minimizing disease transmission. For example, in the case of sexually transmissible infections, individuals are more likely to present for treatment and to follow medical advice if the law protects them from discrimination by health professionals and other service providers.

The second reason why the protection of human rights is central to the effectiveness of public health law is because, in circumstances where human rights are ignored or disregarded, significant sections of the population risk being marginalized. If this happens, their health will suffer, and this, in turn, will defeat the universal goal towards which the right to health aspires: to create the conditions for the highest attainable standard of health across the whole population. In most societies, distinct patterns of health inequality correlate with socioeconomic status and undermine the achievement of other social and economic goals.[36] If countries are to make progress towards realizing the right to health for their populations, they must address the broad range of social, economic and environmental factors that are responsible for health inequalities.

1.2 Concepts and principles for guiding and evaluating law reform efforts

Governments owe a duty to ensure that health care facilities, goods and services, as well as public health services, facilities and programmes, are available, accessible, culturally acceptable, scientifically and medically appropriate and of good quality.[37] These principles, which are discussed further below, can be used by governments and other stakeholders both to evaluate the adequacy of existing laws and to determine the scope of needed reforms.

(a) The goal of universal health coverage

The principles of availability, accessibility, acceptability and quality are not only guiding concepts that help to clarify the nature of the responsibility that governments owe under the right to health. They also highlight actions to be taken to achieve the goal of universal health coverage (UHC) (**Box 1.4**). UHC, in turn, is a way of making progress towards meeting the various treaty obligations that countries have undertaken regarding the right to health.[38]

UHC has been defined as "all people receiving quality health services that meet their needs without exposing them to financial hardship in paying for them".[39] The priority health services referred to in this definition include promotive, preventive, curative, rehabilitative and palliative health services.[40] Defined in this way, the objectives of UHC are: equitable access to priority health services (health for all), quality and effectiveness of health services, and financial protection. Like the concept of a health system (**Table 1.1**), UHC includes but is not limited to affordable access to health care services; it extends to public policies and actions taken outside the health sector to address the determinants of health.[41]

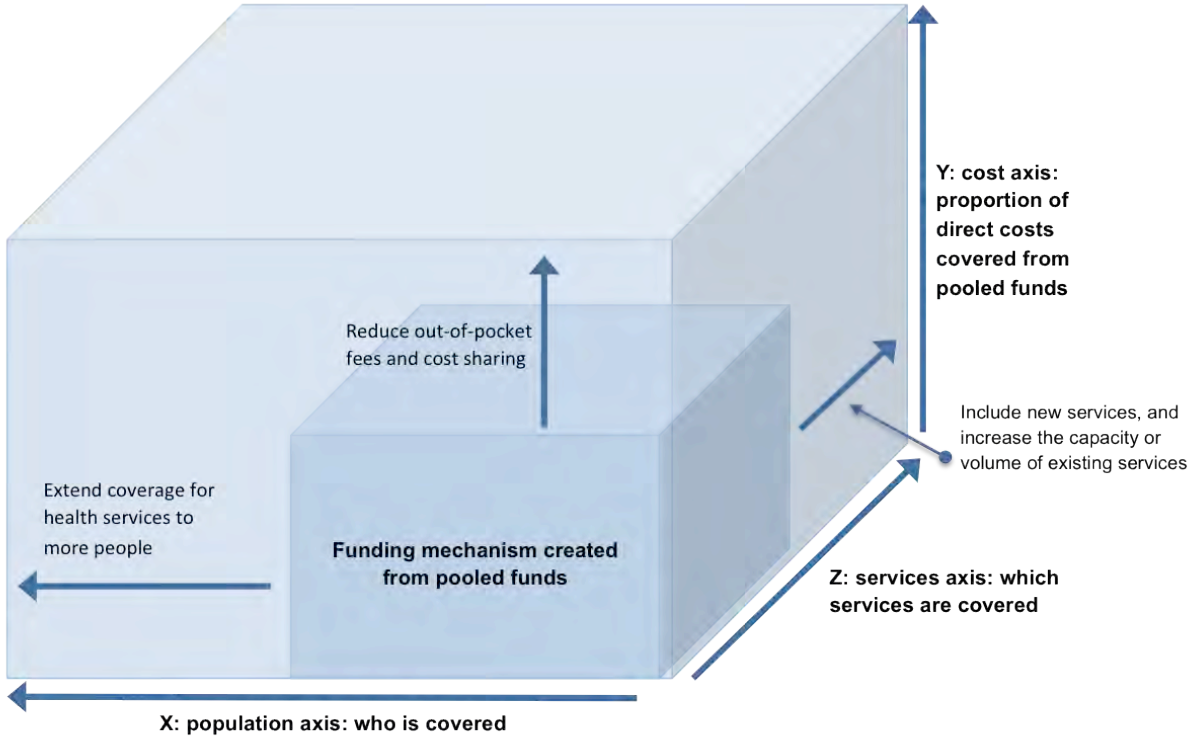
Box 1.4: The concept of UHC

In December 2012, the United Nations General Assembly reaffirmed the goal of UHC, pointing out that the concept implies that:

all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative and rehabilitative basic health services and essential, safe, affordable, effective and quality medicines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable and marginalized segments of the population.[42]

UHC is typically presented as a cube (the "UHC cube") with three dimensions or axes representing the population, health services, and health costs (**Figure 1.1**). The x axis represents the population, and shows the proportion of the population who are covered, and who are not covered, by a funding mechanism created from pooled funds.

Figure 1.1: The UHC cube: services provided, people covered, and cost



The z or services axis represents the range of services that are provided from pooled funds, as a proportion of the full set of quality health services that the population needs. The services axis encompasses all levels of the health system, including health care services provided to individuals in the primary care setting, and in hospitals, preventive services provided in community settings, as well as public policies and laws addressing health risks at the population level, such as taxes on alcohol and bans on the advertising of tobacco. Since it encompasses priority health care services, the services axis encompasses universal access to essential medicines and technologies, a motivated and effective health workforce, and health information systems.[43] Since it encompasses preventive services, the services axis includes immunizations, the provision of family planning and pregnancy care services, water and sanitation infrastructure, regulatory frameworks for a safe and sustainable food supply, and for controlling epidemics of infectious disease, as well as laboratories and other infrastructure for monitoring health risks.

The y axis relates to the cost and affordability of the services provided. It illustrates the proportion of health costs that are met from pooled funds, and the proportion of health costs that impose direct costs on individuals and families, as a proportion of the total cost of providing the population with the health services that it needs. In low- and middle-income countries, health services may be funded in a variety of ways, including through taxes (services provided or funded by government), through pre-payment systems (insurance), through direct payments by individuals, and in some cases through donor contributions. Since the poor may be unable to meet user fees, or may suffer financial hardship in doing so, taxes and insurance systems are vital to increasing health equity.

Pooled funds can reduce health inequalities by increasing the affordability of health costs, as well as the number of services that do not impose direct costs on users.

The UHC cube represents a dynamic system. The population axis will continue to expand as the population grows; the services axis will expand as new health services, treatments, drugs and technologies become available, while the cost axis will expand as treatments and other services become more expensive to provide.[44]

The purpose of the UHC cube is to encourage countries to expand the provision of priority health services, to extend the coverage of those services to more people, and to reduce out-of-pocket payments.[45] This raises critical questions, including which new services to include in the benefits package (services axis), which services to expand to a wider proportion of the population, how to define the eligibility criteria for coverage (population axis), and how to finance the expanded range of services covered by pre-payment mechanisms (cost axis). Increasing coverage requires an understanding of the 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. As explained below, the guiding concepts of availability, accessibility, acceptability, and quality focus attention on each of the axes of the UHC cube, and provide a framework for evaluating the actions taken by governments to expand UHC.

(b) Availability

General Comment 14 emphasized that health care facilities, goods and services, as well as public health services, facilities and programmes should be available in sufficient quantity.[46] The precise nature of the facilities, goods, and services will vary according to many factors, including the level of development of each country, the unique set of health challenges it is facing, the available sources of financing and the mix of public and private sector service providers. Nevertheless, services, facilities and programmes that are essential to an effective health system include: sources of safe and potable drinking water, adequate sanitation facilities, health clinics, hospitals and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs.[47]

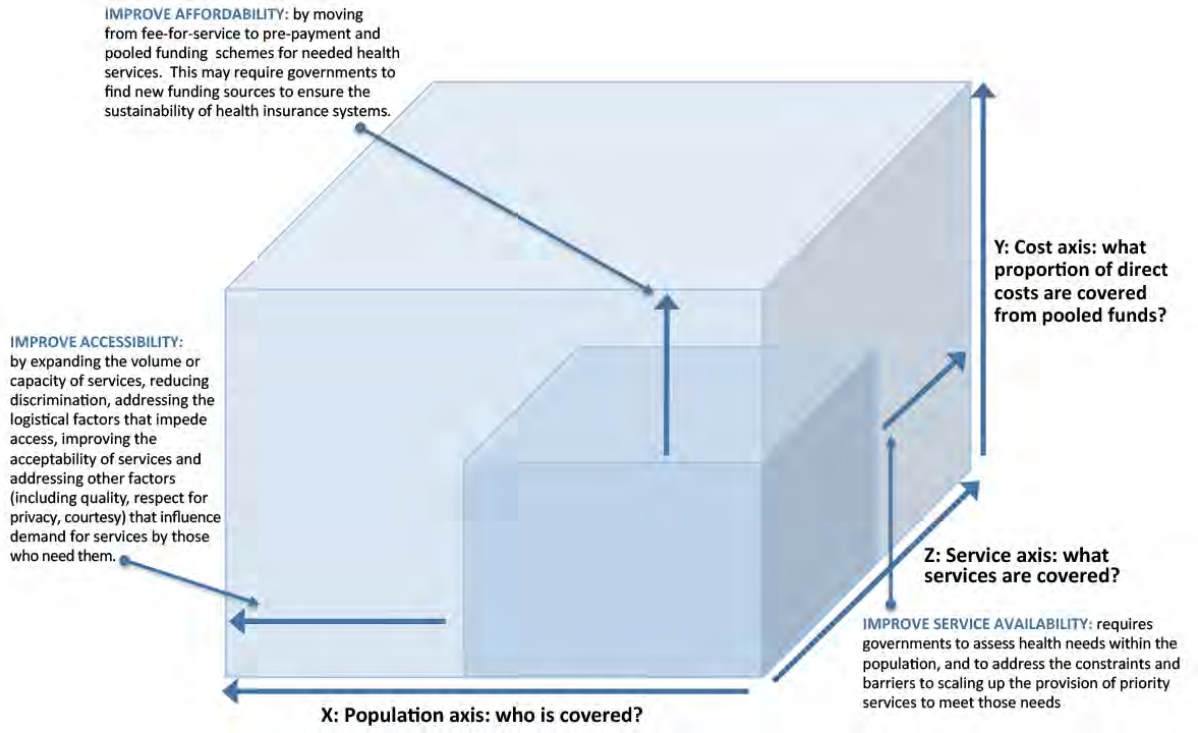
Right to health concepts provide a helpful way of evaluating efforts to move towards UHC. The guiding principle of availability links with the services axis of the UHC cube (**Figure 1.2**). It requires governments to assess health needs within the population, and to address the constraints and barriers to scaling up the provision of priority services to meet those needs. In many cases, these constraints will reflect weaknesses in the building blocks of the health system (**Table 1.1**),[48] including lack of investment in the resources that are necessary to provide the appropriate quantity or volume of services. Common problems may include:

- lack of facilities and infrastructure (including bad roads or transport options to enable people to travel to places where they can register for insurance coverage or receive health services);
- inadequate distribution systems for essential medicines;

- lack of human resources (a skilled and motivated health workforce – especially in rural and remote areas);
- lack of planning and leadership, and
- the absence of legislative and governance frameworks for managing the provision of services and for ensuring accountability.

Improving *availability* requires more investment in the resources that make it possible to increase the range of health services that can be delivered to the population (i.e. more services), as well as the maximum capacity of those services (more of each service).[49]

Figure 1.2: Evaluating progress towards UHC using right to health concepts



The commitment of governments and other service providers to increasing the availability of health services may be formalized through technical, financial and logistic plans, with assistance from development partners, as appropriate. However, law reform is an important and often unacknowledged part of the governance reforms that are necessary to implement health plans, to scale up the delivery of health services, and to manage resources effectively. For example, legislation may be needed to establish a health insurance commission to manage a national health insurance scheme, including registering members, accrediting health service providers, processing claims and managing a national health insurance fund. Similarly, legislation may be needed to establish a national medicines authority to monitor the availability of essential medicines at affordable prices, to encourage the appropriate use of generic medicines, and to recommend the reduction of taxes, tariffs and mark-ups on essential medicines.[50] Legislation may also establish systems for licensing

health care establishments, and training and registering classes of health professional that are adapted to each country's particular needs.

Governments may formalize their commitment to improving the availability of health care and public health services through legislation establishing a national health system. For example, South Africa's *National Health Act* seeks to implement the constitutional right to access health care services, and other health-related rights, by establishing a national health system which provides the population with the best health services that available resources can afford, in an equitable manner (**Box 1.5**). Ultimately, the guiding principle of availability directs attention to the capacity of governments to provide more services from pooled funds and to increase the volume of the services that are offered.

Box 1.5: The goals of South Africa's National Health Act (Act no. 61 of 2003)

2. Objects of the Act

The objects of this Act are to regulate national health and to provide uniformity in respect of health services across the nation by:

a) Establishing a national health system which:

i) encompasses public and private providers of health services; and

ii) provides in an equitable manner the population of the Republic with the best possible health services that available resources can afford;

b) Setting out the rights and duties of health care providers, health workers, health establishments and users; and

c) Protecting, respecting, promoting and fulfilling the rights of:

i) the people of South Africa to the progressive realization of the constitutional right of access to health care services, including reproductive health care;

ii) the people of South Africa to an environment that is not harmful to their health or well-being;

iii) children to basic nutrition and basic health care services contemplated in section 28(l)(c) of the Constitution; and

iv) vulnerable groups such as women, children, older persons and persons with disabilities.

(c) Accessibility

In addition to investing in the resources that are needed to ensure that health facilities, goods and services are more widely available, governments must take steps to ensure that these services are accessible to the entire population.[51] The concept of accessibility has four overlapping dimensions: non-discrimination, physical accessibility, affordability and information accessibility.

Non-discrimination

The guiding principle of non-discrimination relates to the population axis of the UHC cube, since the goal of protecting people from discrimination is to ensure that they are not excluded from receiving the health services that they need (**Figure 1.2**). Members of the population should not be denied access to health services or medicines because of their racial or cultural identity, their sex, language or religion, their physical or mental disability, sexual orientation, political opinions, or their health status (including HIV status).[52] Discrimination entrenches health inequalities by excluding marginalized and vulnerable groups and by treating them less favourably than other individuals and groups. For example, some countries have large, permanent populations of migrants who provide a cheap labour force and may live for many years in the country without gaining citizenship. If governments are to create the conditions in which all members of the population can realize the highest attainable standard of health, then public health and health care services must also be accessible by these populations.

General Comment 14 states that countries have an immediate obligation to respect the right to health by preventing discrimination in access to curative, palliative and preventive services.[53] Governments can honour these entitlements by passing and enforcing non-discrimination laws. Typically, these laws will set out the grounds of prohibited discrimination, or the protected attributes or characteristics that cannot lawfully be used as a basis for discriminating against a person in the provision of health services, employment and education, and in other areas. These laws may also establish a complaints-handling body with power to investigate and conciliate complaints, and to pursue other remedies in appropriate cases.

Physical accessibility

The guiding principle of physical accessibility also links with the population axis, by directing attention to the barriers and obstacles that stand in the way of extending health services to more people (**Figure 1.2**). Health facilities, goods and services will not contribute to the goal of improving public health unless they are within the safe physical reach of those who could benefit from them, including vulnerable or marginalized groups and others who have difficulty accessing services. These may include ethnic or religious minorities, indigenous populations, women, children, the elderly, people with disabilities, and people living in slums or in remote or inaccessible locations.

For example, remote populations will effectively be denied access to health services unless the infrastructure exists to enable them to reach and to use those services.[54] Physical accessibility therefore includes not only physical infrastructure, such as adequate roads and bridges, but also forms of transport, such as bus or ferry services, and other forms of needed assistance, such as child care or disability support services.

Economic accessibility (affordability)

The guiding principle of economic accessibility directs attention to the cost axis (**Figure 1.2**). Essential health facilities, goods and services should be affordable for all. In many countries, health services are delivered through a mix of government, government-funded and privately-funded providers. Payment for health care services (including consultations, diagnostic procedures, and essential medicines), public health services (such as vaccinations), and services related to the underlying determinants of health (such as water, sanitation and the removal of rubbish), should be based on the principle of equity. This requires that these services should be affordable to everyone, including socially and economically disadvantaged groups, those with no fixed income, or with precarious incomes working in the informal sector. **Box 1.6** provides an example of how law can formalize a national government's commitment to keeping health services affordable.

Economic accessibility requires governments to implement funding mechanisms that reduce out-of-pocket payments imposed at the time the service is delivered, while expanding revenues obtained through taxpayer funded health insurance schemes, premiums or other pre-payment mechanisms.[55] By increasing the proportion of health services that are funded from pooled funds, governments can reduce the proportion of the population who suffer catastrophic out-of-pocked expenditures, or who defer or are denied services due to their inability to pay.

Box 1.6: Improving economic access to health care services in the Islamic Republic of Iran

The Constitution of the Islamic Republic of Iran recognizes the rights to the enjoyment of social insurance and social security benefits covering retirement, unemployment, old age, disability and medical care. These rights provided the basis for additional protections recognized in the comprehensive Law of the Fourth Economic, Social and Cultural Development Plan, 2005–2009, enacted on 1 September 2004.[56]

Article 90 of the Plan was intended to enhance fairness in accessibility to health care services by reducing the proportion of low-income households suffering from catastrophic expenditure on health (that is, expenditures consuming more than 40% of income after basic subsistence needs have been met). Article 90 directed the Ministry of Health, Medicare and Medical Education to prepare by-laws ensuring that out-of-pocket payments (the contribution of patients to the costs of health care services) do not exceed 30% of the total cost of those services. The goal of Article 90 is also to reduce the proportion of vulnerable households suffering from catastrophic health care expenditures to 1%.

Economic accessibility does not mean that all services should be provided by government, nor that services should be made available to all individuals free of charge. However, it does require governments to take concrete steps to ensure that the poorest and most vulnerable groups in society are not "disproportionately burdened with health expenses as compared to richer households".[57] For example, this may require government to subsidize the costs of health services in remote and rural areas, where the provision of those services is necessarily less cost-effective, and where the true cost of those services would put them out of reach of poorer, vulnerable groups.

Information accessibility

The principle of accessibility includes the right to seek, to receive and to express information and ideas about health issues to others. Health service providers and health insurance schemes must also ensure that personal health data is kept secure, and that privacy and confidentiality are respected. Both of these aspects of information accessibility relate to the population axis, by directing attention to factors that may undermine demand for health services in the population (**Figure 1.2**).

Protecting the confidentiality of each person's health care information is necessary to create trust and to encourage all members of the population to access health care services. Protecting the confidentiality of particularly sensitive information, such as information relating to HIV infection, sexual health or mental health, is especially important in order to avoid creating disincentives to people seeking information and treatment in these areas.

(d) Acceptability

The principle of acceptability provides that health facilities, goods and services should be delivered in ways that are culturally appropriate, sensitive to gender and to different age groups, and consistent with ethical obligations. Acceptability relates to the population axis, by directing attention to factors that may undermine demand for health services by those who need them. For example, there is good evidence that providing clean needles and syringes to persons who are injecting drug users will reduce the transmission of HIV.[58] However, clean needles must be available in trusted locations where injecting drug users feel safe in accessing them (such as outreach centres, vans, trust points), without the risk of harassment, arrest or criminal liability. Legislation which criminalizes the possession of needles and syringes can undermine efforts to reduce HIV transmission among injecting drug users.

(e) Quality

Health facilities, goods and services should be scientifically and medically appropriate and of good quality. Ensuring quality in the provision of facilities, goods and services requires a skilled health workforce, processes for assuring the supply of officially approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

Quality is an independent variable that is central to the capacity of governments to move towards UHC.[59] Unless the health services that governments provide are effective, and of high quality, they cannot contribute to the realization of the highest attainable standard of health. In addition, quality is relevant to the population axis of the UHC model (**Figure 1.2**): if health services are of poor quality, this may reduce demand for those services, even by those who need them.

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PART 2
THE PROCESS OF PUBLIC HEALTH LAW REFORM

Introduction

The processes involved in reforming or introducing new public health laws are critical to the legitimacy and success of law reform efforts. "Process", in this report, refers to the practical steps that governments and other stakeholders take to advance the goal of law reform, within the political context of each country. In addition to discussing these practical steps, this report points to principles of good governance that the process of law reform ought to reflect. The law reform process provides the opportunity for lawmakers to consult with stakeholder groups and others who will be affected by the law and to build public support for the changes that are required. This can improve the implementation of the law and compliance with legal requirements.

Part 2 of this report begins by explaining the context of public health law reform (Chapter 2). Although the law reform process will vary greatly between countries, Chapter 2 distinguishes between the following three activities:

- Health legislation review: this is the formal process of reviewing public health laws, either generally or in a specific area, and assessing the need for reform.
- Implementing recommendations from a legislative review: this is the process of designing and drafting public health laws. It also includes the political process of passing legislation through parliament, as well as arrangements for the implementation and enforcement of laws.
- Designing the review process: ensuring good governance throughout the process of reviewing, drafting and amending public health laws.

One of the first questions a government will consider is whether the goals that it wishes to achieve require a legislative or regulatory response, or whether other forms of governance (e.g. self-regulation or co-regulation) are more appropriate (see Section 2.3). This question may also arise when a government is considering how best to implement the recommendations from a health legislation review.

In many cases, the decision to review existing public health laws or to introduce new laws will be made for quite specific purposes. As a result, the scope of the legislative review process may be narrowly defined. At the same time, the purpose of this report is to encourage governments to consider the flexible role that law can play in national efforts to realize the right to health for all members of the population. This report therefore takes a broad perspective on the process of public health law reform. Section 3.1 considers some common reasons why public health laws may need to be revised, and encourages governments to consider the benefits of updating and improving their public health laws generally.

Depending on its scope, the process of reviewing public health laws may provide the opportunity to identify priorities for legislative reform, based on evidence of the burden of disease in each country and the major health issues that each country is facing. Despite the differences between them, many

low- and middle-income countries face remarkably similar health challenges. These include the need for legal frameworks to respond effectively to HIV, to epidemics of contagious disease, to the major risk factors for the rising burden of noncommunicable disease (including tobacco use, harmful use of alcohol, poor diet and obesity), and to the large burden of preventable injuries. These priority areas are reviewed in Section 3.2.

Although law reform is primarily the responsibility of the government, civil society organizations can make an important contribution by educating the community about the need for reform, and by mobilizing political support for law reform within government (Section 3.3). In some countries, political and legislative mechanisms facilitate the direct participation of the community in the development of health policy. These mechanisms, as well as public interest litigation, can act as triggers or catalysts for the reform of public health laws, as discussed in Section 3.4.

After it has made a formal commitment to implement recommendations from the legislative review process, government will face the challenge of translating those recommendations into effective public health legislation. The process of designing and drafting new laws will benefit from a good understanding of the range of legal strategies that are available to governments to improve public health and to implement policy recommendations. Chapter 4 reviews some of the components or characteristics of effective public health laws. Governments that have chosen to amend their public health laws should ensure that the law provides a clear mandate for public health actions and sets out the powers and responsibilities of public health officials clearly. Other issues for consideration include the need for coherence between public health laws and laws administered by other ministries, and the need for human rights safeguards (such as protection from discrimination) to be built into public health laws.

The process of formally reviewing public health laws, drafting new ones and gaining parliamentary or executive approval for new laws, is complex and will often be subject to political pressures. Law-makers will need to comply with parliamentary (or other law-making) rules and procedures. Chapter 5 emphasizes the importance of good governance throughout the law reform process. This includes resisting efforts to corrupt the law-making process, and implementing the principles of accountability, transparency and respect for the rule of law.

In some cases, the public health goals that a government is seeking to achieve will require a collaborative approach between the health ministry and other ministries. This may lead to formal consideration of how best to facilitate and coordinate an intersectoral approach to addressing public health priorities. Globally, there is growing awareness of the importance of coordinated, intersectoral action to improve public health and to reduce health inequalities.[1] Chapter 6 considers how law and governance reforms can support and improve the process of collaboration between ministries, and with other stakeholders that are participating in intersectoral health initiatives.

Chapter 2: The context of public health law reform activities

SUMMARY POINTS

- **Laws that protect the health of the population may be organized and administered quite differently in different countries, depending on historical and constitutional factors, and the specific health challenges each country has faced in the past. The concept of public health law is not limited to laws regulating the provision of health care services, but extends to the legal powers necessary for the State to discharge its obligation to realize the right to health for all members of the population.**
- **The scope of any formal review process of public health legislation may vary widely according to the political and legal context and priorities of each country.**
- **The capacity and willingness of governments to amend or replace public health laws, based on the recommendations of a formal legislative review, may be affected by the political ideology of the government concerned, the political feasibility of reform proposals, competing legislative priorities and available resources.**
- **When implementing law reform recommendations, governments should plan to monitor and evaluate their impact. This will involve identifying indicators that are suitable for tracking the impact of the law on relevant practices and health outcomes.**
- **Governments may need to set national priorities and to implement public health law reform recommendations in a stepwise manner, dedicating resources tow a smaller number of cost-effective reforms that will deliver the greatest overall health benefits, and working towards implementation of a broader set of reforms as resources allow.**
- **Countries may use a variety of different forms of regulation to regulate health risks and other health matters. These include legislation, subsidiary regulations, decrees and executive orders, as well as guidelines and codes of conduct. Governments may adopt forms of co-regulation that formally include the participation of industry or professional bodies and/or civil society organizations. Governments may also defer to customary law as a valid source of law, or declare it to be the governing source of law in certain contexts.**
- **In considering whether public health law reform is appropriate, and whether self-regulatory codes and guidelines, or co-regulatory schemes, are failing to achieve public health goals, independent monitoring and evaluation are critical.**

2.1 What are public health laws?

The Constitution of WHO makes it clear that health is not only about the absence of disease or infirmity, but is a complete state of physical, mental and social well-being.[2] Similarly, the concept of public health law, as understood in this report, is not restricted to laws that regulate the provision of health care services, but includes the legal powers that are necessary for the State to discharge its obligation to realize the right to health for all members of the population.

Laws that protect the health of the population may be organized and administered quite differently in different countries, depending on historical and constitutional factors, and the specific health challenges each country has faced in the past. These may include laws that regulate food safety, tobacco control, environmental sanitation, registration of pharmaceuticals, the registration of health practitioners, sexually transmissible infections, the management of communicable diseases, quarantine, public health emergencies, collection and management of health data, the powers and functions of public health officers, and the performance of public health functions by local and regional governments.

Typically, the health ministry will administer laws that affect the provision of health care services and address a range of other health risks. Outside the health ministry, other ministries will administer laws that may also have a significant influence on health risks and health outcomes. Examples include laws relating to pollution and environmental contamination, consumer protection, criminal justice, local government, transport, housing and agriculture. Although the health ministry will usually lead initiatives to reform public health legislation, collaboration between ministries and agencies will be essential where the issue under consideration does not lie within the sole operational domain of the health ministry. For example, the reform of laws that aim to prevent violence against women will necessarily require the involvement of the justice ministry, while any initiative that relates to the taxation of tobacco or alcohol will normally involve the finance ministry. Efforts to reduce the health disparities that arise from social disadvantage may involve ministries with responsibilities for employment, public housing, transport and social security.

Where more than one ministry or agency is involved, the process of legislative review necessarily becomes more complex. Chapter 6 identifies practical steps for initiating intersectoral initiatives to improve public health, and presents several case studies of governance reforms that have supported government-wide efforts in this area.

2.2 Conceptualizing the process of health legislation review

(a) Impetus for a review

The opportunity to review public health laws may arise in many different ways, with many variations between countries. The review process may evolve in response to specific concerns about the failure of current laws or policies, or from broader discussions about how to improve policies, modernize laws or adapt to new challenges. The impetus for a review may come from government itself, from stakeholder groups outside government, or from development partners. International factors may also have an influence, such as the need to discharge obligations owed under international law (e.g. the WHO Framework Convention on Tobacco Control[3] or the International Health Regulations (2005)[4]), or to implement recommendations and action plans, such as WHO's Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020.[5]

(b) Scope of the review process

Assuming that government has formally decided to conduct a review of existing public health laws, the scope of that review may vary widely. It may range from reviewing the adequacy of a particular section within a statute or code to revising or introducing an entirely new public health act. Even more ambitiously, the review process may include consideration of laws and matters administered by ministries outside the health ministry. An intersectoral or cross-ministerial review process may be necessary in order to respond effectively to persistent health challenges; for example, in order to improve food security, to reduce health inequalities, to improve maternal and child health, and to reduce the risk factors for noncommunicable diseases (see Chapter 6).

The scope of the review will often have an influence on the agency or person chosen to undertake the review and the formal processes involved. A review may be carried out by independent consultants at the request of the health ministry, by health ministry officials, by a parliamentary standing committee, by a specially-formed commission or review committee, or by a specialist law reform body such as a law reform commission. The person or committee that undertakes the review may report back to the health ministry, or report directly to those who have political influence, such as the health minister, a group of senior government ministers, or even the prime minister or president. The question of who undertakes the health legislation review, and to whom they report, may have an important impact on how seriously the recommendations of the review are taken, and whether they remain on the political agenda.

The issues considered during a health legislation review will also vary widely, according to the terms of reference of the review. For example, the review may include a consideration of: the specific problems that have arisen with the administration of current laws; the opinions of the key stakeholder groups (including political parties, business and professional groups, faith-based organizations, civil society organizations and development partners); the legislative and constitutional powers of the government to reform the law in a particular area; recent international developments; and the extent to which law reform is occurring in other countries and jurisdictions.

(c) Implementing recommendations

It is helpful to distinguish between the recommendations made during a formal review of public health laws, and any subsequent decision by government to amend or replace existing laws. The capacity and willingness of a government to implement the recommendations of a review may be affected by the political ideology of the government concerned, the political feasibility of the reform proposals, competing legislative priorities and available resources.

The design and drafting of new public health laws raises a wide range of matters for consideration. Law reformers will need to consider the most appropriate legislative mechanism for implementing the recommended changes, and specify who will administer the new law and what legal powers they will require to do so effectively. They should also consider the compatibility of the law with human rights principles and the potential role of regional, city and local governments in making the new law work. Legislative drafters should consider whether those who will administer the new law have the

capacity to understand its requirements, as well as the process of transition from existing laws to new laws.

When implementing law reform recommendations, governments should plan to monitor and evaluate their impact. This will involve identifying indicators that are suitable for tracking the impact of the law on relevant practices and health outcomes.[6] For example, monitoring the impact of tobacco control laws may require both baseline and follow-up surveys to determine smoking prevalence. Governments may also monitor the impact of mandatory helmet laws in terms of infringement notices and road accident fatalities. In many countries, the resources of governments to engage in public health law reform are limited. Governments will therefore need to set national priorities and proceed in a stepwise manner, dedicating resources to a smaller set of cost-effective reforms that will have the greatest overall health benefits, and working towards implementation of a broader set of reforms as resources allow.[7]

This report includes many case studies and examples of legislation from around the world. These are not "model laws", and in many cases simply reflect the local circumstances of each country. However, by sharing the experience of other countries, the report aims to give public health authorities a greater understanding of the options for reform, and a determination to use legal powers effectively to realize the right to health.

2.3 Why legislate?

In many countries, a variety of forms of regulation are used by governments to regulate health risks and to create healthier environments. These range from legislation, subsidiary statutory instruments, decrees and executive orders to "soft law" instruments such as guidelines and self-regulatory codes of conduct. In some countries, governments may also defer to customary law as a valid source of law, or declare it to be the governing source of law in certain contexts.[8] For example, Fiji's Public Health Act states that the Act does not apply to villages (with the exception of those provisions governing infectious diseases), although the Minister of Health retains residual power to extend the application of any provision of the Act to villages by executive order.[9] As a result, customary law and forms of social organization remain the operative source of authority for managing "minor public health risks, sanitation and general village neatness".[10] As with other sources of law, governments should ensure that customary law upholds universal human rights and does not legitimate discrimination.

In addition to statutory regulation, and voluntary forms of regulation, governments may adopt forms of co-regulation that draw on the participation of industry, professional or civil society organizations (**Box 2.1**). For example, government may give an industry-administered code or self-regulatory process official status within a statutory scheme. Alternatively, it may enhance the status of an industry code in other ways, such as through the participation of a government representative on its governing board. As **Box 2.1** illustrates, in some countries, important matters of health policy – such as the regulation of food advertising to children, or regulation of electronic cigarettes – may be regulated by industry-based bodies within statutory schemes that lie outside the responsibility of the health ministry. Governments should consider carefully whether it is appropriate to delegate responsibility for important health issues to industry-based, non-health bodies.

Box 2.1: Advertising regulation in the United Kingdom: an example of co-regulation

In the United Kingdom, both non-broadcast and broadcast advertising are governed by a co-regulatory system. The Committee of Advertising Practice (CAP) is responsible for writing and updating the United Kingdom Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing, while the Broadcast Committee of Advertising Practice (BCAP) writes and updates the United Kingdom Code for Broadcast Advertising. The membership of both Committees is made up of advertising associations, media owners and other industry groups.[11]

Although CAP and BCAP are responsible for the standards that govern the content of advertising in the United Kingdom, an independent body, the Advertising Standards Authority (ASA) administers the codes by acting on complaints and taking action against misleading, harmful or offensive advertisements. The ASA Council hears complaints and decides if advertisements have breached the advertising codes (two thirds of its members are independent of industry).[12] The United Kingdom Office of Communications (Ofcom) remains the statutory regulator for the communications industries, signs off on major changes to the Codes and has ultimate responsibility for enforcing compliance with the Codes.[13]

The co-regulatory advertising scheme of the United Kingdom has addressed concerns relating to the advertising of unhealthy products in a number of ways. In 2007, Ofcom banned the advertising of foods high in salt, sugar and fat (based on a nutrient profile developed by the Food Standards Agency) in television programmes commissioned for or directed at audiences below the age of 16.[14] The ASA's Council has also upheld a number of complaints against advertisers for making misleading and deceptive claims about the health effects of electronic cigarettes (e-cigarettes).[15] In 2014, the CAP and BCAP published new rules for the marketing of e-cigarettes.[16] These rules were intended to operate during the two year period until the United Kingdom became required to implement the requirements of the revised European Union Tobacco Products Directive (2014) into United Kingdom law.[17] The Directive limits the advertising of e-cigarettes, and extends the same legal restrictions to electronic cigarettes as already apply to other tobacco products.[18]

The use of statutory regulation and softer, non-mandatory standards is not mutually exclusive. Governments frequently adopt a mix of regulatory instruments to address different aspects of a health challenge. For example, the government of Mexico has responded to rapidly rising rates of obesity with a variety of regulatory and non-regulatory strategies. These include:

- commissioning voluntary evidence-based guidelines on beverage consumption;[19]
- a "National Agreement for Healthy Nutrition" that committed the Mexican Government, the food industry and other stakeholders to work together to achieve 10 objectives;
- statutory regulations to remove foods and beverages with high levels of sugar and saturated fat from schools and to improve access to clean water and healthy foods;
- a voluntary, front-of-pack scheme to identify the healthiest products in each food category;[20] and
- a tax of around 10% on sugar-sweetened beverages, and 8% tax on high-calorie foods.[21]

The use of statutory instruments does not always mean that the government is adopting a coercive or mandatory approach. For example, legislation can establish institutions that carry out public health functions, as in the case of Tonga's Health Promotion Foundation Act 2007.[22] In general, however, the benefit of statutory regulation is that it enables governments to impose technical standards and requirements that are mandatory, rather than voluntary or discretionary. Statutory regulation is therefore suited to contexts where the protection of public health requires widespread (and ideally, uniform) compliance with common, minimum standards (e.g. sanitary requirements, control of infectious diseases, food safety, tobacco control), or where guidelines and other voluntary commitments impose only weak and ineffectual standards.

Although industries that wish to avoid legislative regulation may point to the existence of a self-regulatory code as evidence that industry is taking health concerns seriously, statutory regulation also has the benefit of creating a level playing field. It prevents businesses from suffering the market disadvantages that might otherwise arise if they were left to decide whether or not to adopt standards voluntarily. In each case, the central issue is whether the incentives that drive business conduct are adequately aligned with the actions and outcomes that are required in order for governments to progressively realize the right to health. In some cases, as with the tobacco industry, the drivers of business conduct are diametrically opposed to public health goals.

Governments may be reluctant to impose additional requirements on businesses or individuals where there is evidence that voluntary standards or self-regulation are working effectively. Co-regulation may also benefit the public interest by maintaining an open dialogue with those who are subject to regulation, by giving government access to the knowledge and expertise of private sector organizations about how to achieve shared goals, and by encouraging a collaborative approach. While the monitoring and enforcement of legislative standards may impose substantial costs on government, the costs of self-regulation may be shared with or transferred onto industry. In evaluating the relative benefits of legislative and non-legislative options, governments must remember their obligation to seek to achieve the right to health for their population (see Section 1.1).

Independent monitoring and evaluation are critical when evaluating the performance of self-regulatory codes, guidelines or co-regulatory schemes in achieving public health goals. Where credible evidence demonstrates that industry standards are inadequate, governments will need to consider the most appropriate and feasible regulatory response. While that may include the introduction of new legislation, the form of that legislation may vary depending on the context. For example, a government may require the registration of an industry code and make such registration conditional on the code meeting specified criteria. These minimum criteria may close off the major loopholes and escape clauses in the voluntary code that undermine the health goals that the government is seeking to achieve. In addition, the government may specify measurable targets and indicators for evaluating the success or performance of industry self-regulation. The government may also mandate regular monitoring, with results reported to parliament, or to an appropriate regulatory agency, thereby enhancing transparency and public accountability.[23] Where an industry code fails to achieve these benchmarks, the case for direct statutory controls will be more compelling.

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[i] All references were accessed on 1 May 2016.

forms of domestic advertising that have no cross-border effects: see Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and repealing Directive 2001/37/EC. Official Journal of the European Union, L127/1, 29.4.2014 (http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:JOL_2014_127_R_0001); European Union, Questions & answers: new rules for tobacco products, memo/14/134, 26 February 2014 (http://europa.eu/rapid/press-release_MEMO-14-134_en.htm).

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Chapter 3: Assessing the case for the reform of public health law

SUMMARY POINTS

· **Countries may review their public health laws for different reasons. For example, public health laws may be outdated, inconsistent or incoherent; major health hazards and current challenges may require new legislative frameworks, and governments may lack the powers they need to discharge their public health responsibilities effectively. Current laws may also fail to appropriately balance the rights and interests of individuals with public health, and with other public interests.**

· **Although the focus of a legislative review process may be quite narrow, it nevertheless provides the opportunity for countries to consider updating their public health laws in a more systematic way, and to consider priorities for the future.**

· **In federal countries, the centralization or decentralization of regulatory power may have important impacts on public health. Subject to the division of legislative powers in the national constitution, federal governments should carefully consider the advantages and disadvantages of centralizing control of a particular issue at the federal level, or alternatively, permitting state, city and local governments to introduce additional laws, provided they are consistent with any relevant federal laws.**

· **Despite their differences, countries need strong legal frameworks to deal with important public health challenges that are shared across nations and regions, including HIV, tuberculosis and pandemics of infectious disease.**

· **Noncommunicable diseases – principally cardiovascular disease, cancer, respiratory diseases and diabetes – are responsible for around 68% of global mortality and have led to a double burden of disease in many countries. As a result, countries need to develop effective legal responses to obesity and dietary risks, and to scale up the implementation of tobacco control.**

· **Injuries have been neglected in many countries. Priority areas for governments include enforcing laws requiring motor cycle helmets, mandatory seat belts and child restraints. Important interventions to reduce violence and intentional injuries include strengthening the control of alcohol, and firearms laws.**

· **Although the health ministry will often take the lead in public health law reform, consultation with other ministries may be critical to effective implementation and enforcement.**

· **A variety of events may trigger the reform of public health laws, including disease outbreaks, sunset clauses in legislation and obligations under international law. In some countries, formal mechanisms may provide opportunities for public health and civil society organizations to put health issues on the government's agenda and to participate in law-making. In countries where constitutional, health-related rights are justiciable, litigation may compel governments to amend their laws and to take action to protect public health.**

3.1 Common reasons for reviewing and updating public health laws

There are many different reasons why governments may undertake a review of public health laws. For example:

1. Over time, a country's public health laws may have become outdated, fragmented and even incoherent in ways that undermine government efforts to manage health challenges effectively.

2. Major health hazards and current challenges may require new legislative frameworks, and provide the impetus for law reform.

3. Governments may lack the specific legislative tools that enable them to discharge their public health and human rights responsibilities effectively.

Public health laws tend to develop in a reactive fashion, in response to the specific health challenges a country has faced over time. A review of public health laws may be similarly narrow, focusing on a specific problem or challenge. Nevertheless, the process of reviewing public health laws provides the opportunity for countries to consider updating their laws in a more systematic and proactive way, and to identify priorities for the future. This chapter considers some of the reasons that may justify carrying out a review of public health laws, either generally or in a specific area.

(a) The problem of outdated laws

In some cases, the political impetus for law reform comes about because public health law statutes are simply too old and have become outdated. A great deal of public health legislation was framed in the late-19th and early-to-mid-twentieth centuries. As a result, public health laws in some countries contain provisions that fail to conform to evidence-based approaches to epidemiology and disease, or to human rights principles (**Box 3.1**). Over time, specific provisions and parts of health legislation may simply fall into disuse.

Box 3.1: The legacy of 19th century British public health laws

Public health laws framed in the 19th century in Britain assumed that disease was transmitted by harmful, airborne "miasmas" that were concentrated in rubbish and in damp, poorly ventilated buildings.[1] Disease was also understood to be transmitted by water, but the agent of infection was not understood. Rapid population growth, together with migration from rural to urban areas contributed to overcrowded and insanitary living conditions that promoted the spread of disease. Public health laws from this period increased the powers of the State over land and premises, particularly in poor urban areas, since public health authorities noticed that this was where epidemics of disease often arose.

Legislation empowered public health officials to impose quarantine, to require the removal of filth and rubbish, to "cleanse" premises, and to regulate offensive trades. For example, the Public Health

Act of 1875 not only required landlords to provide for proper sanitation, ventilation and drainage, but to comply with and to enforce a moral code that was associated with cleanliness and good health. Landlords operating "lodging houses", a type of affordable urban housing, were required to file "certificate[s] of character"[2] and were prohibited from allowing unmarried tenants of the opposite sex to cohabit.[3] There was little in this legislation to ensure that landowners and occupiers were treated fairly, and racial groups sometimes suffered discrimination.

Public health legislation in those countries that inherited their laws from Britain often reflects the legacy of this period. For example, many state public health laws in the United States were influenced by a report published in 1850 which reflected the belief that sanitation, health and morality were closely intertwined.[i] This report has been described as "one of the most farsighted and influential documents in the history of the American public health system", despite the fact that late 19th century developments in scientific understanding about the causes of disease disproved the notion that immorality was the root of poor health.[4]

Outdated public health laws can undermine public health in two main ways. Firstly, due to gaps in the legislation, governments and public health officials may lack the mandate and the legal powers that they need to respond to established and emerging health threats. In some cases, legislation itself may be missing, and the extent of government powers may be ambiguous and uncertain.

Secondly, outdated legislation may undermine effective public health practice because those powers that do exist fail to achieve an appropriate balance between the rights and interests of individuals, public health and other public interests. For example, there are significant differences between the ways in which sexually transmitted infections, including HIV, and airborne infectious diseases (e.g. influenza) are transmitted. The failure to recognize that strategies for the prevention of influenza may not be appropriate for HIV can lead to significant injustice, as when HIV is simply added to existing schedules in legislation, activating a range of generic powers and obligations that are ill-suited to HIV prevention. This can lead to situations such as those in which outdated public health laws prohibit individuals with HIV from riding on public transport, require them to publicly warn others of their infection, or subject individuals to other forms of discrimination that neither reduce the spread of disease nor respect basic human rights. Identifying, removing or updating outdated provisions is an urgent priority, not only because they may be ineffectual, but because they alienate the individuals and communities whose cooperation is required in order to minimize disease transmission.

(b) The problem of multiple layers of law

Public health laws in many countries are made up of successive layers of statutes, regulations and amendments that have accumulated over many decades in response to existing or perceived health threats. Public health laws may contain provisions that were introduced in response to a wide range of epidemics including smallpox, yellow fever, cholera, tuberculosis, polio, HIV and other sexually

[i] For example, Lemuel Shattuck's Report of the Massachusetts Sanitary Commission, published in 1850, adopted the understanding that immorality and disease were closely related: see Institute of Medicine. The future of public health. Washington (DC): National Academy Press: 1988:60–1.

transmitted infections, West Nile virus, severe acute respiratory syndrome (SARS), and more recently, novel forms of influenza. Laws enacted in such an ad hoc, reactive fashion can become inconsistent, redundant, ambiguous and confusing.

(c) The problem of inconsistency

In addition to multiple layers of law, significant variations can develop over time between the public health laws of different jurisdictions. In countries that have state or provincial governments in addition to a national government (i.e. federal systems), state or provincial laws may evolve independently of each other, with little or no coordination. In some cases, the legislative review process can give governments the opportunity to carry out an assessment of inconsistencies, and to consider both the advantages and disadvantages of either centralizing regulatory control, or alternatively, permitting regulation to continue at the subnational level.

In federal countries, the division of legislative and regulatory power between the national or federal government, and state or provincial governments, is usually set out in the national Constitution. The Constitution may grant exclusive regulatory power in a particular area to either the federal or to state governments; alternatively, regulatory power may be shared. One benefit of a federal structure is that state governments will have their own legislative powers, and thus the flexibility to try new approaches. State governments may be able to move ahead with reforms that would be impossible to achieve, for political or economic reasons, at the national level.

In countries where there is an overlap between the legislative powers of federal and state legislatures, federal governments can encourage a shared approach to regulation. For example, federal laws may make it clear that the federal government does not claim exclusive power to regulate, thereby enabling state, city and local governments to introduce additional laws, provided they are consistent with any relevant federal legislation. Australia's Tobacco Advertising Prohibition Act, for example, explicitly preserves the right of the states and territories to pass their own laws restricting tobacco advertising, provided that they are capable of operating concurrently with federal legislation.[5] This federal provision has enabled Australia's states to introduce a number of innovative tobacco control laws, including laws prohibiting all tobacco advertising at point of sale, laws requiring that tobacco products for sale at retail premises must not be visible from either inside or outside the premises, and laws requiring tobacco products to be sold from a single point of sale within premises.[6]

On the other hand, the existence of inconsistent laws at the state level in a federal country may carry disadvantages for health, due to inequality in services provided by states, and inconsistent approaches to contentious issues, such as reproductive health. In some areas, the lack of national consistency can interfere with a rapid or coherent response to health threats of regional, national or even global significance. Lack of consistency in state public health laws may cause particular problems when responding to air or water pollution, disposal of toxic waste and the rapid spread of infectious diseases such as cholera, West Nile virus, Ebola or pandemic influenza.

Inconsistencies may also develop over time between the laws and policies administered by different ministries or portfolios within the same level of government. This can undermine the coherence of

efforts to improve public health and to reduce risk factors for disease. For example, laws and programmes that provide production subsidies and other forms of economic support for tobacco farmers may encourage domestic production and demand, undermining tobacco control laws and increasing the burden of tobacco-related disease. Similarly, policies to stimulate the production of palm oil, and other oils that are high in saturated fats, may have a negative impact on rates of ischaemic heart disease in countries where these policies result in an increase in consumption, given the association between higher palm oil consumption and mortality from ischaemic heart disease.[7]

In summary, a review of public health legislation governing a particular issue or health challenge should include a review of the problems and limitations of existing laws. It is important to understand the historical context in which existing laws were introduced, and to seek out the views of those who are responsible for administering and enforcing the legislation and performing core public health functions (such as licensing, inspections, investigations, prosecutions and responding to health emergencies). The views of professional groups, patient groups, nongovernmental organizations, development partners and international and regional organizations may also be useful. The following questions may assist in identifying the limitations of existing laws, and in making the case for law reform:

- Do existing laws reflect a modern, evidence-based understanding of the causes of disease, routes of transmission (where relevant), and consequences of illness? Or were they framed in ignorance of modern understandings of the causes of diseases and mechanisms of transmission?

- Are current laws antiquated, redundant, ambiguous or even incoherent? How well do they work in practice? Are there any major gaps, and if so, where are they?

- Do public health laws give government officials a clear mandate to protect and promote the health of the population? Do public health authorities have the specific powers that they need to respond effectively to the health challenges that are the focus of the review?

- Are there inconsistencies between public health laws at local, state, or regional levels, and do these inconsistencies threaten a coordinated and coherent approach? Is a national approach required, or are there benefits in protecting the ability of regional and local governments to regulate in this area?

- Do existing laws take account of the legitimate interests and rights of individuals and groups, impinging on those rights to the minimum extent necessary to achieve their health objectives?

- What changes would be required in order to make current laws consistent with best practices?

3.2 Identifying priorities for public health law reform

The specific areas that are the subject of a formal legislative review or enquiry will usually reflect the health challenges, political priorities and specific experience of each country. National priorities for

law reform will typically be identified by government and will be informed by advice from the health ministry. Professional groups, development partners and the media may also seek to place particular law reform issues on the political agenda (see Section 3.3).

However, it is not always the case that the major health challenges that a country is facing will be high on the political agenda. For example, the impact of disease on poor and marginalized populations may be overlooked. Governments may have erroneous views about the causes of disease, and ignore evidence about the best way to combat it. Governments may simply lack the political will to do what is needed to address public health priorities, such as tobacco or alcohol control, due to concerns about the impact that law reform may have on taxation revenues, or the influence and interference of industry bodies. In some cases, issues such as violence against women, or maternal and child health, may have long been neglected due to power imbalances and other inequalities within society. Governments face many challenges that compete for their attention, and the opportunity to review a country's public health laws may only arise infrequently. When it does arise, it is vital to ensure that law reform priorities are informed by evidence of the burden of disease and the leading health challenges the country is facing.

This section highlights some major risks to health that are shared across nations and regions. Both communicable diseases – such as HIV and pandemic influenza – and noncommunicable diseases – such as cancer, heart disease and diabetes – require urgent attention in many countries. Effective prevention and control of these diseases requires strong legal frameworks.

(a) Communicable diseases

Pandemics of contagious diseases, including novel forms of influenza, pose a powerful threat to global health security, with the potential to overwhelm health systems, and threaten economic growth and stability (**Box 3.2**).

Infectious diseases with pandemic potential

The SARS epidemic in 2003 was an important catalyst for the completion of the revised International Health Regulations (2005),[8] which require States to notify WHO if there is the possibility of a "public health emergency of international concern".[9] H1N1 circled the globe in 2009 and 2010, becoming the first global pandemic of the 21st century.[10] SARS, H1N1, and Middle East respiratory syndrome coronavirus illustrate that pathogens can be transmitted from one species to another, and particularly in the case of SARS and H1N1, spread through casual contact.[11]

Box 3.2: Pandemic influenza: a threat to global health and security

Influenza pandemics have occurred at various points in human history, causing widespread illness, death and social disruption.[12] In 1918, the "Spanish Flu" pandemic resulted in an estimated 20 to 50 million deaths worldwide.[13] The 1957 "Asian Flu" and the 1968 "Hong Kong Flu" pandemics also resulted in significant human and economic harm.[14] As global travel, urbanization and overcrowded living conditions increase, novel influenza viruses are more likely to spread rapidly around the

globe.[15] In 2009, WHO declared the H1N1 influenza pandemic to be a public health emergency of international concern. Although the H1N1 virus is not highly pathogenic, modern epidemiological models predict that a severe pandemic could result in as many as seven million deaths.[16]

Law plays a critical role in preventing and mitigating the health consequences of contagious epidemics, in two distinct ways. Firstly, law establishes the institutional structures and formal processes through which governments respond to disease outbreaks. Secondly, law sets limits for the exercise of coercive power over citizens and businesses in order to mitigate the risk of disease spread. This is discussed further in Chapters 9–11.

HIV/AIDS

HIV infection and HIV-related disease are a critical challenge, both nationally and globally. This is especially true in sub-Saharan Africa, where nearly 5% of adults are infected, and the prevalence of HIV infection is 25 times higher than the next most affected regions, South, South-East and East Asia.[17] Sub-Saharan Africa accounts for 70% of people living with HIV, and over 70% of AIDS-related deaths.[18] Globally, in 2014, nearly 37 million people were living with HIV, nearly half of whom were unaware of their infection. In the same year, 1.2 million people died from AIDS-related diseases, and around 2 million people became newly infected with HIV (a 35% decline from 2000; see further in **Box 3.3**).[19]

Box 3.3: The global impact of HIV infection

Since the HIV epidemic was first recognized in the early 1980s, 39 million people have died.[20] In high-income countries, a person with HIV has a similar life expectancy to someone without HIV; however, this depends on access to antiretroviral medication. The percentage of people with HIV who were not receiving antiretroviral therapy fell from 90% in 2006 to 63% in 2013. By June 2015, 15.8 million people were receiving antiretroviral therapy.[21] Yet globally, this means that around three out of five people living with HIV are still not yet receiving the treatment they need.[22]

At the end of 2013, over US$ 19 billion was being invested, with more than half of this coming from domestic spending.[23] However, despite decades of effort, HIV remains one of the most pressing global health problems, with many marginalized and vulnerable groups excluded due to poverty, legal and social inequalities and harmful gender norms. According to the United Nations Development Programme, HIV "has inflicted the 'single greatest reversal in human development' in modern history".[24] HIV exacerbates health inequalities both within countries and between countries and regions, with socioeconomically disadvantaged communities bearing the brunt of suffering and early death. HIV has serious economic as well as health consequences. HIV primarily affects otherwise young and productive workers, interrupting income-generating activities, exhausting family savings, reducing taxation revenues and interfering with schooling, because families can no longer afford school fees or because children are required to look after sick relatives.[25]

The scale of the HIV pandemic, its capacity to rob countries of young and productive people, and the economic and health inequalities it perpetuates, have spurred a number of international initiatives

to support prevention and treatment. Evidence of global political support ranges from the United Nations General Assembly's Declaration of Commitment on HIV/AIDS in 2001,[26] to the creation of the United States President's Emergency Plan for AIDS Relief,[27] and the Global Fund to Fight AIDS, Tuberculosis and Malaria.[28] The international community has focused on achieving several shared goals, including universal access to comprehensive prevention programmes, treatment, care and support.[29] However, these goals cannot be achieved at the national level without strong government, supported by adequate resources and rational laws to optimize the delivery of comprehensive HIV programmes.

Significant work has been done to assist countries to identify the kinds of laws that are best suited to preventing and controlling the spread of HIV, as well as existing laws that create obstacles to effective treatment and prevention.[30] But major challenges remain. For example, in 2012 the Global Commission on HIV and the Law reported that while 61% of countries reported having laws to protect people living with HIV from discrimination, these laws are "often ignored, laxly enforced, or aggressively flouted".[31] The Commission also pointed out that laws explicitly criminalizing the transmission of HIV, and laws criminalizing key populations, including commercial sex workers, men who have sex with men, and injecting drug users, ignore evidence and undermine efforts to prevent transmission and encourage treatment.[32]

Tuberculosis

Tuberculosis (TB) remains a persistent threat to global health. TB is a contagious, airborne infection, second only to HIV in terms of global mortality from a single infectious agent. In 2014, an estimated 9.6 million people developed TB, including more than 1.1 million new cases among people with HIV.[33] Although mortality from TB has fallen by 47% since 1990, 1.5 million people died from TB in 2014; around 25% of these deaths were in people co-infected with HIV.[34] Although TB can be effectively treated, mortality rates are high in the absence of treatment. This problem is exacerbated by the fact that more than one third of new TB cases each year remain undiagnosed.[35]

In addition to the challenge of improving access to antiretroviral therapy and anti-TB drugs for people who are coinfected with HIV and TB is the escalating crisis of multidrug-resistant TB (MDR-TB), defined as resistance to both rifampicin and isoniazid, two first-line anti-TB drugs. Globally, in 2015, around 3.3% of new TB cases and 20% of previously-treated cases were of MDR-TB.[36] Of these, nearly 10% were estimated to have extensively drug-resistant TB (XDR-TB), due to resistance to second-line drugs.[37] By the end of 2014, 105 countries had reported cases of XDR-TB.[38]

MDR-TB and XDR-TB not only jeopardize progress in TB control, they also illustrate the global importance of strengthening health systems, including universal coverage, and in this case universal access to diagnosis, care and treatment for people with TB and MDR-TB. Progress towards universal coverage requires improvements in diagnostic and surveillance capabilities, and uninterrupted, timely access to quality-assured anti-TB medicines, supported by adequate financing.[39] Bottlenecks to improved management of MDR-TB include weak drug procurement and supply systems, limited laboratory capacity, lack of trained staff and adequate treatment facilities, the absence of secure funding, and problems with programme management.[40] In addition to the role that law plays in strengthening the components of the health system, the global challenge of TB draws attention to

the need for adequate legal powers to encourage treatment adherence by those with TB in ways consistent with the human rights and dignity (see Section 10.3).

(b) Noncommunicable diseases

Noncommunicable diseases (NCDs) – principally cardiovascular disease, cancer, respiratory diseases and diabetes – are responsible for around 68% of global mortality (in 2012, around 38 million deaths).[41] The global transition from communicable to noncommunicable diseases is the result of several factors. These include longer life spans due to the relative success of efforts to address communicable diseases, the growth of risk factors for NCDs within populations, and the promotion of harmful products. Important risk factors for NCDs include tobacco use, harmful use of alcohol, excess saturated fat, salt and sugar in the diet, overweight and obesity, inadequate physical activity and high blood pressure. WHO has estimated that if current trends continue, by 2030 there will be 52 million deaths per year caused by noncommunicable diseases.[42]

Obesity

Obesity is now recognized as a major risk factor for heart disease, cancer and diabetes. Between 1980 and 2013, the global prevalence of overweight and obesity increased by 27.5% for adults and 47.1% for children.[43] In 2014, the age-standardized global prevalence of obesity was nearly 11% in men and nearly 6.5% in women; if current trends persist, by 2025 it will reach 18% in men and more than 21% in women.[44] Although in developed countries rates of overweight and obesity are higher in men than in women, the reverse is true in developing countries.[45] In low- and middle-income countries, the rapid increase in rates of obesity has created a double burden of communicable and noncommunicable diseases, with obesity, micronutrient deficiencies, underweight and stunting seen side by side within communities and even within the same household.[46] In 2014, more than 600 million adults were obese, and more than 1.9 billion were overweight.[47] The number of adults with diabetes has been projected to rise from 382 million to 592 million between 2013 and 2035, with a 108% increase in low-income countries.[48] Childhood obesity has also become a serious concern, given the higher risks that obese children will face in adult life (see **Box 3.4**).

Box 3.4: The epidemic of childhood obesity

In 2013, around 8% of children and adolescents in developing countries were overweight or obese. In developed countries, the rate was around 23%.[49] However, rates of increase of child overweight and obesity are around 30% higher in low- and middle-income countries than in high-income countries.[50] Overweight and obese children are likely to remain obese into adulthood and are more likely to develop NCDs such as diabetes and cardiovascular diseases at a younger age.[51]

To reduce levels of obesity among children, governments need to confront the factors that are rapidly changing the food and physical activity environments in many countries. Governments need to moderate the advertising and promotion of foods and beverages that contain high levels of fat and sugar but lack nutritional value. Fresh produce and healthy food options should be available, accessible and affordable, especially in low-income neighbourhoods. Communities need safe areas where children can play and engage in physical activity, both indoors and outdoors. The

meals children eat at school should be healthy and nutritious. In many countries, efforts to reduce childhood obesity should be integrated with policies for improving food security and preventing undernutrition. In addition to population-wide policies and local community initiatives, governments need to allocate resources in order to monitor NCD risk factors, to plan for workforce needs, to develop guidelines and policy advice, and to support partnerships with professional groups, nongovernmental organizations and other stakeholders.[52]

Cardiovascular disease, cancer and tobacco-related diseases

Cardiovascular disease (CVD) is the leading cause of death worldwide, accounting for 17 million deaths each year.[53] This number is expected to increase to more than 22 million by 2030.[54] Over three quarters of CVD deaths, and nearly 90% of deaths from chronic obstructive pulmonary disease, occur in low- and middle-income countries.[55] Cancers caused by infections – such as human papillomavirus, Helicobacter pylori and hepatitis B and C – also have a disproportionate impact on low- and middle-income countries, accounting for 26% of all cancer cases.[56]

In 2012, cancers were responsible for over 8 million deaths; by 2030, WHO estimates that there will be more than 12 million cancer deaths each year.[57] Tobacco use, lack of physical exercise, obesity, harmful use of alcohol, air pollution, infections and ultraviolet exposure are some of the leading modifiable risk factors. However, tobacco use stands apart in terms of the sheer scale of harm caused by a single, preventable risk factor.[58]

Tobacco is responsible for around 6 million deaths each year and nearly 9% of global mortality, including 71% of global lung cancer deaths.[59] Seventy per cent of these deaths occurred in low- and middle-income countries. Due to population growth and aggressive marketing tactics, tobacco consumption is rising in many low- and middle-income economies. By 2030, tobacco is likely to be responsible for 8 million deaths each year, and 10% of global mortality.[60]

The international community has responded to the epidemic of tobacco deaths with the WHO Framework Convention on Tobacco Control (WHO FCTC).[61] The WHO FCTC commits its Parties to passing national laws that address both demand for, and supply of, tobacco products (see Chapter 13). Implementing and enforcing the obligations contained in the WHO FCTC is not only the first priority for reducing mortality from NCDs, but a sure strategy for extending healthy life expectancy and improving productivity.

WHO's Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020[62] sets out a menu of policy options for the prevention and control of the leading NCDs and their risk factors.[63] Law has a significant role to play in implementing many of these interventions, and in strengthening health systems to treat and manage NCDs effectively (see Chapter 7).[64] At the national level, governance reforms will also be required to facilitate cross-sectoral engagement of relevant ministries to reduce risk factors.[65]

(c) Injuries

Injuries from violence, suicide and accidents – including falls, drowning, burns and poisoning – claim more than 5 million lives each year (9% of global deaths), and leave millions more disabled.[66] Around 90% of fatal accidents occur in low- and middle-income countries.[67] Where injury-related disability affects the head of the household, the impact on family income may lead to reductions in family expenditures on food, education, medical care and to greater vulnerability to illness.[68] While injuries affect all age groups, some groups are more at risk: for those between the ages of 15 and 29 years, three of the top five leading causes of death are injury-related.[69]

WHO classifies injuries into two groups: intentional (or violence-related) injuries and unintentional (accidental) injuries. Each year, over 1.3 million people die from violence, and many more are affected by physical, sexual, reproductive and mental health problems as a result of experiencing and witnessing violence.[70] Violence has a negative impact on national economies, costing billions of dollars each year in health care costs, law enforcement and lost productivity.[71] In the second group, road traffic injuries cause over 1.2 million deaths each year, with a further 20–50 million non-fatal injuries.[72]

There are a number of powerful interventions that could save lives and reduce unintentional injury-related disabilities.[73] These include:

- mandatory use of motorcycle helmets, seat belts, and child restraints;
- physically separating pedestrians from motor vehicles and motor cycles;
- enforcing controls on speed limits and on driving while under the influence of alcohol;
- use of safer stoves for cooking;
- child resistant containers for storing poisons;
- barriers to separate children from water.

These interventions rely on improvements in the local environment, the introduction and enforcement of legislation, public education and improved product safety.[74]

Similarly, interventions are available to reduce intentional injuries from violence and self-harm. Specific legislative measures include increasing excise taxes on alcoholic beverages, amending liquor licensing laws to restrict the time of sale and location of retail alcohol outlets, minimum age purchasing laws and restrictions on the promotion and advertising of alcohol.[75] In countries where gun ownership is lawful, violence and accidental injuries can be reduced by requiring background checks on licence applications for all categories of firearm, by imposing licence restrictions that regulate where it is lawful to possess a firearm, and by banning military-style weapons and other firearms, including automatic and semi-automatic weapons, which have a massive and rapid destructive force. Rates of death and disability from both intentional and unintentional injuries can be reduced by improving the availability and quality of emergency care.

3.3 Who can initiate public health law reform?

With so many global health challenges and priorities, who sets the agenda for public health law reform? In many countries, the health ministry will initiative the process of legislative review. However, legislative review and law reform activities can also originate in other ministries or departments, requiring careful collaboration with the health minister. The prime minister or president, the cabinet or a law reform commission may also be instrumental in public health law reform. The leadership or support of senior ministers and other executives within government can be crucial to ensuring that government and parliamentary resources are made available for the drafting and debating of the proposed changes, the conduct of community consultation, and for ensuring that public health law reform retains its place among the other priorities competing for the government's attention.

Even where a formal proposal for the introduction of a new law has taken place, it may need to be submitted several times before it is accepted within government as a credible option that deserves serious consideration. Advocacy for law reform may need to continue through several parliamentary and budgetary cycles before new laws are successfully passed. Throughout this process, the advocacy and support of senior government officials remains crucial.

Whichever agency provides leadership, it is important for consultation to occur with other agencies and departments that play a role in the implementation or administration of the law. Consultation with other ministries can lead to a better understanding of the obstacles that need to be resolved in order to implement the law successfully. The experience of Papua New Guinea illustrates this point (see **Box 3.5**).

Box 3.5: The development of Papua New Guinea's Provincial Health Authorities Act

Papua New Guinea's experience with the Provincial Health Authorities Act illustrates the importance of intensive consultation during the process of drafting new public health laws. This Act reflected the policy decision, by the National Department of Health, to unify the delivery of public health and hospital services at the provincial level. The effective implementation of the new Act required the Department to alter its arrangements for the payment of budgeted health funds in order to accommodate the newly-created provincial health authorities. Treasury planning and budgeting processes required that the payment of funds from the central government to the provincial government (for health services delivery) be redirected to the provincial health authorities in order to avoid loss of funds to non-health purposes. Since the central budget and financial systems were controlled by the treasury, frequent discussions were required in order to fully explain the new policy, and to gain the understanding and support that was necessary for the modification of the budgetary process and implementation of the legislation. One outcome of this consultation process was that treasury guidelines were amended to make explicit reference to the new provincial health authorities and to the need for funds to be paid directly to them.

Outside government, proposals for the reform of public health laws may be improved by consultation with other major stakeholders, including the health professions, the private sector, civil

society, philanthropic organizations, academia and the media. Government can encourage feedback by publishing discussion papers that set out draft proposals and invite comment.

In some cases, civil society organizations may become directly involved in law reform. A dramatic illustration of this occurred in Brazil during the period of constitutional reform in the latter half of the 1980s, when the text of the constitutional amendments dealing with health was developed by a group of nongovernmental organizations working in the health sector. The text of these popular amendments was adopted, with only minor changes, by the Constituent Assembly and now appears in the Federal Constitution of the Brazilian Republic (1988).[76] These provisions confirm the right to health and recognize a corresponding duty at all levels of government to protect and promote it. They also established a public health system (Sistema Único de Saúde, or "SUS"), financed from the social security budget, with contributions from other levels of government, that encompasses the control of health risks and the "promotion, protection and recovery" of health.[77]

Although stakeholder input can influence the design of new laws, governments should take care to ensure that lobbyists and sectional interests do not undermine the public health goals that they are seeking to achieve. The risk of industry interference has been widely recognized. For example, the guidelines for implementation of the WHO FCTC, adopted by Parties to the Convention, emphasize the importance of resisting the tobacco industry's attempts to influence the development and implementation of tobacco control laws and policies.[78] Other industries, including the alcohol, food and pharmaceutical industries, have a strong commercial interest in influencing laws and policies that affect them. In all cases, policy-makers will need to determine whether, and for what specific purposes, consultation or collaboration is appropriate, bearing in mind the possibility that industry groups may seek to weaken regulation and to undermine the goals that the government is seeking to achieve.

3.4 What factors can act as triggers for public health law reform

(a) Triggers for public health law reform within government

Within government, there will be a variety of political opportunities for prioritizing public health policies and for initiating the process of law reform. These may arise within the context of developing a poverty reduction strategy, a national public health strategy, or reporting to development partners. Disease outbreaks and national public health emergencies may also provide opportunities for advocacy to government by professional and nongovernment organizations, and for leadership by government in the area of public health law reform. Sunset clauses may also require the government to formally consider re-authorizing, extending or reforming current laws.

International instruments can draw attention to particular health challenges arising at the country level and serve as a catalyst for national law reform. Examples include the WHO FCTC,[79] the International Health Regulations (2005),[80] the International Code of Marketing of Breast-milk Substitutes,[81] the set of recommendations on the marketing of foods and non-alcoholic beverages to

children,[82] and the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020.[83] In the case of treaties and regulations, countries have an obligation under international law to implement these instruments by amending their domestic laws and developing their national capabilities.

(b) Community participation as a trigger for public health law reform and policy-making

In some countries, formal mechanisms for community participation in government processes may assist civil society organizations to put health issues on the agenda of government and to participate in law-making. For example, citizen-initiated referenda may allow citizens to petition government on a popular issue. In Brazil, legislation enacted in 1990 establishes the National Health Council as a "permanent collegiate deliberative body" representing government, service providers, health workers and health service users, which participates in the development of health policies and monitors their implementation.[84] At the state and municipal levels, the establishment of health councils is a precondition to the receipt of federal funds from the National Health Fund.[85] By 2008 there were over 5500 municipal health councils in Brazil.[86]

Policy conventions and health congresses provide opportunities for citizens to identify national health priorities, to monitor progress in implementation, and to advocate for law reform. In Brazil, the National Health Conference is required to meet every four years to evaluate the health situation in Brazil and to propose health policy directives.[87] In Thailand, the National Health Act of 2007 formalizes community participation in the formation of health policy through the National Health Assembly (NHA).[88] Topics that are successful in reaching the agenda of the NHA are supported by briefing papers and debated. Although resolutions passed at the NHA are non-binding, they are re-shaped by the National Health Commission for consideration by relevant ministries.

(c) Litigation and public health law reform

Civil society organizations have often turned to the courts as a remedy for injustice and discrimination within the health sector, litigating the absence of tobacco control laws, lack of access to health care services, clean water, sanitation and housing, and adequate food.[89] National constitutions frequently protect individuals from legislative and executive actions that interfere with the civil and political rights of the individual. Some constitutions also recognize social and economic rights and oblige the State to take positive actions to secure these rights for the benefit of the population. This section focuses on legal claims which assert that the fundamental protections contained in a national constitution, a bill or charter of rights, or a ratified international agreement, require governments to alter their policies or practices – in ways that advance the realization of the right to health. In some cases, successful litigation may prove to be the catalyst for the subsequent introduction or amendment of public health laws.

Around two thirds of countries have constitutional provisions recognizing a right to health or health care services.[90] Typically, these provisions require the legislature, the executive and other organs of State to take reasonable measures to secure the enjoyment of the right within the limits of available

resources. For example, in several cases the South African Constitutional Court has ruled that the government has a positive obligation to take reasonable measures to fulfil basic socioeconomic rights, including the right to health care, food and water, and housing or land.[91]

In South Africa, the existence of social and economic rights in the Constitution obliges government to protect these rights not only through legislation, but also through the effective implementation of policies designed to improve public health. For example, when ruling that the Constitution imposes a positive obligation on the government to take action to fulfil the right to housing, the South African Constitutional Court stated that legislation alone – without effective change – would not satisfy this duty.[92] **Box 3.6** presents a case study of litigation whose substantive effect was to require the South African government to implement a national plan of action to provide HIV-positive pregnant women with reasonable access to nevirapine, a drug for preventing the perinatal transmission of HIV from mother to child.

Box 3.6: The right to health and reasonable access to nevirapine in South Africa

In Minister of Health v Treatment Action Campaign (No. 2),[93] a coalition of civil society organizations challenged the decision of the South African Government to impose restrictions on the availability of nevirapine within the public health sector.

WHO recommended nevirapine for the prevention of mother-to-child HIV transmission in January 2001, and the Medicines Control Council formally approved its use in South Africa in April of the same year. As a result, medical practitioners in the private sector became entitled to prescribe nevirapine in appropriate cases. The risk of HIV transmission from a pregnant, HIV-positive woman is substantially reduced through a single dose of nevirapine during pregnancy, and by the administration of a few drops to the baby within 72 hours of delivery. According to government estimates at the time, around 70 000 children became infected with HIV perinatally each year.

Despite the fact that the manufacturers of nevirapine had offered it to the South African Government without charge, for a period of five years, the ability to prescribe nevirapine within the public health system was limited to two sites per province, while research continued for a further period of two years into the safety and efficacy of the drug and the operational challenges of making it more widely available. These included the challenges of making confidential counselling and HIV testing services widely available to pregnant women.

The South African Bill of Rights provides that everyone has the right to access "health care services, including reproductive health care".[94] Every child has the right to "to basic nutrition, shelter, basic health care services and social services".[95] The State is required to use legislative and other measures, to progressively realize these rights, within its available resources.[96]

The South African Supreme Court held that the safety concerns about nevirapine were no more than "hypothetical", and that the cost of nevirapine was not at issue. It held that the government was not justified in restricting the availability of nevirapine to those sites where it could be provided as part of a broader "comprehensive package" of services for preventing mother-to-child transmission and that the restrictions on public sector availability unreasonably excluded women who could not access the chosen sites. The Court said: "To the extent that government limits the supply of nevirapine to its research sites, it is the poor outside the catchment areas of these sites who will suffer".[97]

The Court concluded that the government's "inflexible" policy of limiting the availability of a "potentially lifesaving drug" was in breach of both the right to health care in Article 27 and the rights of children as set out in Article 28. As the Court pointed out, this finding required a change in government policy: "The policy will have to be that nevirapine must be provided where it is medically indicated at those hospitals and clinics within the public sector where facilities exist for testing and counselling".[98]

The orders made by the Court emphasized the positive obligations imposed on the government by the constitutional right to health. These included the delivery, within available resources, of a comprehensive health care programme to progressively realize the rights of pregnant women and their children to services to prevent the transmission of HIV, including reasonable measures for testing and counselling of women to reduce the risk of perinatal transmission.

In Colombia, the Ministry of Social Protection initiated a sweeping reform of its health system – including changes in the coverage of health care services – following a finding by the Constitutional Court that systemic problems within the public health system constituted failure to fulfil the right to health.[99] Other courts have mandated that states reallocate funds to secure access to treatment for all, regardless of expense. Peru and the Bolivarian Republic of Venezuela also adjusted their public health spending following such rulings.[100]

Even in countries where the constitution does not protect the right to health, other constitutional rights may nevertheless provide indirect protection. For example, although there is no right to health in the Indian Constitution, the Supreme Court has interpreted the constitutional right to life (Article 21) to impose a duty on the government to safeguard life, which extends to providing for emergency health care services.[101]

In Murli Deora v Union of India,[102] the Supreme Court of India held that smoking in public violates the right to protection of life and personal liberty contained in the Constitution. It issued an order requiring the federal and state governments to ensure implementation of the prohibition on smoking in a number of public settings. These restrictions were included in subsequent national tobacco control legislation, passed in 2003 (**Box 3.7**).

Box 3.7: Protection from exposure to second-hand smoke through the constitutional right to life and to personal liberty in the Indian Constitution

Part III of the Constitution of India sets out a number of fundamental rights and liberties, including Article 21, which states: "No person shall be deprived of his life or personal liberty except according to procedure established by law". Under Article 32 of the Constitution, individuals may petition the Supreme Court to enforce these rights, and the Supreme Court may issue appropriate orders.

In Murli S. Deora v Union of India,[103] the petitioner relied on Article 21 of the Constitution to seek an order protecting non-smokers from harm caused by exposure to tobacco smoke in public places. At the time the case was heard, India's federal Tobacco Act contained no restrictions on smoking in public places, although a bill had been introduced into Parliament and was awaiting consideration by a Select Committee. The Attorney-General of India and counsel for the various states agreed that it

was in the interests of citizens for the Court to make an order protecting citizens from environmental tobacco smoke until the federal Act could be amended.

Referring to the rights guaranteed under Article 21, the Court asked why a non-smoker should be threatened with fatal diseases, including cancer or heart disease, as a result of exposure to tobacco smoke in public: "Is it not indirectly depriving [a person] of his life without any process of law? The answer is obviously – 'yes'."[104]

After considering the effect of smoking on both smokers and non-smokers, the Court issued an order prohibiting smoking in public places and requiring federal and state governments to "take effective steps to ensure [the prohibition of] smoking" in "auditoriums, hospital buildings, health institutions, educational institutions, libraries and court buildings, and public conveyances including railways".[105]

The effect of this order was to give constitutional protection against exposure to second-hand smoke in public places in India. In 2003, the Parliament of India passed the Cigarettes and Other Tobacco Products Act, which prohibits smoking in a "public place", defined to include the places identified in the order of the Supreme Court.[106]

Similarly, in 2001, a public interest applicant, the Environmental Action Network, sought a declaration in the High Court of Uganda that public smoking violated a number of constitutional rights including the right to life (Article 22) and the right to a healthy and clean environment (Article 39). In one of several judgments relating to this application, Justice Ntabgoba commented that "unregulated smoking in public places constitutes a violation of the rights of non-smoking members of the public", depriving them of a clean and healthy environment.[107] As a result of this litigation,[108] the National Environment Management Authority issued regulations in 2004 banning smoking in a range of public places.[109]

Cases like this illustrate that litigants, and public health organizations, can be powerful agents for change. The history, and legal and constitutional context of each country is unique. It follows that stakeholders will need to identify allies, and to consider how the available political, legal and constitutional processes might be used most effectively to build momentum towards the improvement of public health policies and the introduction of effective public health laws. The environment for reform is likely to be most favourable where deficiencies in a country's public health laws have been recognized and demonstrated, where law reform proposals have been identified and discussed with major stakeholders, and where political champions are ready and able to take the issue forward.[110] Civil society organizations and the media play a vital role throughout the public health law reform process.

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Chapter 4: Building blocks for effective public health laws

SUMMARY POINTS

- **Public health legislation should clearly set out the mandate, powers and responsibilities of the government and of public health officials. This not only ensures that public health officials have the powers they need; it also helps to ensure that governments remain accountable for the discharge of their statutory duties and functions.**
- **The responsibilities of regional, local and city councils should be explicitly set out in legislation. However, countries that have devolved public health functions to regional and local levels should ensure that national coordination is not jeopardized, and that the availability, accessibility and quality of public health services is not thereby compromised.**
- **Public health legislation should establish clear mechanisms for coordinating the activities of different levels of government during public health emergencies.**
- **Governments may consider imposing a general duty on persons not to create a serious risk to public health (as defined), and a general power that permits the minister or chief health officer to take action and to make such orders as are reasonable and necessary to deal with a risk to public health. However, except in cases of genuine emergency, legislation should authorize the courts to review the exercise of executive powers.**
- **Governments have an obligation to frame public health laws in ways that are consistent with human rights obligations. In some countries, a human rights commission or equivalent body can investigate complaints of discrimination occurring on the basis of protected attributes set out in legislation. These protected grounds may include sex, religious belief, colour, race or ethnic origins, disability, age, political opinions and marital or family status.**
- **Governments should seek to ensure coherence between public health laws and criminal laws. For example, criminal penalties for the transmission of HIV may have unintended effects, discouraging women from being tested or from having their babies tested for fear of prosecution.**

Introduction

This chapter considers some building blocks for good public health laws that may assist law reformers as they design legislation and implement the recommendations of a legislative review process. Effective legislation must be built on a solid understanding of the specific legal powers and safeguards that are needed in order to respond effectively to the situation at hand. Where they exist, model laws may provide helpful guidance. However, law reform is a country-owned process that will reflect the legal history, legal and constitutional structure and political context of each country. As a result, the legal mechanisms used to implement law reform recommendations may vary considerably, even between countries that share a similar culture, language and geography.

4.1 Legislative goals, mandates and principles

The public health functions of government cover a wide range of activities (**Table 4.1**). In considering public health law reform, governments need to consider the way in which these functions can best be supported by legislation. It is important for public health laws to explicitly set out the mandate, powers and responsibilities of government, and of public health officials. This not only ensures that health ministries and public health officials have the powers they need, but also helps to ensure that they remain accountable for the discharge of their statutory duties and functions. It also ensures that health ministries do not overlook critical functions or responsibilities or adopt an unduly narrow definition of public health.

Table 4.1: The core public health functions of government

Generating evidence for action	**Surveillance and monitoring** of the health status of the population, and of health risks.
Taking action	**Public health protection and assurance**, including through the performance of regulatory functions and the discharge of legislative responsibilities relating to the investigation of health risks and the prevention of disease and injury.
Taking action	**Health promotion**, including education and partnerships to support community-based health programmes and to empower individuals to live healthy lives.
Financing	**Financing of public health interventions**, including financing essential medicines and technologies and health care services.
Training	**Training and capacity-building,** including accreditation and renewal of the public health workforce.
Supporting research	**Research and evaluation,** including funding research and developing research capacity.

There is no single way of expressing the goals and objects of public health legislation, since these goals will reflect the specific needs of each country and the distribution of powers and responsibilities between ministries and levels of government. In the Australian state of Victoria, the Public Health and Wellbeing Act 2008 states that the objective of the Act is: "to achieve the highest attainable standard of public health and wellbeing by:

(a) protecting public health and preventing disease, illness, injury, disability or premature death;

(b) promoting conditions in which people can be healthy;

(c) reducing inequalities in the state of public health and wellbeing".[1]

This legislative mandate encompasses three important themes. Firstly, governments have a duty to protect and promote the health of the population as a whole. This duty extends to those who, for

example, live in remote parts of the country, or who cannot afford to pay for services. Secondly, governments have a duty to work to reduce health inequalities. This means giving special attention to the health needs of the disadvantaged and vulnerable: those people whose health needs might be forgotten if government focused only on improving the average level of health. Both of these ideas are encompassed by the obligation of governments to ensure that health facilities, goods and services are accessible – economically, physically and without discrimination – to all members of the population.[2] Thirdly, by recognizing the goal of promoting the conditions for healthy living, the legislation recognizes the concept of sustainability, understood here to mean that people should possess the resources that enable them to lead a healthy life, now and into the future. Sustainability also has an important intergenerational dimension: governments have a duty to develop policies to protect the health of future generations from emerging threats, such as the health consequences of climate change.[3]

The legislative goals set out in South Africa's National Health Act (see **Box 1.5** in Section 1.2) provide another example. This Act establishes a national health system with the goal of providing equitable access to the "best possible health services that available resources can afford".[4] In view of the enormous and persistent health inequalities suffered by large parts of the population as a result of the policies of apartheid, the Act draws attention to the goal of providing "uniformity in respect of health services across the nation". The Act acknowledges that the achievement of this goal is assisted by the obligation of the State to protect, respect, promote and fulfil key constitutional rights affecting health. These include the right to health care services, including reproductive health care, an environment that does not harm health or well-being, and basic nutrition for children. The Act gives powerful expression to the need for government to protect vulnerable groups, including women, children, the elderly and those with disabilities.

In some countries, public health legislation includes statutory principles that are intended to provide guidance to those who administer the legislation. For example, Victoria's Public Health and Wellbeing Act, discussed above, provides that decisions about public health interventions, and the use of resources to promote and protect public health, should be evidence-based. However, when faced with a serious public health threat, "lack of full scientific certainty should not be used as a reason for postponing measures to prevent or control the public health risk".[5] Balancing the need to act on the basis of evidence with the need to prevent significant threats to public health is an important function of government. In order to ensure accountability, members of the public should have access to reliable information about risks to public health and the opportunity to participate in the development of policies and programmes.

4.2 Powers and responsibilities of the health ministry, and coordination with other agencies

Public health legislation should clearly state the functions and responsibilities of the relevant Minister. In many countries, these Ministerial or departmental functions are exercised through a duly appointed chief health officer (or equivalent). The chief health officer's functions will usually include advising the Minister, and ensuring compliance with public health legislation. These functions may

also include the preparation of public health plans, proposals for improving services and submitting periodic reports to the Minister on the state of public health within the jurisdiction.

The factors that influence health, both positively and negatively, are complex, ranging across a number of sectors and – as a result – government agencies and ministries. For this reason, an effective response to a particular risk or health challenge may require the carefully coordinated exercise of statutory powers by a number of agencies – often referred to as an "all-of-government" approach. For example, while many countries will have an agency or department that regulates tobacco products, misleading and deceptive claims about the health impact of particular products may be more appropriately dealt with by the agency that regulates consumer affairs and business conduct, rather than a health agency. Legislation can facilitate intersectoral and interdepartmental responses to health risks in a variety of ways. For example, public health legislation may explicitly authorize the chief health officer or health ministry to seek the assistance and collaboration of other government agencies in responding to a specific issue.

Regional, municipal, local and city councils play an important role in public health administration, by enforcing legislation within local government boundaries, and by contracting for or ensuring the direct provision of core public health services, such as immunizations, postnatal health checks of mothers and children, and the removal of waste and rubbish. The responsibilities of local government and of local public health officials should be explicitly stated in the legislation. Legislation may require local councils to prepare public health plans, and to report on their progress in meeting local area objectives.[6]

Subject to local circumstances, the delegation of public health functions to the local level may create the risk that these functions will not be performed, a risk which may be exacerbated by lack of resources. To minimize this risk, legislation may set out a process for local councils to cooperate jointly in a broader regional response to public health risks, for a council to transfer its functions to the chief health officer, or for the minister to direct the chief health officer to perform the functions that a local council has failed to perform. Countries that have devolved key public health functions to the local level should ensure that the capacity and obligation of the national government to ensure the availability, accessibility and quality of public health services is not thereby compromised (see Section 1.2).

Coordination is critical during public health emergencies. For example, coordination may be required between different levels of government (national, state, local, and city governments), and between agencies and ministries with specialized responsibilities in the areas of customs, border control, passenger surveillance, human quarantine, contact tracing, travel advisories and the reporting of notifiable and quarantinable diseases. At the global level, the International Health Regulations (2005) require countries to designate a National Focal Point for coordinating the flow of information between WHO and relevant parts of the government of each country.[7] At the national level, law reformers may consider a formal legislative mechanism for ensuring coordination between relevant national, regional, local and city administrations. Formal intergovernmental agreements may also achieve the same result.

4.3 Legal tools and strategies for discharging public health responsibilities

Government officials and other stakeholders engaged in the revision of public health laws need to approach the process of implementing law reform recommendations with a good working knowledge of the variety of legal strategies that the law makes available. The wide range of matters regulated in public health statutes can be understood in terms of these basic strategies, which are summarized in **Table 4.2** and discussed in detail below.

Table 4.2: Some important strategies and targets for public health law[8]

Public health infrastructure and governance structures: A government can use law to establish agencies with legal mandates, and to establish the infrastructure, processes and capabilities that enable the government to discharge its public health functions.
Economic policies: Governments have the power to impose taxes and to spend taxation revenues on funding or subsidizing the provision of health-related goods and services (e.g. health care services, immunizations and subsidized pharmaceuticals). Governments can make grants, offer subsidies and create economic incentives and disincentives to encourage healthier behaviours, choices and purchases.
The informational environment: Governments can use law to shape the informational environment in order to encourage healthier behaviours, to inform consumer choices, to protect the population from misleading and deceptive communications and to moderate exposure to the commercial marketing of unhealthy products. The mandatory collection of information by governments creates information assets that can inform the allocation of resources and ensure a timely response to health risks, including during public health emergencies.
Regulation of businesses, professionals and individuals: Governments can mitigate risks to health by imposing specific technical requirements, and performance standards on businesses, employers and providers of goods and services.
Environmental policies: Law is a powerful tool for improving the environments in which people live, work, eat and play. Governments can use law to mitigate risks to health in the natural environment (in relation to water, air and soil, natural disasters), while shaping the built environment in ways that minimize risks to health and encourage healthy behaviours.
Health inequalities: In considering the use of law in each of the areas noted above, governments have a responsibility to ensure that there is equality of opportunity in access to health services and to other resources that are needed to live a healthy life.
Indirect regulation through the tort system: While government is the key actor in protecting public health, national constitutions and legal systems may also permit individuals to vindicate private rights in ways that benefit the health of the public.

The basic strategies listed in Table 4.2 are described in more detail below.

Public health infrastructure and governance structures

As discussed above, public health law reform begins by establishing the public health infrastructure: setting out the legal mandate of the Minister of Health, and of key public health officials. Legislation supports the administration of the public health system by creating the structures and pathways for communication and coordination between ministries, and between different levels of government.

Economic policies

Secondly, governments can use economic policies in a variety of ways to support public health and the costs of public health administration. For example, governments can impose excise taxes in order to suppress demand for tobacco and for other products whose consumption may carry health risks, such as alcohol and sugar-sweetened beverages. It can impose licensing fees on food establishments in order to offset the costs of performing food safety inspections and other health-related functions.[9] Compliance with legal requirements that prohibit certain kinds of conduct (e.g. dumping toxic waste, polluting a waterway or selling tobacco to children) is often encouraged through the imposition of fines and other penalties. Governments can make grants to lower levels of government to support public health programmes and the delivery of services. These grants may be subject to conditions that recipients must meet, including the provision of matching funds.[10] For example, in the United States, as a condition for receiving federal grants for mental health and substance abuse programmes, the federal government imposed a legislative condition requiring the states to pass laws prohibiting the sale of tobacco products to children.[11] Conditional grants are an important strategy that national governments can use to encourage regional and local governments to discharge their public health obligations.

The informational environment

Thirdly, good information is a foundation for healthy policies and behaviours. Governments have a role in educating the public about health risks, and encouraging healthy behaviours. For example, governments can influence the informational environment through the regulation of food labelling, or by requiring the provision of warnings to consumers about the risks of particular products (e.g. tobacco), or activities (e.g. use of sunbeds).[12] The provision of information by government to support individuals to make informed choices about their health forms part of the obligation of governments to fulfil the right to health.[13] Subject to constitutional considerations, governments can also restrict the advertising of certain goods, including tobacco and alcohol.[14]

Regulation of businesses, professionals, and individuals

Fourthly, governments can regulate businesses and other providers of goods and services in order to mitigate risks to health (e.g. through occupational health and safety standards, emission standards, manufacturing standards, regulations on working conditions and other controls on manufacturers

and retailers).[15] Conventionally, statutory regulation takes the form of technical requirements that are identified and described by the State, and set out in legislation, regulations or codes of practice. However, legislation may also require businesses to meet specific targets and performance standards, while permitting a degree of flexibility in how these will be achieved. This may create incentives for businesses to innovate and find new ways of reducing pollution, improving the nutritional quality of food, or reducing risks associated with their products.

Environmental policies

The capacity to lead a healthy life is powerfully influenced by the physical environment, which encompasses both the natural and the built environment. Public health regulation has long recognized that the quality of the natural environment has direct impacts on health, whether through contaminated air, water or soil or through the health consequences of natural disasters. Governments can use law to shape the built environment in ways that reduce health risks and encourage healthy behaviours, for example by improving access to healthy food, improving safety and security in urban areas, and creating safe, well-lit open spaces that facilitate physical activity.[16]

Health inequalities

In order to discharge their responsibility to provide "equality of opportunity for people to enjoy the highest attainable level of health",[17] governments must address the socioeconomic factors that contribute to health inequalities. Law is a powerful tool for ensuring that the poor and vulnerable are not deprived of access to health care services and other resources for leading a healthy life. The context of government interventions in this area is likely to vary significantly from country to country, and to cover a wide range of economic and regulatory interventions. Examples include: government-subsidized school lunches and breakfasts for the children of low-income families, the subsidized provision of pharmaceuticals to aid smoking cessation, the provision of long-lasting insecticide-treated mosquito nets to high-burden areas (see Section 8.2), and cash transfers to alleviate poverty and stimulate economic growth.[18]

One way that legislation can help to reduce health inequalities is by recognizing the right of individuals to challenge policies and actions that undermine the freedoms and entitlements that comprise the right to health. **Box 4.1** draws on the conclusions of a study of constitutional provisions recognizing the right to health in east and southern Africa, and illustrates the variety of forms that these provisions take.[19] Legislative recognition of the entitlement of everyone to a basic system of health protection (encompassing health care services, vaccination and essential medicines) is likely to increase pressures for these entitlements to be realized, through effective planning and resource allocation by governments. It can also provide the basis for more effective advocacy by civil society organizations, and litigation to challenge denial of these rights.

Box 4.1: Legal recognition of the right to health and to other health-related rights: some best practice examples from eastern and southern Africa

Constitution of the Republic of Mozambique, Article 116: non-discriminatory access to health facilities[20]

1. Medical and health care for citizens shall be organized through a national health system, which shall benefit all Mozambican people.

2. To achieve the goals of the national health system, the law shall establish the ways in which medical and health care is delivered.

3. The State shall encourage citizens and institutions to participate in raising the standard of health in the community.

4. The State shall promote the expansion of medical and health care and the equal access of all citizens to the enjoyment of this right...

Constitution of the Republic of South Africa, Section 27: the right to health care, food, water and social protection[21]

1. Everyone has the right to have access to

a. health care services, including reproductive health care;

b. sufficient food and water; and

c. Social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.

2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.

3. No one may be refused emergency medical treatment.

Constitution of the Republic of Uganda: national objectives and directive principles of State policy[22]

XIV. General social and economic objectives

The State shall endeavour to fulfil the fundamental rights of all Ugandans to social justice and economic development and shall, in particular, ensure that-

…

(ii) all Ugandans enjoy rights and opportunities and access to education, health services, clean and safe water, work, decent shelter, adequate clothing, food security and pension and retirement benefits.

XXII: Food security and nutrition

The State shall:

(a) take appropriate steps to encourage people to grow and store adequate food;

(b) establish national food reserves; and

(c) encourage and promote proper nutrition through mass education and other appropriate means in order to build a healthy State.

Indirect regulation through the tort system

Although the strategies discussed above are principally legislative, governments can also promote the health of the population indirectly by ensuring that individuals who have suffered harm can access the courts and pursue private remedies. Successful claims for compensation, injunctions, declarations and other remedies can create pressure on businesses, employers and others to change their products and practices in ways that reduce health risks. In addition, supporting the capacity of individuals and groups to pursue public interest litigation, and to make effective use of the health-related rights set out in national constitutions, is an important strategy for advancing the right to health.[23] The capacity for public interest litigation to serve as a trigger for public health law reform was discussed in Section 3.4(c).

Governments can also promote public health by properly resourcing an independent agency to protect consumers from harmful, deceptive and manipulative claims and practices that create risks to health. Consumer protection agencies have a unique mandate to protect the public interest by preventing businesses from exploiting the vulnerability and trust of consumers. For example, without regulation, tobacco companies may advertise that "light" or "mild" cigarettes are less harmful than others, pharmaceutical companies may advertise the health benefits of untested or harmful compounds, and food businesses may undermine breastfeeding by making claims about the benefits or superiority of breast-milk substitutes. [24]

4.4 Building flexibility into public health laws

Knowledge and understanding of the determinants of health and disease have evolved rapidly over the past few decades. New risks and hazards continue to emerge and the predominant causes of death and disability are also changing at the country level. These factors support the need for flexibility in the operation of legal powers to enhance the law's capacity to respond to new and emerging health risks. For example, by framing legal powers in generic terms, and by permitting the health ministry to add new diseases or risks through subsidiary regulations or executive orders, lawmakers can dramatically reduce the time involved in responding to new threats (**Box 4.2**).

Box 4.2: Building flexibility into public health legislation

The threats and risks to public health that require regulation are likely to evolve over time. Legislatures have developed a wide variety of statutory mechanisms for building flexibility into public health laws. Examples include:

- **Communicable diseases:** Despite some exceptions (e.g. HIV), it will usually be impractical to enact new laws that are designed specifically to meet each new disease or threat. Typically, communicable diseases are regulated through generic provisions in public health laws. These provisions may impose reporting requirements, and new diseases or threats can be declared by executive order to be "notifiable diseases" as soon as there is an adequate case definition. Similarly, an emerging, highly transmissible disease may be declared to be a "quarantinable disease" under legislation dealing with public health emergencies, thus triggering a range of additional powers.

- **Noncommunicable diseases:** In British Columbia (Canada), the Public Health Act (2008) provides that a "condition, thing or activity" that causes or is associated with a "health impediment" may be prescribed and thereafter regulated in regulations. The concept of a health impediment refers to something that adversely affects public health over a period of time, that causes "significant chronic disease or disability in the population", or that interferes with public health initiatives for the prevention of chronic disease and disability. British Columbia has used this legislative mechanism to prescribe transfats as a health impediment, and thereafter to impose limits on transfats originating from partially hydrogenated vegetable oil and margarine within food service establishments. This mechanism has also been used to authorize the screening of children for vision and hearing impairments, and tooth and gum decay, with test results being communicated to parents.

- **Power to regulate "public health risk activities" and "public health risk procedures"**: In the Australian Capital Territory, the Public Health Act (1997) gives the Minister of Health the power to declare an activity (or a procedure forming part of that activity) that may result in disease transmission or harm to health as a "public health risk activity". Thereafter, the Minister can impose licensing conditions on that activity. An "improvement notice" can be issued to a person carrying on a public health risk activity or performing a public health risk procedure. A "prohibition notice" can also be issued. This mechanism has been used to regulate water utilities and businesses performing skin penetration procedures, including tattooing and body piercing. The same Act contains powers allowing the Minister to issue Codes of Conduct for the performance of particular activities. Codes issued by the Minister must be put before Parliament in the same way as other regulations made under the Act.

Flexibility is an important attribute in public health legislation because it preserves the capacity for judgments to be made by public health officials about whether or not a regulatory response is necessary or appropriate in the circumstances. At the international level, the International Health Regulations (2005) preserve flexibility by requiring countries to respond to any "public health emergencies of international concern", rather than only to specific diseases.[25] In order to determine whether an event may constitute a public health emergency of international concern, within their territories, countries apply an algorithm that requires consideration of whether the outbreak is serious, unexpected and carries significant risk of international spread, and whether there is a significant risk of international restrictions to travel and trade as a result. Within countries, legislation can preserve flexibility by authorizing public health officials to exercise powers that are triggered by the assessment, on reasonable grounds, that a particular outbreak, event or occurrence creates a serious risk to public health.

Flexibility is also important because of the difficulty of predicting emerging health risks or even providing a comprehensive list of current ones. This explains why public health statutes may also contain a general duty not to create a "significant risk" or a "serious risk" to public health (as defined).[26] Legislation may also contain a general power that permits the Minister to take action and to make orders that are reasonable and necessary to deal with a risk to public health. Legislation should clearly define the conditions that must be met before such powers are exercised, and, wherever feasible, authorize the courts to review the exercise of executive powers.

4.5 Integrating human rights protections into public health law

The process of reforming public health laws provides an important opportunity for lawmakers to integrate human rights safeguards into health legislation. Human rights encompass both civil and political rights, such as non-discrimination and privacy, as well as the right to health itself and other social and economic rights (see **Box 1.2** in Section 1.1). While human rights have inherent value, they also have an important instrumental value within public health legislation.

The right to health, as recognized in international law, provides a foundation for development. General Comment 14,[27] discussed in Section 1.1, frames the right to health in terms of the "facilities, goods, services and conditions" that are necessary to realize the highest attainable standard of health.[28] In addition to non-discriminatory access to appropriate health care services, the right to health encompasses rights to a range of underlying determinants of health. These include: access to safe water, an adequate supply of uncontaminated food, adequate sanitation and housing, healthy working conditions and a healthy environment, as well as access to health-related education, including on sexual and reproductive health.[29]

Viewing the public health law reform process through the lens of a country's obligation to progressively realize the right to health carries some important benefits. For example, it ensures that States do not define their responsibilities too narrowly; it also draws attention to the broader social determinants of health and to the importance of considering the health impacts of policies and laws across many sectors of government.[30]

Self-evidently, the violation of human rights (e.g. slavery, torture, violence against women and children, hazardous working conditions, and the maiming and disfigurement of the body) can lead to lifelong ill-health. Failure to protect the human rights of vulnerable groups can also lead to ill-health as a result of the denial or discriminatory provision of services and resources. This is a particular problem for marginalized groups who experience deprivation as a result of absent or inadequate access to basic infrastructure, including water, electricity, adequate sanitation, transport, housing and health care (see Section 1.1). Human rights violations can also harm health in more indirect ways. For example, children deprived of education are less likely to acquire the knowledge and skills that are necessary to lead a healthy lifestyle and to make healthy choices. Discrimination against marginalized groups can affect mental health and well-being, leading to harmful lifestyles, violence and self-harm.

Discrimination against women and children is an important area for countries to address, given the health inequalities that women and children can suffer because of discrimination based on their sex or age. The Convention on the Elimination of All Forms of Discrimination against Women targets discrimination in services affecting women.[31] In particular, Article 12(1) recognizes that States must "take measures … to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning".[32]

The Convention on the Rights of the Child also highlights the importance of protecting children from discrimination.[33] Article 2.1 requires States to respect the protections set out in the Convention,

without reference to the "race, colour, sex, language, religion, political or other opinion, national, ethnic or social origin, property, disability, birth or other status" of the child or of his/her parents or legal guardians. The Convention recognizes the right of children to the "enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health"[34] (**Box 4.3**).

Box 4.3: The right to health for children

International recognition: Article 24 of the Convention on the Rights of the Child requires States Parties to implement the right of the child to the highest attainable standard of health by taking appropriate measures, including the following:

(a) to diminish infant and child mortality;

(b) to provide medical assistance and health care to all children, with an emphasis on primary health care;

(c) to combat disease and malnutrition, including through the provision of adequate nutritious food and clean drinking water;

(d) to provide prenatal and postnatal health care for mothers;

(e) to ensure that parents and children can access education and are supported in their use of knowledge about child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation, and accident prevention;

(f) to develop preventive health care, guidance for parents and family planning education and services.

National recognition: Many countries recognize the rights of children in their national Constitutions. For example, the Constitution of Brazil states that:

"It is the duty of the family, the society and the State to ensure children and adolescents, with absolute priority, the right to life, health, nourishment, education, leisure, professional training, culture, dignity, respect, freedom and family and community life, as well as to guard them from all forms of negligence, discrimination, exploitation, violence, cruelty and oppression".[35]

Significantly, Article 227 also recommends that the State allocate a percentage of its public health care funds to mother and child assistance.

Public health legislation can and should protect individuals from discrimination, and ensure fair access to health services for everyone. However, the precise legal mechanisms for achieving protection from discrimination, and for vindicating human rights protections, may vary between countries. For example, discrimination on the basis of a person's health status may be prohibited in disability rights legislation, health legislation, a principal act or statute, or subsidiary legislation. In some countries, specific anti-discrimination laws provide a complaints mechanism for individuals who have been subjected to direct or indirect discrimination on a range of prohibited grounds. For example, under New Zealand's Human Rights Act, the Human Rights Commission hears complaints of discrimination in a range of areas including: employment, the provision of goods and services (including health care services), access to education, housing and accommodation, and by

professional associations and vocational training bodies. The Act provides protection from discrimination on the basis of a range of protected attributes, including a person's sex, marital status, religious or ethical belief, colour, race or ethnic origins, disability (including physical illness or impairment, psychiatric illness, and intellectual impairment), age, political opinions and family status.

In some countries (or parts of countries), individuals and groups can appeal directly to the courts to vindicate their constitutional rights. For example, in Colombia, the Constitution provides for the protection of specific groups, including women and newborn children,[36] and enables an individual to petition any judge to protect his or her constitutional rights using a special writ known as a tutela. All such decisions are referred to the Constitutional Court, which can review them at its discretion. In one case initiated under this process, the Court recognized a woman's right to equal opportunity in the workforce, holding that dismissal from employment of a pregnant or lactating woman without cause amounts to a violation of the human right to dignity and self-fulfilment.[37] In another case, the Court held that the State owes pregnant or lactating women special protection in terms of job security, particularly women who are the head of a household. The Court declared that the termination of employment during pregnancy or within three months of birth creates a presumption of gender discrimination, placing the burden of proof on the employer if a tutela is filed.[38] The Constitutional Court has also recognized a duty to provide special protection to women affected by forced displacement or civil war.[39]

4.6 Creating coherence between public health laws and other laws

The process of reforming public health laws and implementing the recommendations of a legislative review does not occur in a vacuum, but should include an assessment of the extent to which existing laws are consistent with public health goals. In addition to gaps, there may be inconsistencies in a country's public health laws, and even contradictory approaches to reducing risks from disease and injuries.

One area where inconsistencies may arise is between public health laws and criminal laws. The poor health of vulnerable populations and minorities, including undocumented migrants, men who have sex with men, drug users and sex workers, can be exacerbated by criminal laws that create barriers to the effective delivery of health services. For example, the Global Commission on HIV and the Law has warned that specific criminal offences for the transmission of HIV, and laws imposing compulsory HIV testing and disclosure of HIV status, can be counterproductive.[40] In addition to entrenching stigma and discrimination against people living with HIV, individuals who fear criminal penalties may be less likely to seek testing, to access counselling services or to disclose their HIV status to partners (see Section 10.2(c)). Similarly, criminal penalties for transmission may dissuade pregnant women and mothers from undergoing testing, while leaving them little choice but to continue breastfeeding where breast milk substitutes and clean water are not available.[41]

Inconsistencies may also arise with laws affecting children. For example, laws that prevent persons under 18 years of age from accessing advice about contraception have been described as a manifestation of discrimination on the grounds of both age, and sex:[42] their practical effect may be to

expose young people to sexually transmitted infections and unwanted pregnancies. Laws restricting the availability of abortion may force women to seek unsafe methods for terminating a pregnancy, leading to serious injury or death.[43]

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Chapter 5: Good governance in the process of public health law reform

SUMMARY POINTS

- **To maximize the success and legitimacy of the public health law reform process, countries should integrate the following six principles into the law reform process: stewardship, transparency, participation, fairness, accountability and following the rule of law.**
- **Like other forms of corruption in the health sector, corruption in the development and implementation of public health laws threatens progress towards national health goals. Civil society organizations and an independent media play important roles when powerful industries or other vested interests seek to weaken legislation or to subvert the will of Parliament through the corruption of public officials who are charged with enforcing legislation.**

Previous chapters in this Part of the report considered some of the issues that may arise for governments as they review their public health laws, and following review, as they seek to implement recommendations for law reform. This section emphasizes the importance of good governance throughout the law reform process. "Governance" can be understood to refer both to the capacity of a government to develop and implement policies, and to the ways in which power is exercised for the purposes of managing a country's economic and social resources.[1] "Good governance" refers to governance processes that reflect the values and principles that will contribute most effectively to economic and social development, including the progressive realization of the right to health. The World Bank has pointed out that:

Good governance is epitomized by predictable, open and enlightened decision-making (that is, transparent processes); a bureaucracy imbued with a professional ethos; an executive arm of government accountable for its actions; and a strong civil society participating in public affairs; all behaving under the rule of law.[2]

Good governance maximizes the capacity of States to develop and implement policies for the public's benefit, to manage resources in a prudent manner, and to provide services efficiently and effectively.[3] Understood in this way, the "good" in governance refers to those distinctive features that characterize how governments formulate and implement policies, rather than the content of policies themselves.

5.1 Public health law reform, good governance and human rights

Good governance is essential to a successful law reform process. Like any other policy process, the process of public health law reform may be inappropriately influenced by those pursuing their own economic or political interests. Attempts to undermine public health law may take the form of

lobbying efforts and other attempts to influence the content of the law or to undermine its implementation and enforcement. By ensuring transparency, and by providing opportunities for community participation, governments can improve the quality of the information available to lawmakers while also protecting the process from attempts to undermine the public good.

Within the context of public health law reform, there are close connections between the principles of good governance and human rights. For example, ensuring the participation of those who are affected by public health laws is both an important principle of good governance[4] and a well-recognized dimension of the right to health.[5] Similarly, the principle of fairness, if honoured in the law reform process, will help to ensure that law does not legitimate the discriminatory treatment or exclusion of individuals or vulnerable groups, in violation of the right to health. The process of reforming a country's public health laws also illustrates the obligation of States to fulfil the right to health.[6] Without good governance, however, the State cannot discharge its obligation to respect, protect or fulfil that right in a systematic and sustainable manner.[7]

5.2 Good governance and corruption

In some cases, the process of developing, passing, implementing or enforcing the law will be vulnerable to corruption. Like other forms of corruption in the health sector, corruption in the process of public health law reform threatens progress towards national health goals (see **Box 5.1**). Civil society organizations and an independent media can play an important role when powerful industries or other vested interests seek to weaken legislation, or to subvert the will of parliament through the corruption of public officials who are charged with enforcing legislation. For example, by investigating and documenting corruption, and publicizing the findings, civil society organizations may be able to generate the necessary political pressure for an independent investigation into inappropriate actions or activities. Similarly, by publicizing the results of investigations and keeping the issue of corruption before the public, media organizations can help to keep governments accountable and generate political pressure for police or prosecutors to investigate corruption and take action against corrupt officials.

Box 5.1: Good governance and corruption in the health sector

Generally, corruption can be understood as "the abuse of entrusted public power for private benefit".[8] The principles of good governance help to strengthen the law reform process against corruption and other failures by governments or government officials to faithfully serve the public interest. Whereas the attributes of good governance are stewardship, transparency, participation, fairness, accountability, and adherence to the rule of law, "corrupt governance fails to offer citizens adequate and accurate information about government and policies, curtails the public's opportunities for participation, violates the public's right to be informed about government activities and procedures, and compromises the right to political participation. Thus, corruption weakens the accountability of State officials, reduces transparency in the work of State institutions and allows human rights violations to go unpunished".[9]

Corruption can be problematic in the health sector, especially in low-income countries.[10] Prominent

examples of corruption in the health sector include poor health facility construction, absenteeism of health professionals, improper spending and diversion of funds, theft of drugs, soliciting of informal payments to improve levels of service, and accreditation and licensing bribery.[11]

5.3 Principles of good governance

There are a variety of conceptual frameworks that seek to identify the attributes of good governance.[12] This section draws on the attributes of good governance identified by the United Nations Development Programme (UNDP),[13] and adds the concept of stewardship, which is a core public health function of government.[14] To maximize the success and legitimacy of the public health law reform process, countries should integrate the following six principles into the law reform process: stewardship, transparency, participation, fairness, accountability and following the rule of law.

(a) Stewardship

Stewardship refers to the "careful and responsible management of something entrusted to one's care".[15] Those who exercise the authority to make policy – the minister of health and others who work to reform public health laws – must exercise stewardship, putting aside personal desires and working to maximize the health interests of the people they serve. Unless law reformers approach the task of law reform with the public's benefit in mind, public health laws cannot maximize their potential to assist countries to progressively realize the right to health for all members of the population.

(b) Transparency

Transparency is "built on the free flow of information".[16] It requires that, as far as possible, the process of developing, implementing and enforcing the law should be open and visible to the public. Transparency helps to build public understanding about the law, and confidence that legal powers will be exercised for the benefit of society as a whole.

A variety of processes can help to ensure transparency during the law reform process. These include public forums, parliamentary debates and a political environment that permits media scrutiny and public reporting of government actions. Transparency supports the human right to participation because it allows members of the public to provide feedback on law reform proposals and draft laws. Once new laws have been passed, governments can enhance transparency by ensuring that legislation, regulations, executive orders and other laws remain accessible to members of the public and to representative groups. This principle also applies to the judgements of courts and tribunals.

(c) Participation

In cases where the law is intended to influence and alter behaviour, it is important that those who are directly affected by the law should be aware of it, understand it and also appreciate the goals

that the law is seeking to achieve. To achieve public support for a new public health law, lawmakers should consult affected communities, civil society groups, public health organizations and other stakeholders. When the community is given a seat at the negotiating table, it is more likely to support and comply with a new law. On the other hand, engaging with those who have a vested interest in defeating or weakening the law may be harmful to public health. For example, the *Guidelines for the implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control* recommend that government officials should avoid conflicts of interest and "interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products".[17]

There are a variety of other ways that governments and health ministries can ensure community participation in the law reform process. For example, by publishing discussion papers and making draft legislation available (including on the Internet), governments can ensure that members of the public and representative organizations can give comments and other feedback. Where a commission or government committee considers options for law reform, it is customary for these bodies to accept submissions and to consult extensively. An example of this occurred in South Africa, where the Ministry of Justice conducted a "road show" as part of the process of amending the Marriage Act, sharing information and building community support for the proposed changes.[18] As discussed in Section 3.4(b), formal mechanisms for community participation can also serve as the trigger for public health law reform.

(d) Fairness

The principle of fairness makes a significant contribution to good governance because it encompasses the related human rights of equality and non-discrimination. Article 26 of the International Covenant on Civil and Political Rights states:

All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.[19]

Discrimination entrenches health inequalities and undermines the capacity of governments to pursue the right to health for all members of the population. Governments have an obligation to take immediate action to eliminate discrimination; doing so will help to ensure equality of access to health services and to the resources needed to lead a healthy life.[20] This does not necessarily mean that the State must provide health services and other social services to everyone free of charge. On the other hand, the State does have an obligation to ensure that individuals and vulnerable groups do not miss out on health care and health services because of their inability to pay. Law is a powerful tool for establishing the principle of "equality of opportunity for people to enjoy the highest attainable level of health".[21]

(e) Accountability

Accountability means taking responsibility for the success and failure of laws and policies, and putting processes in place to ensure that changes are made to improve decision-making and the performance of public health functions in future. In the context of public health law reform, accountability requires that legislation should set out the responsibilities and functions of public health officials so that it is clear who is accountable for enforcing the law and for exercising powers to protect the public's health.

In countries where resources and administrative capacity are limited, even the best laws and policies may be poorly implemented. As part of normal budgetary processes, therefore, governments should allocate resources to ensure that laws are administered effectively at both national and local levels. In circumstances where the activities and behaviour of businesses and individuals are subject to legal requirements, the law should set out the consequences for non-compliance, including the penalties imposed for offences.

Many of the factors that influence the health of the population may fall outside the authority of the health ministry. As a result, accountability for the progressive realization of the right to health must be shared across government as a whole. Discharging this responsibility will require coordination between ministries, as discussed in Chapter 6.

(f) The rule of law

Good governance is based on the rule of law. The principle of the rule of law means that all persons, officials and institutions, including the State itself, are accountable under laws that are publicly disseminated, equally enforced, independently adjudicated, and consistent with international human rights standards (**see Box 1.1** in Section 1.1). The rule of law ensures that the law reform process itself is clear, fair and that it remains focused on the public interest.

In summary, each of the principles of good governance create an enabling environment for the effective management of the law reform process so that it can best achieve its goal of realizing the right to health for all members of the population. Where opportunities exist for civil society to participate in the law reform process, through a transparent and well managed process, there is a greater chance that a consensus will form around the need for reform. This improves the chances of success in the implementation and administration of public health laws.

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Chapter 6: Coordinated, intersectoral action to improve public health

SUMMARY POINTS

- **The factors that influence health outcomes are complex and extend well beyond the provision of health care services. Many also fall outside the authority of the health ministry. As a result, accountability for the progressive realization of the right to health must be shared across government as a whole. Coordinated, intersectoral action to improve health, including between ministries, between different levels of government, and with stakeholders outside government, is necessary in order to address complex and persistent health challenges.**
- **Legal and regulatory reform can support intersectoral action in health in a variety of ways, including by establishing new governance structures and processes for advancing shared goals, by establishing an accountability framework that sets out the responsibilities of participants, and by providing a clear mandate for intersectoral actions by relevant government agencies and authorities.**
- **The processes and structures that are used to formalize intersectoral and intergovernmental collaboration will vary between countries and will be influenced by existing institutions, traditions and constitutional arrangements, as well as the specific priorities that are being pursued. Governments may choose to invest in a number of structures and processes that vary in scale and focus in order to address different health priorities. Some intersectoral initiatives may be framed largely in terms of the health benefits they aim to achieve, while others may aim to achieve a number of related economic and social objectives.**
- **Securing high-level political commitment to an intersectoral initiative is vital, and may help to reduce resistance from ministries whose goals may conflict with public health.**
- **A successful partnership across sectoral boundaries requires the active participation and goodwill of all partners. The political commitment of partner ministries may be strengthened by formalizing the partnership in a declaration, memorandum of understanding or other framework document that sets out shared goals and the key responsibilities of each partner.**
- **Where different levels of government are involved, the unique legal status, legislative powers and comparative advantage of each level should be assessed.**
- **WHO has identified a number of practical steps that may assist health ministries as they seek to work with other ministries to realize the benefits of an intersectoral approach.**
- **Governance reforms have played an important role in many successful intersectoral initiatives, including in the areas of disease prevention, reducing health inequalities and improving food and nutritional security.**

The factors that influence health outcomes are complex and extend well beyond the provision of health care services.[1] The physical, economic, social and political environments in which people live have a profound impact on the health of individuals and populations. They affect life opportunities,

exposure to health risks, knowledge and access to information, preferences, choices and the capacity for self-protective behaviour, as well as access to – and the affordability of – health care services.

The wide range of factors influencing the health of the population creates profound challenges for governments and public health policy-makers. These include the need to work with a broader range of health stakeholders than has traditionally been the case, and to develop new structures for collaborating across portfolio boundaries. The need for a coordinated, intersectoral approach to health policy-making has been called many things, including an "all-of-government" approach, "health in all policies", and "joined-up government". This chapter discusses how legal and regulatory reforms can help to create an enabling environment for intersectoral action on health. For example, regulation can:

- provide a clear mandate for engaging with other sectors and stakeholders, both within and beyond government;
- establish new governance structures and processes for advancing shared social goals (including health); and
- establish a framework for accountability that sets out the responsibilities of all participants for achieving shared goals, and requires the evaluation of progress.

6.1 The purpose and scale of intersectoral reforms to improve public health

The structures and processes that are used to formalize intersectoral and intergovernmental collaboration will vary between countries and will be influenced by existing institutions, traditions and constitutional arrangements, as well as the specific priorities that are being pursued. Policies tend to evolve incrementally, rather than through a dramatic process of re-invention. For this reason, there may be benefits to building on existing structures and processes, while shaping and adapting them in new directions.[2]

There is no single blueprint for intersectoral action in health. Governments may choose to invest in a number of structures and processes that vary in scale and focus in order to address different goals and priorities. Some intersectoral initiatives may be framed largely in terms of the health benefits they aim to achieve, such as obesity prevention or active living. More ambitious, cross-sectoral partnerships may aim to achieve a number of economic and social objectives, including improvements in health and well-being. Examples of broader, intersectoral partnerships include:

- initiatives to reduce road traffic injuries;
- initiatives to improve the safety and security of the food supply;
- initiatives to improve child health, well-being and educational attainment; and

- integrated approaches to improving the quality of the local environment encompassing, for example, improved housing, infrastructure, social services, crime prevention and environmental remediation.[3]

Intersectoral structures may also provide a solution when governments have already passed multiple pieces of legislation that overlap and share common goals, but which are administered across a number of ministries. For example, the Republic of Korea has passed 25 Acts, administered by six ministries, which seek to improve the physical health and nutrition of children, and to reduce obesity. While the overlapping tasks mandated under these Acts could be merged within a single ministry, another alternative is to create an intersectoral committee to facilitate collaboration among ministries.[4]

Intersectoral initiatives may generate benefits that extend well beyond health. Public health leaders should consider how best to present the case for intersectoral action, remembering that collaboration with other sectors and ministries may be easier to achieve when initiatives are framed in terms of language, concepts, goals and values that are familiar or appropriate to that sector. For example, an integrated approach to reducing rates of violence in disadvantaged urban communities is relevant to the goals and values of policing and the justice sector. In addition, however, intersectoral action on the underlying social determinants of violence could include policies and programmes to respond to drug and alcohol problems, mental illness, poverty and unemployment. Laws, policies and programmes to create safer and healthier communities, in turn, will contribute to broader, societal goals; for example, reducing reliance on government welfare payments, creating a more socially cohesive environment that attracts local businesses, attracts tourism and reduces the pressure on over-burdened health systems and health care workers.[5]

Public health leaders can help to overcome inertia and to generate political support for intersectoral action by highlighting the health benefits that could result from coordinated action. For example, the threats to health and health equity are not the only grounds for action on climate change. Nevertheless, mitigating the impacts of climate change on health is an important argument supporting an all-of-government approach to improving environmental sustainability and reducing greenhouse gas emissions.[6]

Intersectoral action in health: the evolution of an idea

This subsection briefly reviews highlights in the evolution of intersectoral action in health, and identifies some priority areas where intersectoral governance structures could be used to advance the right to health.

In the Alma Ata Declaration (1978),[7] intersectoral action was recognized as a key to improving primary health care, through coordinated action across a range of sectors, including agriculture, animal husbandry, food, industry, education, public works and communications. In 1986, the Ottawa Charter for Health Promotion recognized that intersectoral action is fundamental to reducing inequalities in health status within the population.[8] The Charter emphasized health promotion both as a concept and strategy for re-orienting health systems in order to improve health equity and to achieve greater control by individuals and communities over the determinants affecting their health.

The Charter emphasized that health promotion includes building healthy public policy. This means putting health "on the agenda of policy-makers in all sectors and at all levels, directing them to be aware of the health consequences of their actions and to accept their responsibilities for health" (see **Box 6.1**). Like the Alma Ata Declaration, the Ottawa Charter emphasized the importance of community and individual self-reliance, and drew attention to health impact assessment as a strategy for making healthier public policies.

Box 6.1: Intersectoral action in the Ottawa Charter for Health Promotion[9]

> The prerequisites… for health cannot be ensured by the health sector alone. More importantly, health promotion demands coordinated action by all concerned: by governments, by health and other social and economic sectors, by nongovernmental and voluntary organizations, by local authorities, by industry and by the media. People in all walks of life are involved as individuals, families and communities. Professional and social groups and health personnel have a major responsibility to mediate between differing interests in society for the pursuit of health….
>
> Health promotion goes beyond health care. It puts health on the agenda of policy-makers in all sectors and at all levels, directing them to be aware of the health consequences of their decisions and to accept their responsibilities for health.
>
> Health promotion policy combines diverse but complementary approaches including legislation, fiscal measures, taxation and organizational change. It is coordinated action that leads to health, income and social policies that foster greater equity. Joint action contributes to ensuring safer and healthier goods and services, healthier public services and cleaner, more enjoyable environments.

In 2008, the WHO Commission on Social Determinants of Health emphasized that disparities in health between rich and poor countries, and between rich and poor people within the same country, are fundamentally linked to disparities in power and income, goods and services. These factors are reflected, in turn, in disparities in living and working conditions, in the quality of the surrounding natural environment, and in access to health care, education, leisure and other opportunities for a flourishing life (**Box 6.2**). The Commission called for a new approach to development that involves the participation of all levels of government, civil society, business and local communities.[10] It also emphasized the importance of political leadership:

Policies and programmes must embrace all the key sectors of society, not just the health sector. That said, the minister of health and the supporting ministry are critical to global change. They can champion a social determinants of health approach at the highest level of society, they can demonstrate effectiveness through good practice, and they can support other ministries in creating policies that promote health equity.[11]

Box 6.2: Conclusions of the WHO Commission on the Social Determinants of Health[12]

> "The poor health of the poor, the social gradient in health within countries, and the marked health inequities between countries are caused by the unequal distribution of power, income, goods and services, globally and nationally, the consequent unfairness in the immediate, visible circumstances

of people's lives – their access to health care, schools and education, their conditions of work and leisure, their homes, communities, towns or cities – and their chances of leading a flourishing life. This unequal distribution of health-damaging experiences is not in any sense a 'natural' phenomenon but is the result of a toxic combination of poor social policies and programmes, unfair economic arrangements and bad politics. Together, the structural determinants and conditions of daily life constitute the social determinants of health and are responsible for a major part of health inequalities between and within countries."

In 2010, the Adelaide Statement on Health in All Policies pointed out that the interdependence of public policy requires not only an integrated response across government departments, but partnerships with the business sector and civil society.[13] The Statement identified important attributes that are reflected in successful approaches to intersectoral action in health, as well as examples of regulatory tools and processes that governments can consider when designing an intersectoral response (**Box 6.3**).

Box 6.3: Adelaide Statement on Health in All Policies

"Health in All Policies works best when:

- a clear mandate makes joined-up government an imperative;
- systematic processes take account of interactions across sectors;
- mediation occurs across interests;
- accountability, transparency and participatory processes are present;
- engagement occurs with stakeholders outside of government;
- practical cross-sector initiatives build partnerships and trust.

Tools and instruments that have [been] shown to be useful at different stages of the policy cycle include:

- inter-ministerial and inter-departmental committees;
- cross-sector action teams;
- integrated budgets and accounting;
- cross-cutting information and evaluation systems;
- joined-up workforce development;
- community consultations and Citizens' Juries;
- partnership platforms;
- Health Lens Analysis;
- impact assessments;
- legislative frameworks."

In 2011, the World Conference on Social Determinants of Health in Rio de Janeiro considered how intersectoral action and structures could reduce health inequalities by tackling the social determinants of health. Participants discussed strategies for institutionalizing intersectoral action

and emphasized the need to integrate intersectoral governance at all levels, from the level of United Nations agencies to local communities. At all levels, effective intersectoral engagement and action requires "a long-lasting sustainable process rather than a single event or programme".[14]

At the international level, partnerships for multisectoral action have been recognized as an essential strategy for improving global health, in order to reduce fragmentation, conserve resources and maximize impact and influence at the country level. For example, a key feature of the global response to chronic, noncommunicable diseases is the emphasis on partnerships between governments, WHO and other United Nations agencies, development assistance agencies, civil society organizations and, where appropriate, the private sector.[15] This has been formalized in the United Nations Task Force on noncommunicable diseases, which is led by WHO and coordinates the activities of United Nations organizations and intergovernmental organizations in implementing the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020.[16] A separate global coordination mechanism established by WHO facilitates engagement and partnerships between a broader group of stakeholders including WHO Member States, United Nations funds, programmes and agencies, civil society groups and the private sector, while protecting against conflicts of interest.[17]

The Rio conference on social determinants of health highlighted the importance of ensuring the participation of civil society in intersectoral structures, and of civil society's role in keeping governments accountable. Evaluation and accountability require both good information and "permanent structures and forums (such as intersectoral committees) that [facilitate] comparison of data".[18]

6.2 Practical steps for initiating intersectoral action

Intersectoral action can be initiated at a variety of levels, depending on its scope and purpose. In many cases, political leaders at national, regional, city or local level, in consultation with public health leaders will have a vision or a preliminary plan of what could be achieved through an intersectoral partnership. In some cases, a parliamentary interest group (such as a cross-party parliamentary diabetes support group)[19] may provide the initial impetus, support and advice. Securing high-level political commitment to an intersectoral initiative is vital: it gives legitimacy to the open-ended process of negotiating a partnership with relevant sectors, and can help to reduce opposition from ministries whose goals may conflict with public health. Where different levels of government are involved, the unique legal status, legislative powers and comparative advantage of each level should be considered.

A successful partnership across sectoral boundaries requires the active participation and goodwill of all partners. The political commitment of government to intersectoral action on health may be strengthened by formalizing the partnership in a declaration, memorandum of understanding or other framework document. Such a commitment may even be formalized in the national constitution. For example, Thailand's Constitution (2007) provides that if a public programme might have a serious impact on natural resources or the environment, a participatory health and environmental impact assessment must be carried out before the programme can begin (**Box 6.4**).[20]

Box 6.4: Constitution of the Kingdom of Thailand (2007), Article 67[21]

Article 67 states, in part:

Any project or activity which may seriously affect the quality of the environment, natural resources and biological diversity shall not be permitted, unless its impacts on the quality of the environment and on the health of the people in the communities have been studied and evaluated, and consultation with the public and interested parties has been organized, and opinions of an independent organization, consisting of representatives from private environmental and health organizations and from higher education institutions providing studies in the field of the environment, natural resources or health, have been obtained prior to the operation of such a project or activity.

Civil society organizations, professional associations, academia and the private sector are important partners for achieving shared health goals. In Brazil, governments and civil society organizations signed a Declaration for the Prevention and Control of Noncommunicable Diseases, which commits the parties to implementing the WHO Framework Convention on Tobacco Control, the WHO Global Strategy on Diet, Physical Activity and Health and other strategies. Signatories committed to placing these policies on the work agendas of national, state and local governments, ensuring integrated action between sectors, access to resources and broad community participation.[22] The Declaration constitutes an important statement of intent which supports the implementation of a coordinated, intersectoral approach to noncommunicable diseases encompassing surveillance, prevention and treatment.

Although helpful, declarations and statements of intent are not a substitute for action by governments. Governments must ensure that they take the concrete steps that are required to deliver on their promises, by enforcing public health laws, reforming and improving them and honouring human rights obligations. Governments should ensure that partnerships with the private sector, where appropriate, do not undermine their capacity to use legal and regulatory powers effectively to protect public health. For example, the *Guidelines for the implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control* recommend that: "The tobacco industry should not be a partner in any initiative linked to setting or implementing public health policies, given that its interests are in direct conflict with the goals of public health".[23]

Despite the importance of high-level political support, health ministries, rather than other ministers or heads of government, will often be the leaders of intersectoral initiatives for health, with practical responsibility for moving them forward. WHO has identified a number of practical steps that may assist health ministries as they seek to realize the benefits of an intersectoral approach.[24] For example, health ministries should:

- Build understanding among health sector personnel of the need for an intersectoral approach to implement health priorities or to advance shared societal goals;
- Strengthen the capacity of health sector personnel to interact with and develop alliances with other Ministries;
- Use health impact assessment as a tool to identify how health department priorities will have an impact on the goals and interests of other ministries and their constituencies.

- Identify areas where interests are aligned, but be aware of areas where disagreements and rivalries could also arise. Create alliances where possible without undermining health goals;
- Identify existing structures and processes for cross-ministerial, intersectoral action and cooperation. Are these appropriate? Review existing laws and mandates for intersectoral action. Are they adequate? Identify new potential mechanisms for intersectoral cooperation. Seek high-level political support for these to be formalized and used;
- Be responsive to initiatives led by other sectors that provide opportunities for improving health and achieving health goals. For example, initiatives to improve food security, led by the agricultural sector, may also provide opportunities for improving diets, diversifying away from tobacco cultivation and supporting the cultivation of healthier oils;
- Explain the health impact of policies administered by other ministries, and the health benefits of a collaborative approach to policy development. Share relevant health data with other ministries;
- Choose the best method of collaboration for implementing each initiative, remembering that the most appropriate implementation strategies may vary according to the priority in question.
- Develop a strategy for engaging other sectors and ministries, and a common framework that assists all sectors and partners to understand the issues and the required actions;
- Support community participation in the development and implementation of health initiatives through public consultation, preparation of discussion papers, web-based tools and mass media;
- Look for ways to ensure political accountability through reporting requirements and access to information. Reporting mechanisms mandated by international agreements provide opportunities for reporting on government commitments and progress made in intersectoral activities;
- Monitor and evaluate the progress of intersectoral efforts to advance priority health goals, and identify and promote good practices.

6.3 Case studies of governance reforms supporting intersectoral action on health

This section presents three case studies of intersectoral structures and processes designed to advance health in three important areas: firstly, health promotion and disease prevention; secondly, reducing health inequalities through action on the social determinants of health; and thirdly, reducing hunger and improving nutritional security. The discussion highlights key features of the governance structures adopted in each case.

(a) Disease prevention and health promotion

Effective disease prevention strategies require action to be taken outside the health sector in order to promote healthy living, to improve access to information, to reduce risk factors for disease, and to improve the quality of the environments in which people live. National leadership can take a variety of forms.

In Mexico, a National Council for the Prevention and Control of Chronic, Noncommunicable Diseases was established by presidential decree.[25] The National Council acts as the permanent coordinating body for national action on noncommunicable diseases and their risk factors, linking Secretariat of Health officials with their counterparts in the finance, agriculture, education and trade ministries. The Council coordinates activities both among federal government agencies, and between the federal government and the states under the National Health Council.

A similar model operates in the United States of America. In 2009, Congress passed legislation calling on President Barack Obama to establish an intersectoral National Prevention, Health Promotion and Public Health Council.[26] The Council now comprises the heads of 20 federal government agencies, and is supported by an Advisory Group of experts appointed by the President (**Box 6.5**). Legislation required the Council to develop a national prevention and health promotion strategy, setting out specific goals for improving health through federally funded prevention and health promotion programmes.[27] The Council is also required to publish an annual report setting out corrective actions that federal agencies can take to achieve national goals for reductions in tobacco use, harmful use of alcohol, physical inactivity and poor diet.[28]

Box 6.5: The National Prevention, Health Promotion and Public Health Council (United States)[29]

The Council: The National Prevention Council, established by executive order of President Obama, 10 June 2010, comprises:

- The Surgeon-General (Chair)
- Secretary, Department of Health and Human Services
- Secretary, Department of Agriculture
- Secretary, Department of Education
- Chairperson, Federal Trade Commission
- Secretary, Department of Transportation
- Secretary, Department of Labour
- Secretary, Department of Homeland Security
- Administrator, Environmental Protection Agency
- Director, Office of National Drug Control Policy
- Director, Domestic Policy Council
- Assistant Secretary, Indian Affairs, Department of the Interior
- Attorney-General, Department of Justice
- Acting Chief Executive Officer, Corporation for National and Community Service
- Secretary, Department of Defence
- Secretary, Department of Veterans Affairs

- Secretary, Department of Housing and Urban Development
- Director, Office of Management and Budget
- Secretary, Department of the Interior
- Administrator, General Services Administration
- Director, Office of Personnel Management

The Advisory Group: The Council is supported by an Advisory Group on Prevention, Health Promotion and Integrative Public Health. Members of the Advisory Council include a diverse group of licensed health professionals with expertise in:

- worksite health promotion;
- community services, including community health centres;
- preventive medicine;
- health coaching;
- public health education;
- geriatrics; and
- rehabilitation medicine.
- Key duties of the Council include:
- providing coordination and leadership among federal agencies on disease prevention, health promotion practices, and integrative health care;
- developing a national strategy for disease prevention and health promotion that includes the most effective and achievable strategies for reducing preventable illness and disability in the United States. This strategy must set out specific goals for improvements in health, together with specific, measurable actions and timelines for implementing the strategy;
- providing recommendations to the President and to Congress on changes in federal policy required in order to achieve national goals for reducing tobacco use, reducing sedentary behaviour, and improving nutrition;
- reporting annually on corrective actions recommended to federal agencies to meet the goals and actions taken by relevant agencies. This annual status report must contain a list of national priorities for improving lifestyles, covering: smoking cessation, proper nutrition, appropriate exercise, mental health, behavioural health, substance abuse and domestic violence. It must contain "specific, science-based initiatives" to achieve national goals for nutrition, exercise and smoking cessation and for preventing the five leading disease killers in the United States.

Four features of this model for intersectoral action deserve emphasis. As a national council comprising the heads of federal executive agencies, the Council has a clear mandate for shaping and implementing new programmes and policies. In order to discharge these responsibilities, the Council is served by an Advisory Group of experts in preventive health. Although the legislative mandate is

imposed directly on heads of government agencies, the presence of the Advisory Group ensures that the policy-shaping process is less vulnerable to entrenched departmental cultures and goals, which may run contrary to public health objectives.

Secondly, the authorizing legislation by Congress seeks to ensure accountability for the implementation of the national prevention strategy by ensuring that it contains specific indicators for measuring progress, and by requiring preparation of an annual status report which enables Congress and the President, to monitor progress.

Thirdly, in addition to encouraging collective action by federal agencies, the National Strategy envisages that the National Prevention Council and the Advisory Group will engage with a broad range of partners to ensure implementation of the national prevention strategy.[30] These include state and local governments, businesses, community organizations and faith-based organizations.

Fourthly, the authorizing legislation illustrates how rising health care costs are a driver for government investment in intersectoral initiatives for preventive health. In this case, the legislation established a Prevention and Public Health Fund to provide sustained funding for preventive health programmes, reaching US$ 2 billion per year by 2015, in order to reduce the rate of growth in health care costs.[31]

(b) Promoting health equity and reducing health inequalities

The WHO Commission on Social Determinants of Health found that health inequalities arise from the "societal conditions in which people are born, grow, live, work and age". These social determinants include "early years' experiences, education, economic status, employment and decent work, housing and environment and effective systems of preventing and treating ill-health".[32] It follows that reducing health inequalities within the population requires an intersectoral approach that addresses areas of sustained disadvantage in social and economic living conditions. The priority areas for government action to promote health equity vary between countries, but often include policies to address the following kinds of problems:

- inadequate income;
- unemployment;
- substandard housing;
- fuel poverty;
- lack of sanitation and lack of access to clean water;
- low levels of education;
- hunger;
- lack of access to fresh fruit and vegetables and to nutrients required for a healthy diet at reasonably affordable prices;
- high rates of risk factors including smoking, binge drinking and substance abuse;
- poor access to health care services, including prenatal and mental health services;
- high rates of crime and violence;

- high rates of teenage pregnancy;
- high rates of suicide and self-harm;
- lack of access to safe public areas for recreation and physical activity;
- lack of public transport;
- dangerous and contaminated physical environments;
- social isolation and lack of social supports.

Making progress on a complex set of issues like these calls for an integrated response that coordinates the work of all relevant ministries, coordinates actions by different levels of government, and provides opportunities for partnerships between government, community groups, businesses and other stakeholders.

In England, the foundation for government action to reduce health inequalities was an independent scientific review that documented the widening gap between the health outcomes of different social groups and made policy recommendations covering a range of sectors.[33] By the 1990s, the mortality rate of working age men in England was almost three times as high for those in the lowest socioeconomic quintile (unskilled workers) as it was for the highest quintile (professionals).[34] A subsequent joint review by the Department of Health and the Treasury identified a set of priority interventions for public spending. This review provided the basis for the government's national strategy for tackling health inequalities.[35]

In 2001, the government adopted a national health inequalities target: to reduce inequalities in health outcomes by 10%, as measured by infant mortality and life expectancy at birth.[36] Additional targets were added in 2004, including a target to reduce (by 10%) the gap between the most deprived 20% of local area authorities and the population as a whole. The government used indicators for health and for deprivation in different local government areas to measure the gap and progress towards the target.

The national health inequalities strategy was adopted in 2003. It grouped policies and services under four themes: supporting families, mothers and children; engaging communities and individuals; preventing illness and providing effective treatment through the National Health Service (NHS); and addressing the underlying, long-term determinants of health (**Box 6.6**).

Box 6.6: A programme for action for reducing health inequalities in England[37]

In 2003, the Department of Health in England outlined a strategy for tackling health inequalities. The strategy focused on four themes:

- supporting families, mothers and children: in order to provide children with the best possible start in life, and to break the intergenerational cycle of poor health;
- engaging communities and individuals: the strategy recognized the need for the government to respond to local problems and "pools of deprivation" through specific and targeted interventions. These would operate alongside the delivery of mainstream services to local communities and socially excluded groups;

- preventing illness and providing effective treatment and care through the NHS. The strategy included policies to reduce tobacco use, to tackle cancer and coronary heart disease, and to improve primary care through the government-funded NHS;
- addressing the underlying determinants of health. The strategy included long-term activities undertaken by the government, at national and local levels, to address the underlying social determinants of health; for example: by reducing poverty and improving employment opportunities and living conditions for disadvantaged groups.

One important feature of the government's strategy was the recognition that government services needed to be tailored to local circumstances in order to meet local needs. The strategy envisaged that this would occur through "local strategic partnerships" between local government authorities, primary care trusts (which commission the provision of health services from health care providers on behalf of the NHS), as well as communities, businesses and the voluntary sector. Under the government's strategy, local government authorities were required to negotiate Local Public Service Agreements with the central government, to include performance targets covering a range of sectors, as well as the national health inequality targets. Local governments were invited to use the local strategic partnership process to review local challenges together with other stakeholders and to agree on additional outcome-focused targets for local performance, with a reward grant paid to those authorities that met their target.[38] The entire strategy was supported by a set of health and social indicators for measuring local area performance, national performance and the difference between national performance and performance in deprived local areas.

(c) Improving food and nutritional security in Brazil

Institutions, laws and governance reforms have played an important part in Brazil's efforts to reduce hunger and improve food security. Brazil is the world's seventh largest economy and a large agricultural producer and food exporter. Nevertheless, a significant segment of the population lives in conditions of hunger and food insecurity, due to lack of income to purchase adequate food, exacerbated by variations in food production between geographical regions.

Despite these problems, Brazil has achieved significant reductions in poverty, hunger and food insecurity over the past decade. In 2003, using the methodology developed to track poverty and food insecurity across all regions in Brazil, there were 50 million people, including nearly 11 million families, living below the poverty line (now frequently defined as US$ 1.25 per day).[39] By 2009, over 20 million people (nearly 4 million families), had been removed from poverty.[40]

When Luiz Inácio Lula da Silva became the President of Brazil in 2003, he made hunger and food insecurity a priority of his Presidency, stating in his first speech that "If at the end of my mandate every Brazilian can eat three times a day, I will have fulfilled my life's mission".[41] President da Silva immediately launched Fome Zero (Zero Hunger), a national programme that combined emergency activities to increase income and access to food with longer-term structural activities to reduce poverty and increase the supply of food at affordable prices.[42] This section highlights the key governance reforms involved in the implementation of Fome Zero, together with a brief description of the programme's leading policies.

Intersectoral governance reforms

Fome Zero was supported by a number of governance reforms that made it possible for civil society to originate and participate in policy proposals, and which also facilitated coordination between different federal ministries and different levels of government. Together, these reforms created the National System for Food and Nutritional Security (SISAN), which was formalized in the Federal Law on Food and Nutrition Security (2006).[43] SISAN comprised:

- the National Conference on Food and Nutritional Security;
- the National Council of Food and Nutritional Security;
- the Inter-ministerial Chamber for Food and Nutritional Security;
- agencies and entities implementing policies and programmes for food and nutritional security at federal, state and municipal levels; and
- private institutions that respected the goals of SISAN and wished to participate in it.

"Food and nutritional security" was defined in 2004, during Brazil's Second National Conference on Food and Nutrition Security, and this definition was subsequently included in federal law (**Box 6.7**). The concept draws attention to a number of underlying variables including: sufficient quantity of food; the quality of food, including its safety and nutritional balance; regularity of access to food; as well as choice and dignity: freedom to choose food that is culturally appropriate without compromising other needs.[44]

As reflected in Article 4 of the Federal Law, the achievement of food and nutritional security rests on intersectoral policies and programmes addressing a range of underlying factors which affect the capacity of low-income families to participate in the domestic food market, both as food producers and consumers. Effective policies on food and nutritional security must seek to:

- expand access to food through support for traditional and family farming;
- ensure biodiversity and the sustainable use of resources;
- promote good health and nutrition, especially among vulnerable social groups;
- ensure the safety and quality of food;
- improve access to information; and
- implement participatory public policies to improve food production, commercialization and consumption.

Box 6.7: Food and nutritional security in Brazil: a multifaceted concept

Organic Law of Food Security and Nutrition, Brazil[45]

Article 3. Food and nutritional security consists of the realization of the human right to regular and permanent access to good-quality food, in sufficient quantity, without compromising the fulfilment of other basic needs, having as its basis healthy nutritional habits that respect cultural diversity and that are environmentally, culturally, economically and socially sustainable.

Article 4 Food and nutritional security comprises:

I. Expansion of access to food through its production, particularly via family and traditional farming, food processing, industrialization and commercialization, including international agreements; better food supply and distribution, including of water; job creation and redistribution of wealth;

II. The conservation of biodiversity and the sustainable use of resources;

III. The promotion of health, food, and nutrition for the population, including specific population groups and those more socially vulnerable;

IV. The guarantee of the biological, sanitary, nutritional and technological qualities of the food, as well as its good use, which stimulates healthy food practices and lifestyles that respect the ethnic and racial diversity of the population;

V. The production of knowledge and the access to information; and

VI. The implementation of public policies and sustainable and participatory strategies of food production, commercialization and consumption, respecting the diverse cultural characteristics of the country.

At the federal level, three governance reforms played a critical role in shared efforts to achieve these goals. Firstly, Fome Zero was initially administered by a new, Extraordinary Ministry for Food Security and the Fight against Hunger, which subsequently became the Ministry for Social Development and the Fight against Hunger. The functions of this Ministry included "formulating and coordinating the implementation of the National Food and Nutrition Security Policy for the purpose of ensuring the human right to food", and creating links between policies and programmes administered by federal, state and municipal governments, as well as those of civil society.[46] The creation of a ministry devoted to the coordination of hunger and food security initiatives reflected the high level of political commitment to hunger prevention within the da Silva administration, and maintained the relative political priority of Fome Zero among other programmes competing for attention and resources.

Secondly, President da Silva re-established the National Council of Food and Nutritional Security (CONSEA), a unique body which is attached to the Presidency and ensures the participation of civil society in national policy-making on food security. One third (currently 19) of the delegates to CONSEA are ministers and secretaries from portfolios related to food and nutritional security. The remaining two thirds of delegates come from civil society and represent nongovernmental organizations, social movements and professional and religious organizations.[47]

CONSEA is required to convene the National Conference on Food and Nutrition Security every four years. The national conferences are a unique aspect of participatory democracy in Brazil, proposing and prioritizing policies and guidelines that form the foundation of the National System for Food and Nutrition Security (SISAN). The national conference is preceded by state conferences convened by the 27 state CONSEAs, which debate issues of food security relevant to their geographical constituencies, nominate delegates to the national conference, and submit proposals which are included in the base document for the national conference. A similar process occurs at the municipal level. For example, the Fourth National Conference on Food and Nutrition Security, held in 2011, was

attended by 1626 delegates representing the 26 states, and carried forward the work of over 75 000 people from 3000 municipalities.[48]

Thirdly, CONSEA's legal role includes considering and framing resolutions and guidelines adopted by the national conference into specific proposals that take account of the politics and institutions of government.[49] These proposals, which include budgetary requirements for their implementation, are submitted to the Inter-ministerial Chamber for Food and Nutritional Security (CAISAN), a purely governmental body that comprises over a dozen Ministers and Secretaries who participate in CONSEA. CAISAN is charged, in turn, with transforming the proposals received from CONSEA into government programmes (with supporting directives, goals, budgets and resources), and with implementing and monitoring them.[50] CAISAN is chaired by the General Secretary of CONSEA and its Executive Secretariat is maintained by the Ministry for Social Development and the Fight against Hunger.

Fome Zero: leading policies

Fome Zero was a political programme that began with the government of President da Silva but developed over time. The first set of policies aimed to increase access to food by boosting the purchasing power of the unemployed and those on low wages. The largest initiative here was the family grants programme, Bolsa Família, which consolidated a range of income assistance payments. In 2010, these payments reached over 12.7 million families living in poverty and extreme poverty (nearly 50 million people).[51] The conditions for receipt of the Bolsa Família – that children are vaccinated, receive regular health checks and attend school – are monitored by municipal and state secretariats within the Ministries of Education and of Health, which communicates the data to the Ministry for Social Development and the Fight against Hunger. Since 2006, municipalities have received economic incentives to improve their monitoring of these conditions and for maintaining up-to-date data on municipal enrolees.

A second set of policies aimed to increase access to food by strengthening family farming, which (unlike Brazil's export-oriented agribusiness sector) accounts for production of most of the domestic food supply.[52] Family farmers represent the majority of the rural population, but many live in conditions of food insecurity. The Family Farming Food Acquisition Programme, funded jointly by the Ministry for Social Development and the Fight against Hunger and the Ministry of Agrarian Development, involves direct procurement of food from family farmers, traditional peoples and groups resettled under agrarian reform programmes. Under one set of initiatives, the National Food Supply Company purchased products from farmers at market prices, and used these to re-establish public food security stocks. Under another set of initiatives, based on agreements with states, cities and local family farmers' associations, products purchased from farmers' associations are donated to municipal food security programmes, including subsidized restaurants and school meal programmes which, by law, must purchase 30% of food from family farmers.[53] A further set of initiatives aimed to boost milk production and distribution in semi-arid regions.

Other programmes supporting food production included agrarian reforms to resettle displaced groups, regularization of land tenure, expansion of credit to family farmers, harvest insurance, the

building of rainwater cisterns to encourage self-sufficiency and independence from water utilities, and technical assistance.

A third set of policies aimed to directly increase access to food. Under President da Silva's administration, the school meals programme was expanded to include all students in kindergarten, elementary and high school. Other initiatives included the federally-funded workers' food programme for low-income workers, as well as the Network of Public Utilities for Food Security and Nutrition (RedSAN), administered by the Ministry for Social Development and the Fight Against Hunger. RedSAN activities include subsidizing restaurants and food banks and distributing emergency food baskets, which include products produced by family farmers.

Strengthening the National System for Food and Nutrition Security

Brazil's National System for Food and Nutrition Security (see **Figure 6.1**) is both intersectoral and decentralized. Since Brazil has a highly decentralized political system, the federal government relies for implementation on governance relationships with over 5500 municipalities. The National System for Food and Nutrition Security has been strengthened through the establishment, by presidential decree, of the National Food and Nutritional Security Policy, together with a National Food and Nutritional Security Plan which reflects that policy (**Box 6.8**). This law clarifies the roles and obligations of the bodies that make up the National System for Food and Nutrition Security. This includes the establishment and resourcing of CONSEAs at the state and municipal levels to ensure comprehensive engagement with civil society at all levels. It also includes the establishment of CAISANs at state and municipal levels to coordinate the actions of state and municipal agencies in food security at each level (**Figure 6.1**).

Box 6.8: Key goals of Brazil's National Food and Nutritional Security Policy[54]

Brazil's National Food and Nutritional Security Plan is based on the following goals and principles:

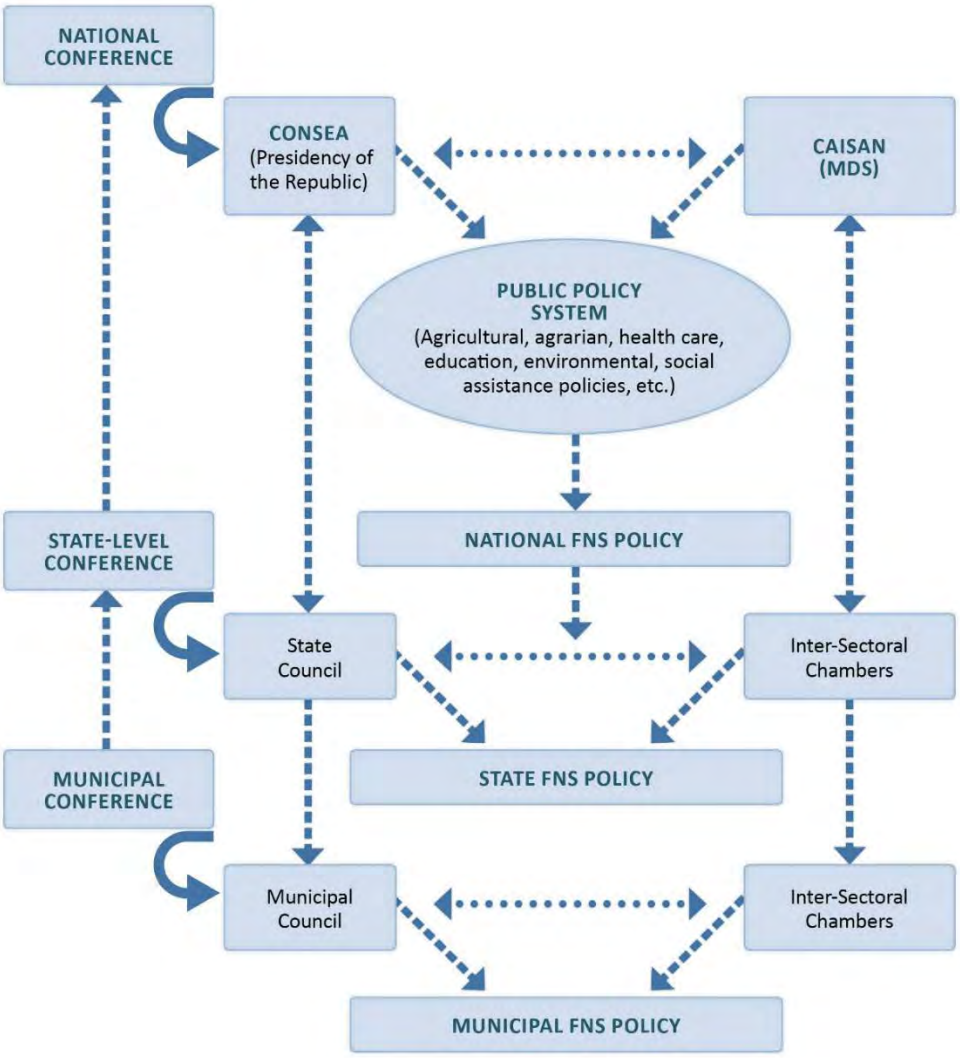
- The promotion of universal access to adequate and healthy food, especially for those living in conditions of food and nutritional insecurity;
- Sustainable, decentralized systems for food production, extraction, processing and distribution;
- Permanent processes for education, research and training in relation to food and nutritional security and the human right to adequate food;
- The coordination of actions to secure food and nutritional security for quilombolas and other traditional communities, and indigenous peoples;
- Integrating activities on food and nutritional security with activities undertaken at all levels of health care;
- Ensuring universal access to a sufficient quantity of water, with priority for those living in conditions of water insecurity, and for family food production, fisheries and aquaculture;
- Support to initiatives to promote food sovereignty, food and nutritional security, and the

human right to adequate food in the international arena;

- Monitoring of the realization of the human right to adequate food.

The articulation of policies and programmes for food security between the federal, state and municipal levels of government occurs through tripartite forums, convened by CAISAN, which provide the link between the intersectoral coordinating agencies of each level of government.[55] These structures are intended to facilitate the administration of programmes which, like the Bolsa Família, depend upon a range of actions being taken by government agencies at every level. The presidential decree specifies the criteria to be met by states and municipalities, and non-profit organizations that wish to become members of SISAN, as well as the financing responsibilities of each level of government.[56] In 2010, Brazil's efforts to improve food and nutritional security were further strengthened through a constitutional amendment recognizing the right to food.[57] Brazil's model for addressing hunger has become an important model for other countries that wish to ensure community participation while integrating government actions across sectors and between different levels of government.

Figure 6.1: Brazil's national food and nutrition security system and policy[58]



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PART 3
PRIORITIES FOR PUBLIC HEALTH LAW REFORM

Introduction

Public health laws provide governments with the tools to protect their populations from avoidable injury and disease, to encourage and support healthy behaviours, and to respond to public health emergencies. Part 3 of this report provides guidance about the content of effective public health laws, together with examples of how governments in different countries are using public health laws to address key challenges affecting their populations.

This Part includes discussion of the legislative powers and duties that often form the core parts of public health laws at national or regional level. The core public health functions of government include: ensuring sanitation, hygiene and vector abatement; conducting surveillance and monitoring of risks to health; controlling infectious diseases; dealing quickly and effectively with public health emergencies; and implementing policies and laws to encourage safe and healthy behaviours.

This Part also describes how public health law can make a substantial contribution to public health in five additional areas. These are: tobacco control, the migration and retention of health care workers, access to essential medicines, obesity and malnutrition, and maternal and child health. These areas were identified during the expert consultation as being critically important to national efforts to realize the right to health. An overarching goal for governments in discharging their obligations under the right to health is to deliver universal access to quality health care and public health services, supported by an effective health system. Chapter 8 outlines the relationship between law and this overarching goal.

Chapter 7: Achieving universal access to quality health services

SUMMARY POINTS

· **Universal health coverage is the goal of ensuring that all members of the population and their communities have access to promotive, preventive, curative, rehabilitative and palliative health services that are of sufficient quality to be effective, without being exposed to financial hardship.**

· **To expand health insurance systems towards achievement of universal health coverage, governments need to make progress along three axes: to "expand priority services, include more people and reduce out-of-pocket payments".[1]**

· **Making progress towards universal health coverage requires governments to strengthen those building blocks of the health system that make it possible to deliver services of high quality. This includes investing in basic infrastructure, human resources and financing systems; developing an effective health information system; systems for procuring and distributing essential medicines, vaccines and technology, and systems for governance and accountability.**

· **Different countries will take different pathways towards universal health coverage. Priorities for law reform are likely to emerge incrementally as countries identify particular problems with the performance of their health systems and seek to remedy them. However, many of the regulatory issues that governments will need to consider relate to: (i) defining membership and entitlements under a health insurance scheme; (ii) regulating health service providers; (iii) financing health services; and (iv) and establishing governing institutions.**

· **Governments scaling up health insurance systems may wish to formally recognize the right of members of the population to access a defined set of benefits or services. Governments may strengthen the implementation of this right – as well as the quality of the health services provided – by creating a formal complaints scheme for those who are not treated in accordance with their entitlements under the scheme.**

· **The right to health imposes an immediate obligation on governments to protect members of the population from discrimination, including discrimination in access to benefits under a health insurance scheme. Governments may consider creating statutory protection for the privacy, confidentiality and security of the health information of members of a health insurance scheme.**

· **Governments should pursue financing systems for health services that avoid two important risks. The first is the risk of catastrophic expenditure (leading to improverishment), caused by the need for large out-of-pocket payments for medical services when a person falls ill. The second is the risk that even modest user fees may dampen demand and create barriers to access for the poorest members of the population. Governments can mitigate these risks by raising funds for expanded coverage through compulsory pre-payment mechanisms, such as taxation and/or compulsory insurance contributions, and by providing an exemption from contributions for those who cannot afford to contribute at any level.**

· **Legal regulation of the financing of health services includes the regulation of revenue collection, legal control of the funding pools that are used to pay for health services, and regulation of the purchasing of health services provided to covered populations.**

· **WHO has recommended that governments consider new ways of increasing their revenues, including by imposing or increasing excise taxes on tobacco and alcoholic beverages, sugary drinks,**

airline tickets or currency transactions.

- **Depending on the structure of the health insurance system, governments may regulate funding pools to ensure capital adequacy and to impose controls over the investment of funds. They may also impose requirements to report to the central government, and impose governance requirements on the entities (health insurance schemes) that administer insurance schemes based on pooled funds.**

- **Private health insurance schemes often coexist with the public schemes that are the vehicle used by governments to scale up coverage. In the case of private insurers, governments typically regulate a wide range of matters including registration and prudential requirements, competition, advertising, premiums, adverse selection and reporting requirements.**

- **In scaling up the health services that are provided from pooled funds, governments have been advised by WHO to place particular emphasis on primary care. Robust primary health care systems are associated with reduced morbidity and premature mortality as well as lower costs.**

- **The health workforce is a crucial input in strategies to scale up the coverage of health services. In addition to regulating the purchasing of services and the remuneration of health care providers, legislative frameworks perform important gateway functions. These include licensing health care providers to practice their profession in the jurisdiction, and accrediting service providers under the health insurance scheme. Governments may also establish quality agencies to support the improvement of quality standards and governance processes across all facilities.**

- **Formal recognition of new professional categories and roles may be required as countries scale up the training and education of the health workforce and adapt to the changing burden of disease.**

- **By imposing licensing requirements on the practice of medicine and other health professions, governments can protect the public from unskilled and poorly skilled individuals who claim the right to provide medical services. Some countries have introduced national councils that oversee registration, continuing professional education and professional conduct across a range of health professions.**

- **Licensing requirements for health professionals should be sufficiently flexible to permit the delivery of emergency health services by authorized personnel following a natural disaster or other public health emergency. This may include foreign health professionals contracted to international agencies or to accredited nongovernmental organizations.**

- **Legislation may create a range of offences for inappropriate medical practice; for example, forging documents, using unapproved medicines, carrying out experimental treatment without consent, and soliciting or illegally accepting money and gifts from patients.**

- **Governments may consider requiring accredited health care providers to contribute to premium-based compensation schemes for individuals who are injured through medical negligence or substandard care, or who are victims of criminal offences committed by health professionals.**

- **Establishing governing institutions is an important part of the law reform process as countries scale up towards universal health coverage. Two important institutions commonly seen in health insurance systems are a national health insurance authority, and a medicines regulation authority. In some countries, the functions of both agencies may be merged into a single institution.**

- **The key functions of a national health insurance authority charged with improving population coverage include registering members, collecting health insurance contributions, managing pooled funds, accrediting, contracting and reimbursing health service providers, and complying with government reporting requirements.**

· **The functions of a medicines regulatory authority include assessing and authorizing the entry of medicines into the country (drug registration), monitoring safety and effectiveness, regulating domestic manufacturing, importation and distribution of drugs, and regulating pharmaceutical advertising. In order to perform these functions, regulatory authorities commonly perform a wide range of more specific functions set out in legislation.**

· **The experience of Ghana illustrates the role of legislation in establishing and expanding a national health insurance scheme.**

Universal health coverage (UHC) has emerged as a unifying concept and goal for governments as they seek to strengthen their health systems and to discharge their obligations under the right to health.[2] UHC is the goal of ensuring that all members of the population have access to promotive, preventive, curative, rehabilitative and palliative health services that are of sufficient quality to be effective, without being exposed to financial hardship.[3] In 2015, the United Nations General Assembly adopted a global target for UHC as part of the Sustainable Development Goals. This target states: "Achieve UHC, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all" (Target 3.8).[4] The right to health, as recognized in international human rights law, directs attention to a wide-ranging set of features that may assist governments to strengthen their health systems and to accelerate their progress towards UHC.[5]

7.1 The concept and scope of universal health coverage

The quality services that governments are obliged to make universally accessible include health services delivered to individuals in hospitals, in primary care facilities and in other community settings. These include diagnostic services, medical procedures, the provision of essential medicines, palliative care and preventive services such as immunizations and perinatal health assessments. In addition, UHC encompasses the delivery of services to the population as a whole, or targeted segments of it, through information campaigns, vector control, the performance of public health regulatory functions, and other public policies addressing the determinants of health.

Making progress on the overarching goal of UHC requires governments to strengthen those building blocks of the health system that make it possible to deliver services of high quality (see Table 1.1). Health financing is a critical component, since all functions of the health system depend upon adequate and sustainable financing. Other vital components of the delivery of quality health services include the training, development and retention of the health workforce; strategies for achieving universal access to essential medicines, vaccines and technology; the development of an effective health information system; management of infrastructure and capital investments; mechanisms for governance and accountability, and effective leadership at senior levels.[6] Health systems are complex: making progress with each of the building blocks is necessary to make progress towards the overall goal of UHC. For example, it will not be feasible to expand the range of health services available under a health insurance system, or to extend the coverage of services to more people, unless countries simultaneously invest in the development of their health workforce. Countries that

have made strong progress towards UHC have prioritized their health workforce needs, investing in workforce planning, training, improving remuneration systems and in governance frameworks.[7]

In addition to investing in the health system itself, the goal of UHC requires governments to implement public policies to address the broader determinants of health, many of which lie outside the health sector.[8] This is partly why the goal of UHC requires a government-wide commitment, supported by governance mechanisms and other practical ways of achieving cooperation between government sectors (see further, Chapter 6).

This report provides examples of the law's role in both strengthening health systems and addressing the broader determinants of health that lie outside the health sector, as governments seek to move towards UHC (see **Table 7.1**). Progress towards UHC will be reflected in efforts to:

- expand the range of health services that are accessible by individuals and populations (a generous benefits package);
- expand the proportion of the population who are covered by those services (by scaling up the capacity of service providers to deliver a sufficient volume of services to meet the needs of the covered population);
- increase the quality of health services; and
- improve the affordability of health services (financial protection).

Table 7.1: Important ways that law can support progress towards universal health coverage

Strengthening the building blocks of the health system	**Implementing public policies to reduce health risks affecting the population**
Examples: • Reducing financial exposure when accessing health services: Section 7.2(b); Section 7.3 • Establishing legal frameworks for surveillance, and the management and use of health information: Chapter 9 • Retention and regulation of the health workforce: Chapter 14 • Facilitating universal access to essential medicines at affordable prices: Chapter 15 • Strengthening leadership and coordination within government, including through processes to facilitate intersectoral action on health risks: Chapter 6	*Examples:* • Establishing legal frameworks for clean water, sanitation and vector abatement: Chapter 8 • Controlling infectious diseases: Chapter 10 • Establishing legal powers and agreed processes for dealing with public health emergencies: Chapter 11 • Reducing the occurrence of injuries: Section 12.2 • Reducing the burden of disease from tobacco use (Chapter 13), obesity and undernutrition (Chapter 16), and other risks for noncommunicable diseases: Section 12.1. • Preventing violence, discrimination, and other risks to maternal and child health: Chapter 17

7.2 Legislative frameworks supporting the provision of health services

Legal frameworks are an essential part of the fabric or structure of an effective health system. Seen from outside, the function and purpose of legal and regulatory structures may not always be visible, but without them, roles, powers and responsibilities may be unclear, accountability absent, institutions may be missing, and vital functions may be performed haphazardly, or not at all. However, laws are neither self-executing, nor sufficient by themselves. Laws must be enforced, and legislative frameworks function as parts of broader, integrated systems for the financing, administration and delivery of health services.

This section adopts a very simple framework for presenting some examples of legal and regulatory issues that may arise as governments move towards expanding national health insurance systems. Building on the UHC cube discussed in Section 1.2, governments may use legislation and regulatory processes to:

- define membership and coverage under a health insurance scheme (the population axis);
- introduce funding mechanisms and regulate for greater affordability (cost axis);
- regulate health service providers and service provision (the service axis); and
- establish governing institutions and processes.

(a) Memberships, coverage and entitlements

Recognizing the legal entitlement of all members of the population to have access to essential health services, vaccinations, essential medicines and technologies – without discrimination based on inability to pay – provides a foundation for planning and resource allocation as governments move towards UHC. Recognition of such a right does not require the government to become the sole provider of all health services. However, it does commit the government to pursuing those intermediate objectives that will help to achieve the broader goal of UHC.

The process for expanding coverage under a health insurance scheme will usually involve formally defining the parameters of programme entitlements, including any means-tested exemptions, co-payments, safety nets and rights of access for those who cannot afford to pay. Registration systems for government-subsidized health insurance schemes may involve systems for ensuring proof of identity and membership (e.g. identity cards or other identifiers), in order to enable the monitoring of claims submitted by health providers and utilization of the scheme by enrolled members.

In order to facilitate access to the scheme by those it is intended to benefit, governments may consider building a right of access into the design of the scheme, such as through a patient charter of rights, coupled with a complaints system for the investigation and conciliation of complaints by those who are not treated in accordance with their entitlements. The right to health imposes an immediate obligation on governments to prevent discrimination in access to services on a range of prohibited grounds. These grounds include race, colour, sex, language, religion, political opinion, national or social origin, property, physical or mental disability, health status and sexual orientation.[9] Protection from unlawful discrimination implies that individuals will have adequate access to a

mechanism for making complaints about discrimination, such as an ombudsman or discrimination commissioner. Discrimination may occur not only by excluding an individual from coverage or by refusing to provide services covered by the scheme on grounds prohibited by law, but by failing to treat an individual with dignity, through inferior levels of service, or by imposing unjustified additional requirements. The regulation of membership and coverage under a health insurance system extends to statutory protection for the security, privacy and confidentiality of health information about enrolled members.

(b) Financing of health services

There are vast discrepancies between countries in the amount of total spending on health per person, in total government spending on health per person, and in the share of private expenditure on health as a percentage of total expenditure. For example, in 2012, Norway, a high-income country with a well-developed social security net spent US$ 9312 on health, although US$ 7919 of this total was made up of government spending, meaning that private spending was about 15%. By contrast, in a number of low-income countries around the world, total health spending per capita is only a few tens of dollars, and a high percentage of this is private spending (exceeding 70% in some countries).[10]

Access to a set of priority health care services for all members of the population requires a financing system that avoids two important risks. The first is catastrophic expenditure (leading to improverishment),[11] caused by the need for large out-of-pocket payments when a person falls ill. The second is the risk that even modest user fees, and other bureaucratic requirements (eg the need for annual re-enrolment) will dampen demand and create barriers to access for the poorest households in low-income countries.[12]

Countries that have come closest to achieving UHC raise funds to pay for health and medical services through compulsory pre-payment mechanisms, such as taxation, compulsory insurance contributions or, frequently, a combination of both.[13] At the same time, universal access to priority health services cannot be achieved unless governments cover the cost of services for those who cannot afford to contribute at any level.[14] There is strong evidence that both community-based health insurance schemes, and social health insurance schemes (typically based on mandatory, salary-based contributions), can improve financial protection as well as the use of health care services by insured persons.[15]

For example, Rwanda first introduced community-based health insurance schemes (known as *mutuelles*) in 1999, with participation and annual premiums organized on a household basis. Enrolled households are affiliated with a local health care centre, which provides referral for hospital services covered by their *mutuelle.*[16] In 2012–2013, 86% of the population was covered under this scheme. The government pays premiums for 25% of the population, consisting of people who are classified as vulnerable, subsidizing the provision of services through payment of block grants to administrative districts.[17]

In nearly all OECD countries, public sector financing accounts for the majority of health care financing.[18] The World Health Assembly has urged Member States to develop their health financing systems in order to reduce out-of-pocket payments at the time of service delivery and to pool risks

among the population in order to avoid catastrophic health care expenditure by those in need of care.[19]

Legal regulation of the financing of health services includes the regulation of revenue collection, legal control of the funding pools that are used to pay for health services, and regulation of the purchasing of health services provided to covered populations.[20] WHO has recommended that governments increase the public funds that are available for health financing by improving revenue collection, and by giving greater priority to health within national budgets.[21] WHO has also encouraged governments to consider innovative ways of increasing revenue, such as imposing or increasing excise taxes on tobacco and alcohol products, sugary drinks, airline tickets or currency transactions.[22]

The regulation of revenue collection is conceptually distinct from the regulation of fund pooling. Revenue collection includes the mobilization of funds through general taxes, voluntary or compulsory insurance premiums paid by employers or households, and donations from development partners. Fund pooling refers to the control of those monies for the benefit of the beneficiaries of the health insurance system, and includes the governance of institutions that control fund pools.[23] Fund pooling permits governments to reduce duplication and to create economies of scale, and to require that revenues from higher income contributors are used to cross-subsidize the provision of services to those on lower incomes.

Depending on the structure of the health insurance system, the government may regulate funding pools to ensure capital adequacy and to impose controls over the investment of funds. It may also impose requirements to report to the central government, and impose governance requirements on the health insurance entities that administer insurance schemes based on pooled funds.[24] Governments may also make scheme membership mandatory for eligible households, prohibit medical underwriting (risk-adjusted premiums based on medical history), and link premiums to household income. In many countries, private health insurance schemes pre-date social health insurance schemes, community-based health insurance schemes and other vehicles used to pursue the goal of UHC.[25] In the case of private insurers, governments may need to address a wide range of issues, including prudential requirements, consumer protection, competition, advertising, adverse selection, premiums and mechanisms for government oversight.[26]

The regulation of purchasing refers to the regulation of the financial relationship between providers of health services and government agencies, health insurance schemes or other entities purchasing health services on behalf of enrolled populations.[27] For example, providers may be employed on salary, or remunerated on the basis of fee-for-service, but strong demand, cost escalation and/or the risks of over-servicing often require governments to trial other approaches, such as capitation or use of fixed rate reimbursement based on diagnosis-related groups.[28] A number of countries have considered performance-based financing as a way of expanding child immunization and coverage of other health services (**Box 7.1**).

Box 7.1: Improving health systems through performance-based financing

While performance-based financing can take many forms, the common theme is to formalize the relationship between a central government or funder of health services and the different

organizational units of the health system. Payment is then based on organizational units meeting the performance criteria set out in a contract or agreement with the funder, rather than being based on inputs, such as salaries and pharmaceuticals.[29] Well-designed performance-based financing systems can attract a high level of commitment from health professionals, through incentives or additional funding for those organizational units that exceed basic performance standards.

Health service providers that are subject to performance-based funding may be more likely to demand performance and accountability from other parts of the health system that they depend upon (for example, for data collection, the supply of pharmaceuticals, or the roll-out of national programmes) and to respond to the populations they serve in more flexible ways (e.g. with home visits, community outreach programmes, subcontracting to community organizations and more flexible workings hours). Performance-based financing may be useful not only for the funding of child immunization, and the provision of antenatal and postnatal health care, but for improving diabetes management, smoking cessation and other risk factors for noncommunicable diseases.[30]

(c) Health services and health service providers

UHC requires governments not only to expand the range of services provided in the benefits package, but also to expand the capacity or volume of the services provided in order to achieve greater population coverage. The service axis therefore requires a focus both on the services themselves, and on the production and regulation of service providers and on other inputs that are needed in order to expand service provision.

WHO has advised governments that are moving towards UHC to place particular emphasis on primary care, taking account of the health inequalities that exist within countries based on disparities in income, education, employment status, geographical location and membership of different ethnic, racial or religious groups.[31] Some key features of primary health care, as this term is used by WHO, are set out in **Box 7.2**. Providing a minimum package of integrated services, based upon population health needs, that ensures continuity of care and affordable access to all members of the population, including those in rural and remote areas, should be the overriding goal.

Box 7.2: Distinctive features of people-centred, primary health care systems[32]

A responsive, people-centred primary health care system:

- focuses on the health needs of the population and aims to provide a comprehensive package of health services for all ages, rather than targeting particular groups, or a limited set of priority diseases;
- provides continuity of care, through well-articulated referral systems, rather than fragmented and episodic relationships, or disease or programme-specific interventions;
- makes health care available to all, irrespective of ability to pay;
- resists all forms of discrimination that create obstacles to access and equity;
- places the emphasis on “close-to-client” care provided locally, rather than on hospitals or specialist practitioners;

- uses the primary care team as a coordinating centre for referral to specialist health care services when required;
- is responsive to the population it serves, providing both curative and palliative care, as well as preventive services and health promotion;
- works in partnership with people to improve their health and the health of the wider community, builds bridges to the wider community, and addresses the social determinants of ill-health.

The health workforce is a crucial input – but all too often a limiting factor – in strategies to scale up the coverage of health services.[33] In addition to regulating purchasing and remuneration, legislative frameworks perform important gateway functions: licensing health care providers to practice their profession in the jurisdiction and accrediting health clinics and health service providers under a health insurance scheme. Licensing and accreditation play an important role in safeguarding quality of care and in improving accountability for the delivery of health services. In addition, they may enable countries to innovate and to adapt their health workforce to meet new challenges. For example, in 2014, Tonga graduated its first cohort of nurses specializing in the prevention, detection and management of noncommunicable diseases.[34] Tonga's noncommunicable disease nurses illustrate the fact that new professional categories and designations may be required as countries both expand the production of health care workers and adapt to the changing burden of disease.

Licensing requirements allow authorities to impose prerequisites for those who wish to practise medicine, the allied health professions and other technical roles. For example, medical practitioners are typically required to complete a medical training course or degree at a recognized medical school, to successfully pass State medical exams, to complete a period of practical training in a medical facility (a medical internship), to fulfil ethical and character requirements and to maintain their knowledge of their field. Additional requirements apply to medical specialists. In some countries, a national council oversees and supports the operations of professional boards representing the different professions (**Box 7.3**). By imposing licensing requirements on the practice of medicine, or by formally recognizing the entry requirements imposed by respected professional bodies, governments can protect the public from unskilled and poorly skilled individuals who claim the right to provide medical services. Licensing requirements may be imposed upon medical practitioners, nurses, and other allied health professionals at national or state level.

Box 7.3: Gateway requirements for the practice of medicine: an example from South Africa

The Health Professions Council of South Africa (HPCSA), a national body established by the Health Professions Act 1974, regulates the medical and allied health professions in matters including registration to practice, education and training and professional conduct.[35] The South African Nursing Council, established by the Nursing Act 2005, performs a similar function for the nursing profession. Registration by the HPCSA is a prerequisite for practising as a medical practitioner or in one of the other professional categories recognized by each of the 14 professional boards.[36] The HPCSA accredits medical programmes and aspiring doctors are required to attend an accredited university and participate in an internship at an accredited facility. The Medical and Dental Board

registers practitioners who meet specified criteria under a range of professional categories. Each of the boards that operate within the framework of the HPCSA may enquire into allegations of unprofessional practice by health practitioners and impose penalties in appropriate cases, including fines, suspension from practice or removal of registration.[37]

Under China's law on medical practitioners, adopted in 1998, health administration departments at the county level and above are responsible for regulating medical practitioners within their respective regions, overseen by the health administration department under the State Council.[38] Those with bachelor degrees in medicine who have completed a one year internship may sit the state exam; those who pass may apply to their local health administration department for registration, and following registration, may practice at medical institutions in accordance with the location, category and scope of their registration.[39] Doctors with five years' experience at medical institutions may apply for approval for private practice. Local health administration departments have a variety of responsibilities, including maintaining a list of registered and deregistered doctors, assessing the continuing professional performance of practising doctors, and providing continuing medical education.[40] The law specifies a number of legal responsibilities of practicing doctors and provides for warnings, suspension or revocation of registration for those who fail to meet these requirements. Grounds for prosecution (including criminal prosecution) include malpractice, forging documents, using unapproved medicines, carrying out experimental treatment without consent, soliciting or illegally accepting money and gifts from patients, and making improper use of one's position.[41] The law authorizes local health administration departments to close unapproved medical treatment facilities and to confiscate illegally-obtained income, medicines and equipment.[42]

When framing licensing requirements, governments should be aware of the need for flexible arrangements for authorizing the delivery of emergency health services by authorized personnel following a natural disaster, pandemic or other public health emergency. Creating a process to expedite approval by executive order during an emergency ensures that communities will not be deprived of medical care at the time they most require it. Where appropriate, medical and health care services may be delivered by health professionals contracted to international agencies, accredited nongovernmental organizations, or attached to the security forces of a friendly government that is performing disaster relief functions in partnership with national authorities.

Governments may also consider requiring accredited health care providers to contribute to premium-based compensation schemes for individuals who are injured through medical negligence or substandard care, or who are victims of criminal offences committed by health professionals. Although individuals can seek legal remedies through court actions, governments in some countries have established health care complaints agencies as alternative dispute resolution systems to investigate and conciliate complaints about medical care and to uphold compliance with codes of conduct adopted by the profession. Legislation may also support health care complaints schemes by defining what constitutes inappropriate care or medical misconduct.

In addition to licensing health professionals, governments may also impose licensing requirements and accreditation criteria upon hospitals, nursing homes and other health care establishments, not only to improve accountability and to identify the best-performing institutions, but to support the improvement of quality standards across all facilities.[43] In some countries, government agencies or

an independent agency perform accreditation functions. In Argentina, the Technical Institute for Accreditation of Health Care Organizations – a nongovernmental non-profit organization – provides voluntary accreditation to both public and private hospitals according to Pan American Health Organization standards.[44] In performing these functions, regulatory agencies must avoid any conflict of interest with businesses that own or run health care establishments for profit.

(d) Governing institutions

The capacity of governments to expand the range, coverage, affordability and quality of health services will depend on their capacity to manage, coordinate and expand the underlying resources (inputs) needed to deliver those services. Underlying resources include physical infrastructure, human resources, health information, medicines, vaccines, health technology, funding streams and payment systems.[45] Expanding towards UHC requires simultaneous investments in each of these areas, as well as governing institutions to coordinate and integrate their functions. In some countries, this coordinating role may be performed by a single national health insurance commission or authority; in others, a large number of community or employment-based health insurance schemes may share governance functions. Key functions include registering members, collecting health insurance contributions, managing pooled funds, accrediting, contracting and reimbursing health service providers, and complying with government reporting and other legislative requirements.

However the system is organized, governments nevertheless retain an overarching stewardship role, which may be partly delegated to purpose-built institutions.[46] Stewardship functions include the overall design of the health insurance system, assessment of its performance, advocacy for the policies and coverage goals of the system within the political structures of government, the performance of regulatory functions, and accountability for progress towards the realization of the right to health for all members of the population.

Improving the performance of institutions is an important part of the law reform process as countries move towards UHC. In turn, institutions will themselves be subject to administrative and financial requirements. For example, governing legislation may include requirements relating to: the appointment, tenure and removal of senior executives, the establishment of principal committees, units and directorates, and provisions relating to meetings and conflicts of interest. Governing legislation may also specify a level of direct government control over the organization (e.g. through ministerial directives), and include provisions relating to accounts, auditing requirements and annual reports.

Two important institutions commonly seen in health insurance systems include a national health insurance authority (discussed in the following section), and a drugs and medicines regulation authority. A drug regulation agency performs three important roles. The first is drug registration, including assessing and authorizing the entry of medicines into the market, and monitoring their safety and effectiveness. The second is regulation of manufacturing, importation and distribution of drugs. The third is regulation of pharmaceutical advertising and the provision of information.[47] In order to fulfil these roles, regulatory authorities may perform a range of more specific functions (see **Box 7.4**). In order to fulfil all of these roles effectively, and to negotiate contracts for the bulk

purchasing of essential medicines, drug regulatory authorities should be centralized at the national level.

Box 7.4: Some regulatory functions of a national medicines administration authority[48]

- Establishing a national list of essential medicines that responds to country-specific needs and disease burden, with a focus on primary care;
- Licensing drug manufacturers, wholesalers and other drug dispensers, and monitoring good manufacturing practices;
- Establishing evidence-based clinical guidelines for rational use of prescription medicines;
- Monitoring demand for essential medicines and monitoring prices in the public and private sectors;
- Educating prescribers and establishing financial incentives for prescribers to substitute generic brands;
- Preferential registration and quality assurance of generic medicines;
- Working with donors to reduce duplication of distribution systems;
- Investigating counterfeit medicines and referring cases to law enforcement authorities;
- Negotiating prices and licences on behalf of government-funded or subsidized health insurance schemes;
- Monitoring safety and quality of medicines and investigating safety issues – using legal powers to inspect premises, to remove, test and recall products, and to restrain misleading and fraudulent practices;
- Negotiating prices on behalf of government-funded and subsidized schemes;
- Advising the government on use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

7.3 The role of legislation in defining a national health insurance scheme: case study from Ghana

Ghana's National Health Insurance Scheme provides a helpful case study of the role of legislation in creating the governing institutions and formalizing the funding mechanisms for UHC. Ghana's experience may be relevant to other countries where responsibility for the provision of health services is decentralized, where a large proportion of the uninsured population works in the informal sector, and where many of those covered by the scheme cannot afford to contribute through premiums or user fees. The national health insurance model Ghana introduced in 2003 was based on service provision through a network of semi-autonomous, district-based mutual health organizations, strengthened by national governance and financing mechanisms. A decade later,

however, Ghana passed legislation that created a single agency (the National Health Insurance Authority) with district offices.[49]

(a) Legislative regulation of Ghana's National Health Insurance Scheme

Governing institutions

Ghana's National Health Insurance Act 2003 established the National Health Insurance Authority (NHIA), with the goal of replacing a user pays policy with a national health insurance scheme providing basic health care services to all residents.[50] The Act required each district to establish a mutual health insurance scheme for residents of that district, which was registered as a company limited by guarantee under Ghana's Companies Act.[51] The Act authorized three kinds of health insurance schemes: district mutual health insurance schemes, private mutual health insurance schemes, and private commercial health insurance schemes.[52] However, it was the district schemes that provided the basis for a system of national coverage. The NHIA's functions included registering, licensing and regulating health insurance schemes, granting accreditation to health care providers, monitoring their performance and ensuring the quality of services delivered to beneficiaries of schemes. The NHIA maintained a register of licensed health insurance schemes and accredited health care providers[53] and was authorized to inspect and investigate schemes and issue enforceable directives.[54] The NHIA also managed the National Health Insurance Fund, which subsidized the provision of health services by district mutual health insurance schemes.[55]

Membership and coverage

The 2003 Act made district schemes responsible for enrolling residents of each district as members, obtaining membership contributions, issuing health insurance identity cards, and administering a means test for indigent persons.[56] The legislation prohibited schemes from discriminating against a person with respect to their admission as a member of a scheme on the basis of "race, sex, disability, marital status, ethnicity, social origin, nationality, religion or creed".[57] The Act also stipulated that the subsidy that mutual health insurance schemes received from the National Health Insurance Fund would not be paid unless the Council (the governing body of the NHIA) was satisfied that persons had not been excluded from membership based on their physical disability, social, economic or health status.[58]

Regulation of health services and health service providers

The 2003 Act required health insurance schemes to use the services of health facilities and health care providers that had been accredited by the NHIA.[59] The Regulations set out the accreditation requirements for defined classes of health care facilities and for health professionals.[60]

The 2003 Act also required all licensed schemes to provide the minimum health care benefits set out in the Regulations, thus ensuring a nationally applicable set of priority services.[61] These included outpatient services (including laboratory, X-ray and ultrasound services), inpatient services, oral

health and eye care services, maternity care (antenatal and postnatal care, deliveries – including caesarean sections), and all emergencies.[62] Minimum benefits also include the prescription medications included in the National Health Insurance Scheme Medicines List.[63] The Regulations set out a list of public health services that were to be paid for by the government and were to be free to all members of the population, including immunization, family planning, treatment of mental illness, HIV testing, and treatment of tuberculosis, onchocerciasis, Buruli ulcer and trachoma.[64] Health care services excluded from the scheme were also defined.[65]

Except in emergencies, the Regulations required primary health care facilities to act as gatekeepers, referring patients to secondary and tertiary care services as appropriate.[66] All health care facilities were required to adopt the referral protocols, practice guidelines and health resource sharing arrangements approved by the Council as a requirement for accreditation.[67] Accredited facilities were required to submit quarterly reports containing specified data to enable the Council to monitor the performance of health care facilities and pharmaceutical service providers.[68] The Regulations also set out the circumstances in which health insurance schemes were authorized to refuse payment for services provided by health care facilities.[69]

Financing

The 2003 Act required members of district mutual health insurance funds to make membership contributions. However, several classes of people were exempt, including dependent children under 18, pensioners, persons aged 70 years or older, and (subject to a means test) indigent persons with no fixed place of residence or source of income.[70] Unlike private schemes, district mutual health insurance schemes were paid a subsidy from the National Health Insurance Fund, at a level determined by the Council and approved by Parliament.[71] The Fund was financed from a number of sources. These included:

- membership contributions (subject to exemptions including those mentioned above);
- a health insurance levy of 2.5% on selected goods and services (with exemptions on medical services, pharmaceuticals, water, education, and mosquito nets);[72]
- a 2.5% deduction from formal sector contributions to Ghana's Social Security and Pensions Scheme Fund;
- parliamentary allocations, and investment income.[73]

No co-payments or up-front fees were required at point of service for services covered by the scheme.[74] Under the 2003 Act, the Council, as the governing board of the NHIA, determined the tariffs or levels of reimbursement for health services, in consultation with health care facilities and schemes. The Act authorized payment on the basis of fee-for-service, capitation payments or on any other basis that the Council determined.[75]

Evolution of the scheme under the 2012 Act

Community-based, mutual health insurance schemes have the advantage of being flexible, responsive to their members and based on the values of solidarity and mutual assistance.

Community-based schemes may therefore have greater capacity to generate trust and to enrol members from among those who were previously excluded from health coverage for financial or administrative reasons. However, in order to harmonize National Health Insurance Scheme operations, improve service delivery, and address a number of problems (including inefficiencies, difficulties in achieving portability, and irregular billing practices), Ghana repealed its 2003 Act and introduced a centralized health insurance scheme through the National Health Insurance Act 2012.[76]

The 2012 Act created a single-payer system, overseen by the NHIA, with the stated goal of universal health insurance coverage and access to health care services for all residents of and visitors to Ghana.[77] The Act established a multidisciplinary governing board for the NHIA,[78] and three specialist committees with specific oversight functions. These included the Finance and Investment Committee, overseeing the management of the National Health Insurance Fund, and the National Health Insurance Oversight Committee. This last committee advises the Board with respect to systems for registration of members in the national scheme, the benefits package available under the scheme, the credentialing of health service providers, tariffs payable to health care providers, and mechanisms for submission and adjudication of claims by service providers.[79] The Act provides for the appointment of executives of the Authority, and members of the board, and authorizes the board to establish directorates for the performance of functions of the Authority. The key functions of the Authority under the 2012 Act are set out in **Box 7.5.**

Box 7.5: Key functions of Ghana's National Health Insurance Authority

In order to achieve its objective of attaining universal health insurance coverage for all residents, the National Health Insurance Act 2012 (Act 852) authorizes the Authority to:

(a) implement, operate and manage the National Health Insurance Scheme;

(b) determine in consultation with the Minister contributions that should be made by members of the National Health Insurance Scheme;

(c) register members of the National Health Insurance Scheme;

(d) register and supervise private health insurance schemes;

(e) issue identity cards to members of the National Health Insurance Scheme;

(f) ensure

(i) equity in health care coverage;

(ii) access by the poor to health care services;

(iii) protection of the poor and vulnerable against financial risk;

(g) grant credentials to health care providers and facilities that provide health care services to members of the National Health Insurance Scheme;

(h) manage the National Health Insurance Fund;

(i) provide a decentralized system to receive and resolve complaints by members of the National Health Insurance Scheme and health care providers;

(j) receive, process and pay claims for services rendered by health care providers;

(k) undertake public education on health insurance on its own or in collaboration with other bodies;

(l) make proposals to the Minister for the formulation of policies on health insurance;

(m) undertake programmes that further the sustainability of the National Health Insurance Scheme;

(n) develop guidelines, processes and manuals for the effective implementation and management of the National Health Insurance Scheme;

(o) ensure the efficiency and quality of services under the national and private health insurance schemes,

(p) protect the interest of members of private health insurance schemes;

(q) identify and enrol persons exempt from payment of contributions to National Health Insurance into the National Health Insurance Scheme;

(r) monitor and ensure compliance with this Act and any Regulations, guidelines, policies, processes and manuals made under this Act; and

(s) perform any other function conferred on it by this Act or that are ancillary to the object of the Authority.

Under the 2012 Act, membership of the scheme is mandatory for all residents, although residents must still apply for registration to the Authority, which issues membership cards.[80] The Act requires the Minister to prescribe the health care benefits package provided under the National Health Insurance Scheme, and the Authority must assess the continued suitability of the benefits package every six months.[81] The Authority must also develop a list of the medicines that may be prescribed under the scheme and the prices that can be charged for these medicines, and review these annually. Similarly, the Authority must review the list of health services and service tariffs that may be charged by health care providers, and may add or remove diagnoses, procedures and examinations and review prices.[82] The 2012 Act also sets out a variety of offences that apply to officers of the Authority, to members of the National Health Insurance Scheme, and health care providers who provide services under the scheme.[83]

(b) Ghana's National Health Insurance Scheme and the dimensions of universal health coverage

Ghana's experience illustrates the central role of legislation in implementing a national health insurance scheme. This includes creating governing institutions and providing for their administration and financial accountability. It also includes formalizing the roles and responsibilities of the government and of health service providers, and the entitlements of members of the scheme. This section briefly reviews how Ghana's legislation addressed each of the three axes or dimensions of UHC, as discussed in Section 1.2. WHO's UHC model directs attention to ways of:

- expanding the population covered by the scheme;
- expanding the services provided under the scheme; and
- improving affordability, by reducing out-of-pocket payments and moving towards pre-payment.[84]

The key institutions created by or under the 2003 Act included the NHIA itself, and the district-based, mutual health insurance schemes. Other significant governance mechanisms included the

establishment of the National Health Insurance Fund and the National Health Insurance Levy. Under the 2012 Act, the network of mutual health insurance schemes became branch offices of the NHIA.

Population axis

Under the 2003 Act, district schemes were responsible for expanding the covered population by enrolling new members. This was supported by legislation prohibiting discrimination on a number of grounds. Under the 2012 Act, the NHIA assumed responsibility for registering members, and its functions included educating the population about the benefits of the scheme. Employers were also required to ensure that employees are registered under the scheme.[85]

Expanding membership includes registering new members and verifying identities, in order to reduce the risks of over-servicing and inappropriate billing. There is also a human dimension to expanding population coverage: members must be treated with dignity and respect at point of care, regardless of their economic or social circumstances. Ghana is moving towards biometric registration and on-the-spot issuance of identity cards to new members. Other challenges include identifying and enrolling those who, although not exempt from paying premiums, exist on low and precarious incomes in the informal sector.[86]

Services axis

Under the 2003 Act, the range of covered health services was defined in the Regulations, and the licensing of schemes and the accreditation of health facilities and health care providers was stipulated as a central function of the NHIA. The inspection and accreditation of health care providers and health facilities continued under the 2012 Act. The NHIA reviews the benefits package regularly, and conducts an annual review of the medicines that providers are entitled to prescribe under the scheme, and of the services and supplies for which providers are entitled to charge.[87]

The provision of health services and the administration of the health insurance system both depend on human resources. The scaling up of Ghana's national health insurance scheme therefore depended on parallel strategies to increase the production of health workers.[88]

Cost axis

The 2003 Act sought to eliminate out-of-pocket payments by switching from fee-for-service to pre-paid membership contributions paid by enrolled members with defined exemptions, including for indigent persons. Mutual health insurance organizations were subsidized by the National Health Insurance Fund, which was financed from a variety of sources. Arrangements for the regulation of the Fund, and the administration of the National Health Insurance Levy that partly funds it, were continued under the 2012 Act.[89] Like its predecessor, the 2012 Act provides for oversight of private commercial and private mutual health insurance schemes that operate independently of the national health insurance scheme. Private schemes are not permitted to be subsidized from the National Health Insurance Fund.[90]

As population coverage increases, the cost of paying for cover under the scheme is also likely to increase. Revenue sources to support financial sustainability could include higher excise taxes on tobacco and alcoholic beverages, a tax on sugary drinks or electronic communications services, a levy on extractive industries, or an increase in the National Health Insurance Levy.[91] Raising membership contributions and reviewing exemptions is also possible, but carries the risk of further excluding those on low incomes and in precarious employment.

A single-payer health insurance scheme also creates risks of over-servicing. Administering authorities need the capacity to monitor claims, strong clinical and internal audit capabilities, and the capacity to investigate inappropriate billing practices and to refer appropriate cases for prosecution. No insurance scheme can remain financially sustainable if a culture of inappropriate billing practices takes root among health service providers, or if additional fees are gouged from members in ways that drive indigent and low-income persons away from the scheme. In response to cost pressures, Ghana's NHIA has trialled capitation payment systems, strengthened its clinical and internal audit divisions, introduced a centralized, consolidated account for collecting premiums, centralized its claims processing and payment functions, strengthened the enforcement of the Ministry's gatekeeper policy, improved the rational prescribing of medicines by linking diagnosis to treatment, and introduced electronic claims submission.[92] Like several other African countries, Ghana is also moving towards innovative, mobile systems for registering members and collecting premiums.[93]

Quality

The 2003 Act sought to address service quality in a number of ways; for example, by requiring health care facilities to adopt quality assurance standards,[94] by requiring schemes to pay accounts submitted by service providers within four weeks, and by requiring licensed schemes to provide a procedure for settling complaints.[95] The 2012 Act requires the Minister to appoint an Adjudication Committee, with membership from a range of professional associations, to hear complaints made by a member of the scheme or by a health care provider accredited to the scheme, or complaints referred to it by the Board.[96] Members of the National Health Insurance Scheme must also be informed about complaint and dispute resolution mechanisms at the time of registration.[97] The Authority is also required to ensure that health care providers "implement policies that guarantee quality health care to members … and carry out clinical audits".[98]

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Chapter 8: Clean water, sanitation and vector abatement

SUMMARY POINTS

· **Safe, clean drinking water and sanitation facilities are essential to the enjoyment of life and to the right to health. Water and sanitation laws are also fundamental components of a modern public health system.**

· **Water management laws may impose general duties on local governments and town councils to provide, protect and conserve sources of clean drinking water. Discharging this duty will require a range of supporting powers. These may include the power to enter and acquire land, to access sources of water on just terms, to purchase water rights, to construct reservoirs and water storage tanks, to inspect waterworks and maintain pumping and other equipment, to test water supplies, and to enter into contracts for the supply of water sourced from within or beyond the relevant local government area.**

· **Health inspectors should be empowered to test water quality and to control or regulate any activities that are reasonably likely to contaminate public water supplies. These powers should extend to the disposal of waste and refuse, including animal remains. Subject to constitutional considerations, governments should consider ways to ensure that the health ministry retains oversight and ultimate responsibility for the provision of clean drinking water.**

· **Water management and sanitation laws should include duties on landowners and occupiers of premises to ensure adequate drainage of waste and flood water, to dispose of domestic waste appropriately, as well as a general duty not to pollute or contaminate sources of drinking water and water catchment areas.**

· **Although imposing user fees may help to conserve scarce water supplies, the privatization of water provision services may potentially result in inequitable levels of access or increase disease rates. Governments should only proceed with privatization if this is accompanied by a closely monitored strategy to safeguard access by those who are most disadvantaged. Governments may consider legislation that prohibits the disconnection of water services to private dwellings, or consider pricing policies that only permit user fees to apply for water use that exceeds basic needs.**

· **In order to plan for future needs, public health laws should authorize governments to collect and analyse data on water resources, take samples, monitor quality and install and remove monitoring equipment.**

· **Public health laws may set out the kinds of premises that must have water supplies and functioning sanitation facilities that are connected to a sewerage system or septic tank. Public health laws may also authorize health and sanitation inspectors to direct an owner or occupier of premises to install sanitary facilities, to dispose of sewerage and contaminated waste, and to take such actions as are necessary to prevent a wastewater system from causing a risk to public health.**

· **Public health laws may require local and city governments to install public toilets, washing facilities and associated septic tanks or sewerage systems in public areas where members of the public travel and congregate. These include train and bus stations, sporting facilities and petrol stations.**

· **Governments should consider gender when planning sanitation reforms. Women and girls should have access to clean water and sanitation facilities that protect their health, safety and privacy.**

· **Effective malaria control requires universal access to measures for the prevention, diagnosis and treatment of malaria. Public health laws should mandate vector surveillance and authorize public health authorities to take all such actions as necessary to implement evidence-based control strategies. Key malaria control interventions include providing long-lasting insecticide-treated mosquito nets to high-burden populations, and indoor residual spraying.**

· **Governments should prohibit the marketing, sale and use of oral, artemisinin-based monotherapies and promote the use of artemisinin-based combination therapy for treatment of malaria.**

· **Indoor residual spraying with DDT remains an important intervention for malaria control, in accordance with WHO recommendations and the Stockholm Convention on Persistent Organic Pollutants. WHO has published operational guidelines for safe and effective indoor residual spraying.**

· **Public health laws can support vector control through statutory offences for causing or permitting a nuisance that applies to owners or occupiers of premises.**

· **Public health laws should authorize public health authorities to issue an abatement notice that requires the owner or occupier to take such actions as reasonably necessary to abate or prevent the nuisance. Typically, public health laws authorize local authorities to enter and inspect premises, and to take actions themselves to abate a nuisance when an owner or occupier fails to do so.**

8.1 Sanitation and hygiene

The right to safe and clean drinking water and sanitation facilities is a human right that is essential for the full enjoyment of life and all human rights.[1] Access to safe and potable water and adequate sanitation are also underlying determinants of health which form part of the right to the highest attainable standard of health contained in the International Covenant on Economic, Social and Cultural Rights.[2] Between 1990 and 2015, the percentage of the world's population with access to an improved source of drinking water – such as a protected well, hand pump or public tap – rose from 76% to 91%.[3] Despite this, in 2015, an estimated 663 million people still lacked access to a safe and reliable source of drinking water; nearly half of these people lived in sub-Saharan Africa.[4]

In 2015, around one in three of the global population lacked access to sanitation facilities. In 47 countries, fewer than 50% of the population had access to improved sanitation,[5] and open defecation was still practiced by more than 900 million people.[6] Lack of hygiene and access to clean drinking water, including inadequate management of water distribution systems,[7] are significant causes of avoidable mortality. Unequal levels of access to these services are also significant causes of health inequalities.[8] Improving access to adequate sanitation and clean drinking water are

foundational strategies for reducing health inequalities and for fulfilling the right to health (**Box 8.1**).[9]

Box 8.1: Clean drinking water and sanitation: foundations of a modern public health system

- Faecal-oral transmission of disease, caused by unsafe water and inadequate sanitation, are the primary drivers of diarrhoeal diseases – the second leading cause of death in children under five, killing around 760 000 children annually.[10]
- Contaminated water and poor sanitation cause a range of other diseases that affect millions of people each year, including cholera, hepatitis A, fluorosis, dracunculiasis, intestinal worms, malaria, schistosomiasis, trachoma, arsenic poisoning and typhoid fever.[11]

In 2008, ministers and heads of delegations responsible for health, sanitation and water programmes in 32 African countries signed the eThekwini Declaration, aspiring to commit at least 0.5% of gross domestic product to new budget lines created expressly for improved sanitation and hygiene development.[12] In 2010, the United Nations General Assembly called on States to provide financial resources, capacity-building and technology transfer, particularly to developing countries, in order to scale up the provision of clean, accessible and affordable drinking water and sanitation for all.[13] In 2015, the General Assembly adopted the goal of ensuring the "availability and sustainable management of water and hygiene for all", as part of the Sustainable Development Goals (SDGs). This goal is supported by six technical targets relating to drinking water, sanitation and hygiene, wastewater management, water efficiency, integrated resource management and protection of aquatic ecosystems. **(Box 8.2)**.[14] Since the right to health encompasses safe and potable water, and adequate sanitation, governments must also consider the availability, accessibility, acceptability and quality of these services (see Section 1.2). Investment in infrastructure to improve access to water and sanitation should also be accompanied by education about hygiene. For example, handwashing with soap is a powerful public health intervention that has been estimated to reduce diarrhoea by around 48%.[15]

Box 8.2: Goals and targets for clean drinking water and sanitation in the Sustainable Development Goals

Goal 6: Ensure availability and sustainable management of water and sanitation for all

Targets for Goal 6:

- 6.1 By 2030, achieve universal and equitable access to safe and affordable drinking water for all.
- 6.2 By 2030, achieve access to adequate and equitable sanitation and hygiene for all and end open defecation, paying special attention to the needs of women and girls and those in vulnerable situations.
- 6.3 By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally.
- 6.4 By 2030, substantially increase water-use efficiency across all sectors and ensure

sustainable withdrawals and supply of freshwater to address water scarcity and substantially reduce the number of people suffering from water scarcity.

- 6.5 By 2030, implement integrated water resources management at all levels, including through transboundary cooperation as appropriate.
- 6.6 By 2020, protect and restore water-related ecosystems, including mountains, forests, wetlands, rivers, aquifers and lakes.
- 6.a By 2030, expand international cooperation and capacity-building support to developing countries in water- and sanitation-related activities and programmes, including water harvesting, desalination, water efficiency, wastewater treatment, recycling and reuse technologies
- 6.b Support and strengthen the participation of local communities in improving water and sanitation management

(a) Clean water supplies

Public health laws in relation to clean water should address three key areas: water management, sanitation facilities and water contaminants. Water management laws may impose general duties on local governments and town councils to provide sources of clean drinking water, to carry out water assessments in order to identify, protect and conserve drinking water catchment areas and to mitigate potential sources of contamination. The duty to provide a sufficient supply of clean water requires planning and monitoring by local authorities on an ongoing basis, due to the impact of population growth and changing land-use patterns as well as the impact of agriculture on traditional sources of water supplies. In order to discharge this duty effectively, local governments and town councils may require a range of additional powers. These may include the power to enter and acquire land, to access sources of water on just terms, to purchase water rights, to construct reservoirs and water storage tanks, to inspect water management facilities, to maintain pumping and other equipment, to test water supplies, and to enter into contracts for the supply of water sourced from within or beyond their local government area.

Where resource constraints prevent the construction of public storage tanks, governments may encourage point-of-use water treatment and safe storage through education and funding strategies.[16] Low-cost and effective treatments include boiling, solar disinfection (exposing clear containers of water to sunlight for at least six hours), ceramic or biosand filtration systems, and use of sodium hypochlorite or chlorinated isocyanurates.[17] Laws can encourage self-sufficiency in water supplies by requiring landowners to collect, store and conserve rainwater (**Box 8.3**). Governments can encourage compliance by subsidizing water storage containers and chemicals for water purification.[18]

Box 8.3: Regulating the quality of drinking water: an example from Belize

Public Health Act[19]

Section 52. Surface drains. Every Town Council may, and when required by the Director of Health Services shall, construct and maintain in proper order in convenient places drains for the removal of surface and floodwater and for the proper drainage of swamplands situated within its jurisdiction.

Section 53. Draining of houses and lots, etc.

(1) Where any lot, house or premises is without a drain sufficient for the effectual drainage of flood water or domestic wastewater a Medical Officer of Health may by written notice require the owner or occupier of the lot, house or premises within a reasonable time therein specified to make a drain or drains emptying, in the case of flood water, into any public drain, and in the case of domestic wastewater, emptying into such sump or pit or place as a Medical Officer of Health may direct.

(2) A Medical Officer of Health may require any such drain or drains to be of such material, construction and size and to be laid at such level and with such fall as may appear to [him or her] to be necessary and proper and may require any sump to be of a size and type approved by the Director of Health Services.

(3) If such notice is not complied with the Medical Officer of Health may after the time specified in the notice do the work required and may recover in a summary manner the expenses incurred by [him or her] in so doing from the owner, or may declare the same to be private improvement expenses.

Section 54. Public Tanks. Every Town Council may, and when required by the Minister shall, construct and maintain tanks and reservoirs for the storage of rain or fresh water as may be necessary, and may sell the water so stored or permit the free use thereof.

Section 55. By-laws regulating issue of water. Every Town Council may make by-laws for regulating the issue of water from any tank or reservoir under its charge.

Section 61. Dwelling houses to be provided with tanks.

(1) Every owner of a dwelling-house, the roof of which is not a thatched one, shall erect and maintain in good order a tank or tanks in connection with the dwelling-house, for the storage of rain water, and in respect of every new building to be used as a dwelling-house erected on or after the coming into force of this Act, the tank or tanks shall be capable of storing not less than five gallons of water for each square foot of floor space contained within such dwelling-house.

(2) No tank required to be maintained under this section shall be deemed to be in good order-

(a) If it is not connected by suitable pipes to gutters attached to a sufficient surface of roof or platform exposed to the weather or if such gutters or pipes are not in good order; or

(b) If the tank is not fitted with apparatus for draining off water there from without waste; or

(c) If the tank is not watertight; or

(d) If the tank is not provided with a suitable covered or screened opening for conveniently inspecting and repairing the inlet and outlet, and for cleaning.

Section 63. Inspection of premises and receptacles for water. Any health officer may from time to

time with or without assistance enter into, visit and inspect for the purposes of sections 60 to 63 inclusive all or any premises, tanks and receptacles for water.

Water management and sanitation laws may impose additional duties on landowners and occupiers of premises. These may include the duty to ensure adequate drainage of waste and flood water (thereby minimizing standing water, an optimal breeding ground for mosquitoes), to dispose of domestic waste appropriately, as well as a general duty not to pollute or contaminate sources of drinking water and water catchment areas.

Local councils may vary in their financial and administrative capacity to manage the supply of clean drinking water and to enforce water laws. Subject to the constitutional division of powers in each country, government officials considering the revision of public health laws may consider ways of ensuring that the health ministry shares some oversight and responsibility for the provision of clean drinking water, in order to ensure universal access to disadvantaged groups.

Factors that may contribute to poor coverage of clean water services include lack of capital for the infrastructure investments that are needed for the distribution and management of water, as well as inefficient management and lack of accountability on the part of governing agencies.[20] When countries struggle with water scarcity problems, governments often face pressure to privatize water systems to discourage wasteful use. While attaching user fees to water may conserve supplies and prevent wasteful use, in some circumstances privatization may result in inequitable access or increase disease rates.[21] When considering the privatization of water services, governments should carefully weigh the potential risks of privatization, and ensure that any privatization of supplies is accompanied by a closely monitored strategy to safeguard access. After privatization led to price increases in the United Kingdom, increasing numbers of households were disconnected from water lines after failing to make payments.[22] In response to growing public health concerns, the government passed legislation prohibiting disconnection or the use of limiting devices to reduce use for non-payment reasons.[23] Governments can also establish financing schemes to support investment in the provision of clean water to low-income communities, or impose pricing standards that only permit user fees for water use that exceeds basic needs.[24]

In order to ensure the ongoing quality and sufficiency of drinking water, and to plan for future needs, governments need information about the volume, flow and quality of water sources. Public health laws should therefore authorize governments to collect and analyse water resources data, to take samples, and to construct, install, repair and remove recording and monitoring equipment (**Box 8.4**).

Box 8.4: Laws authorizing the monitoring and investigation of water supplies: an example from Australia

Water Act (Northern Territory)[25]

Section 34. Water resources investigation

To enable effective planning for water resource development and environmental protection, it is the duty of the [Controller of water resources] to ensure as far as possible that a continuous program for the assessment of water resources of the Territory is carried out, including the investigation,

collection, collation and analysis of data concerning the occurrence, volume, flow, characteristics, quality, flood potential and use of water resources, and for that purpose the Controller may:

(a) systematically gauge stream flow, record climatic data and monitor groundwater levels;

(b) construct, operate, repair, maintain, alter and remove gauging, recording and monitoring stations and investigation and monitoring bores;

(c) sample and analyse water and waste.

(b) Sanitation facilities

Laws that regulate the provision and maintenance of sanitation systems, including toilets and washing facilities, make a vital contribution to public health infrastructure by minimizing faecal-oral transmission of disease. The WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation has provided guidance on the range of facilities that provide a basic level of health protection.[26] An important component of protecting water supplies is to specify the kinds of premises, including hotels and lodging houses, workplaces, schools, homes and building sites, that must have functioning toilets or sanitation facilities connected to a sewerage system or septic tank. Public health laws may also authorize health and sanitation inspectors to direct an owner or occupier of premises to install sanitary facilities, to dispose of sewerage and contaminated waste, and to take such actions as are necessary to prevent a wastewater system from causing a risk to public health (**Box 8.5**).

For example, the Public and Environmental Health Regulations of the Northern Territory, in Australia, authorize the Chief Health Officer to direct an owner or occupier of premises to install sanitary facilities within a specified period, and create an offence for failure to do so.[27] The Chief Health Officer may also give directions about the management or disposal of "biosolids, septage, or sludge", as defined in the regulations. **Box 8.5** illustrates the power of the Chief Health Officer to give directions to an owner or occupier of premises in order to ensure that a wastewater system does not create a risk to public health.

Box 8.5: Power to give directions in relation to wastewater systems: an example from Australia

Public and Environmental Health Regulations, Northern Territory, Australia[28]

Section 89 CHO [Chief Health Officer] may give directions

(1) This regulation applies if the CHO has reasonable grounds to believe that a wastewater system at a place is causing, or is likely to cause, a serious public health risk.

(2) The CHO may direct an owner or occupier of a place to do any thing the CHO considers reasonably necessary to prevent the wastewater system from causing, or continuing to be, a serious public health risk.

(3) A person commits an offence if the person:

(a) is an owner or occupier of the place; and

(b) is given a direction by the CHO under subregulation (2); and

(c) does not comply with the direction within the time specified in the notice.

(5) If the person does not comply with the direction, the CHO may take any action the CHO considers necessary to prevent the wastewater system from causing, or continuing to be, a serious public health risk.

Where resource constraints prevent the construction of a sanitary facility in every place of accommodation, the law may instead provide for public or shared facilities until the State develops the capacity to provide sanitary services in every dwelling. Governments considering law reform may require local government authorities and city councils to plan for the provision of public toilets, washing facilities and associated septic tanks or sewerage systems in public areas where members of the public travel and congregate. These include train and bus stations, sporting facilities and petrol stations. As noted above, hand washing is an important strategy for avoiding diarrhoea; governments may consider funding education programmes on hygiene and subsidizing the provision of soap for poor populations.[29]

Access to improved sanitation can increase productivity by minimizing absences from work and school as a result of faecal-oral transmission of disease. Sanitation facilities must be acceptable to the communities they are intended to serve (see Section 1.2). For example, sanitation reforms may be more effective where public health laws require schools and workplaces to install separate facilities for men and women, since women and girls are less likely to use these facilities when doing so compromises their safety or privacy.[30] Belize's public health law empowers the health ministry to require an employer or school to provide separate facilities for men and women (**Box 8.6**).

Box 8.6: Providing for sanitation facilities for both sexes: an example from Belize

Public Health Act[31]

Section 23. Schools and factories to be provided with privies for both sexes

(1) Where it appears to the Director of Health Services, that any house or building is used or intended to be used as a factory or school by persons of both sexes he may if he thinks fit by written notice require the owner or occupier to construct a sufficient number of water-closets, earth-closets or privies, for the separate use of each sex within a time specified therein.

A fundamental principle of public health is that sources of water intended for drinking, bathing and washing by humans should be protected and separated from drains and run-off, floodwater and watercourses potentially contaminated by animals. In addition to waterborne diseases caused by inadequate sanitation, poisoning and illness can also occur when groundwater is contaminated with industrial waste, fertilizers and pesticides. Public health laws should empower health inspectors to test water quality and to control or regulate any activities that are reasonably likely to contaminate public water supplies. These powers should extend to the disposal of waste and refuse, including animal remains. With due regard to religious beliefs and customs, human burials should be restricted to cemeteries that are safe from scavenging and physically separated from water courses.

Modern public health laws often create general offences that cover different kinds of actions that may contaminate watercourses and sources of drinking water, causing environmental harm or a risk to human health.

8.2 Vector abatement

Vector control measures aim to reduce the transmission of disease by reducing the number of animals and insects that act as vectors for disease transmission, or by reducing interactions between animal and disease vectors, and people. Vector-borne diseases, such as malaria, are preventable and curable, and yet malaria caused more than 580 000 deaths in 2013, mostly among African children (**Box 8.7**).[32] This section focuses on mosquito and rodent control, although region-specific health threats may also require attention to vectors such as cockroaches, or sand and tsetse flies.

Box 8.7: Progress in malaria control

- In 2015 there were an estimated 214 million new cases of malaria, and 438 000 deaths.[33] Although the estimated malaria mortality rate has fallen by 60% since 2000, a child still dies from malaria every two minutes.[34]
- In recent years, a number of countries have been certified as malaria-free. These include the United Arab Emirates (2007), Morocco (2010), Turkmenistan (2010) and Armenia (2012).[35] Nevertheless, in 2015, 95 countries and territories had cases of malaria transmission.[36]
- In the WHO African Region, between 2000 and 2015, malaria mortality declined by 48%. Nevertheless, in 2015, most cases of malaria (88%), and most deaths (90%) still occurred in this region.[37] The longer lifespan and stronger tendency of African mosquito species to bite humans explains why around 90% of malaria deaths occur in this region.[38]

(a) Malaria and other mosquito-borne diseases

WHO's Global Technical Strategy for Malaria 2016–2030 encourages countries to move towards malaria-free status by adopting a strategy based on three pillars.[39] The first pillar involves universal access to measures for the prevention, diagnosis and treatment of malaria. This means universal coverage of malaria control interventions for all populations at risk, including indoor residual spraying (IRS), and the distribution of long-lasting insecticide-treated nets (LLINs) in high-burden areas. IRS and LLINs are the "two core, broadly-applicable vector control interventions" for effective malaria control.[40] Better outcomes have been achieved when LLINs are distributed for free or at subsidized cost.[41] In areas with seasonal transmission patterns, distribution of LLINs should be focused on areas at highest risk due to climatic conditions or lack of access to health services. Public education on LLINs is critical to reduce improper and sporadic use (or no use at all), re-selling, improper washing practices, and/or failure to replace damaged nets. IRS is also an effective means of vector control in areas where the majority of the population sleeps and rests indoors and where a high percentage of homes have spray-able surfaces. In areas where this is not the case, other strategies include larviciding (where vectors breed in permanent or semi-permanent bodies of

water), environmental management, window screens and area spraying during peak vector activity time.

Effective vector control should be complemented by preventive courses of antimalarial medication for the most vulnerable groups (including pregnant women and infants), universal diagnostic testing for all suspected cases, and quality-assured treatment of all confirmed cases. In order to prevent drug resistance, the World Health Assembly has urged Member States to cease progressively the provision in both the public and private sectors of oral, artemisinin-based monotherapies and to promote the use of artemisinin-based combination therapy.[42] The WHO strategy urges regulatory authorities to ensure that artemisinin-based monotherapies are removed from health facilities, pharmacies and the private market.[43]

The second pillar of WHO's malaria strategy involves accelerating efforts towards malaria-free status and elimination of malaria in low-transmission settings. This includes strengthening the epidemiological surveillance of malaria, with compulsory notification of all confirmed cases (see Chapter 9), and a ban on the sale of over-the-counter antimalarial medicines to prevent inappropriate use. The elimination of malaria requires a multisectoral approach, with renewed political commitment and enhanced regional collaboration. The third pillar involves upgrading malaria surveillance within all national and subnational malaria strategies, and investing in health information systems to support surveillance.

The Roll Back Malaria Partnership, hosted by WHO between 1998 and 2015, is made up of more than 500 partners including malaria-endemic countries, OECD donor countries, multilateral development partners, foundations, the private sector, nongovernmental organizations and researchers.[44] Since 2013, these efforts have been strengthened by the Multisectoral Action Framework for Malaria, which recognizes that malaria is a symptom of low levels of human development, and aims to accelerate malaria control by integrating it within strategies for social and economic development.[45] Financing plays an important role in the Multisectoral Action Framework, including the provision of financial support for the costs of malaria interventions incurred directly by households.[46]

Public health law can support national programmes to control mosquito-borne illnesses in several important ways. For example, legislation can mandate vector surveillance and the provision of public education programmes, and give local health authorities a clear mandate to take all such actions as are necessary to fully implement national malaria control strategies. There may be benefits in incorporating environmental management strategies directly into public health regulations, and including a requirement for provincial health officers to educate local populations about vector control requirements. Provincial health officers should have a duty to report annually in an independent manner, and to issue reports at other times as necessary.

Despite its effectiveness in malaria control, some countries may face pressure to reduce IRS in order to eliminate the use of DDT. DDT is a closely regulated and cost-effective insecticide that has been controversial in malarial control efforts. The Stockholm Convention on Persistent Organic Pollutants expressly allows the use of DDT for disease control purposes (subject to reporting to the Secretariat).[47] In some countries, the replacement of DDT with other insecticides has compromised malaria control programmes.[48] Following a risk assessment,[49] WHO published an updated position

statement that confirms the necessity of the use of DDT, in accordance with the requirements of the Convention and WHO recommendations (**Box 8.8**).[50] WHO has published operational guidance for IRS programmes.[51] Governments should consider adopting national standards for safe storage and use of pesticides in IRS and incorporating these within public health legislation, including the use of warning labels on insecticides, childproof dispenser designs, by creating offences for leakage and misuse of pesticides, and by mandating the reporting of DDT use to the Secretariat of the Stockholm Convention.

Box 8.8: WHO's position statement on the use of DDT in malaria control

Indoor residual spraying (IRS) using DDT is an important intervention for malaria control. From 12 insecticides recommended by WHO for IRS, DDT has the longest residual efficacy against malaria when sprayed on walls and ceilings (6–12 months). WHO's position statement concludes:

DDT is still needed and used for disease vector control simply because there is no alternative of both equivalent efficacy and operational feasibility, especially for high-transmission areas. The reduction and ultimate elimination of the use of DDT for public health must be supported technically and financially. It is essential that adequate resources and technical support are rapidly allocated to countries so that they can adopt appropriate measures for sound management of pesticides in general and of DDT in particular. There is also an urgent need to develop alternative products and methods, not only to reduce reliance on DDT and to achieve its ultimate elimination, but also to sustain effective malaria vector control.[52]

For dengue control, WHO encourages national control programmes based on environmental management strategies and insecticides.[53] Public health laws should provide a clear mandate for the development of national strategies, and for locally led surveillance, monitoring and enforcement of regulatory requirements. These include requirements to ensure that water storage containers are covered and cleaned regularly, that large waste items (such as used tires) are disposed of, and avoidance of the use of hollow building materials (such as bamboo).[54] Improving the delivery of potable water (e.g. through installation of piped water systems) will reduce reliance on storage bins and thus reduce potential vector breeding grounds.[55] Chemical control strategies may also be incorporated into dengue control programmes. WHO has recommended substituting the use of DDT with organophosphate insecticides for dengue control,[56] and has issued guidelines for the safe use of pesticides.[57] Incorporating controls for safe use into national public health laws or regulations improves clarity around the specific standards that public health officers should implement and enforce in order to discharge their mandate in this area.

(b) Rodent control

Rodents are vectors for the transmission of disease, particularly in urban or overcrowded areas. Rodent control measures include improving environmental sanitation practices, securing the storage of food, grain and animal feed, washing dishes and removing food scraps, removing household rubbish and waste, and removing deceased animals from areas near living spaces.[58] In emergency situations, use of rodenticides may be necessary to control outbreaks. Rodenticides should be

targeted narrowly towards areas of greatest infestation, which can be identified through use of traps.[59] As with the chemical control strategies discussed above, public health law should require adherence to stringent safety guidelines.

Public health law has a long history of using environmental management strategies to reduce diseases transmitted by rodents. These include strict compliance with (and auditing of) food storage and hygiene requirements in food establishments, as well as contractual requirements in landlord-tenant laws to remove waste and to keep premises free of vermin. Due to their flexibility, most public health statutes include nuisance abatement provisions authorizing public health officers to inspect premises and to order owners or occupiers of premises to take such actions as are reasonably necessary to reduce the health risks posed by rats or other vectors. A public nuisance may be broadly defined to include any act or omission that is harmful or that is likely to be harmful to the public's health, and also includes acts or omissions that may jeopardize a public good, such as a potable water supply, that is needed to maintain public health.[60]

Public nuisance laws are a critically important public health tool, and can be framed in both general and specific ways. In many countries, nuisance laws give a wide range of examples to illustrate the broad coverage of the concept of a public health nuisance. For example, Jamaica's Public Health (Nuisance) Regulations create an offence for causing or permitting a nuisance that applies to owners or occupiers of premises. The regulations authorize public health authorities to issue an abatement notice that requires the owner or occupier to take such actions as reasonably necessary to abate or prevent the nuisance. The schedules include a list of examples that are included within the concept of a nuisance (**Box 8.9**). Typically, public health laws authorize local authorities to enter and inspect premises, and to take actions themselves to abate a nuisance when an owner or occupier fails to do so.

Box 8.9: Using public health nuisance laws for vector control: an example from Jamaica

Public Health (Nuisance) Regulations 1995[61]

Section 3(1) No person shall cause or permit a nuisance on any premises owned or occupied by him.

(2) No person shall cause a nuisance on any premises or aid and abet any other person to cause or permit a nuisance on any premises.

Section 4(1) A Medical Officer (Health), a Public Health Inspector or any person authorized by the Minister in writing in that behalf (hereinafter referred to as an "authorized person") or a Local Board may, on becoming aware of the existence of a nuisance on any premises, serve on the owner or occupier of the premises or on the person causing or permitting the nuisance, a notice in writing in the form set out in the Second Schedule requiring the owner, occupier, or person-

(a) to abate the nuisance within such reasonable time not being more than thirty days, as may be specified in the notice;

(b) to perform such act as the Medical Officer (Health), the Public Health Inspector, an authorized person or Local Board considers to be reasonably required to abate or prevent the recurrence of the nuisance.

(2) Where a person, without reasonable cause, fails to comply with the requirements specified in the notice under paragraph (1), the Medical Officer (Health), the Public Health Inspector or authorized

person shall make a report in writing to the Local Board and the Local Board may authorize in writing any person to enter upon the premises and do such things as are necessary to abate or prevent a recurrence of the nuisance.

First Schedule

Nuisances

1–(1) A building or structure which, because of structural defects or insanitary conditions, is or is likely to become a health hazard.

(2) Any premises or other place which because of insanitary conditions is or is likely to become a health hazard.

2. An accumulation or deposit of solid waste of human or animal excreta.

3. Dust, smoke, fumes, gases or effluvia emitting from any manufacturing process or caused by the carrying on of any trade or business or otherwise by the action of any person.

4–(1) Any animal which is kept in such a manner as to become hazardous to health.

(2) The carcass of any animal which is not buried or destroyed within twenty-four hours of the animal's dying.

5. A tree, bush or structure which interferes with the flow of air or the letting in of sunlight into any building or premises.

6–(1). The lack of water or a water supply system.

(2) A water supply system that is not maintained in a sanitary condition.

(3) The running to waste of water from a tap, pipe or pump or from any other device from which water is obtained.

(4) The accumulation of stagnant water.

7. Any sanitary convenience which is so designed, located or kept which is or is likely to become a health hazard.

8. The infestation of flies, fleas, cockroaches, lice, rats, mosquitoes, mosquito larvae and other vermin on any premises.

9. Excess vegetation or overgrowth of bush on any building, land or structure which harbours or is likely to harbour vermin.

10–(1) The discharge of any sewage, industrial waste or any other noxious matter into the sea or any watercourse or onto any land.

(2) In paragraph (1) “watercourse” includes any river, stream, creek, canal, drain, natural channel or any permanent and defined course for water or flood-water.

11. Offensive smells. including the emission of noxious fumes, gases or powerful smells, as a result of agricultural, domestic or industrial processes or otherwise.

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Chapter 9: Monitoring, surveillance, and investigation of health threats

SUMMARY POINTS

· **Monitoring, surveillance and investigation of health threats are vital capabilities for an effective health system. The International Health Regulations (2005) require countries to maintain an integrated, national system for public health surveillance and response, and set out the core capabilities that countries are required to achieve.**

· **Systematic monitoring of serious infectious diseases and other conditions is typically achieved through notifiable diseases legislation based on clinical observation and laboratory confirmation. Clinical and laboratory-based surveillance also provides the basis for systematic collection of vital statistics (births, deaths, causes of death), and may extend to the reporting and analysis of risk factors for noncommunicable diseases and injuries. Systematic collection of these data informs the allocation of resources and facilitates evaluation of community-based and population-level prevention strategies.**

· **Clinical and laboratory surveillance are passive systems that may be enhanced by sentinel surveillance and/or community-based surveillance strategies that rely on a wider range of people, including non-medical personnel. Suspected cases identified in this way must be treated with respect, protected from discrimination, with diagnosis confirmed by qualified health workers at the earliest opportunity.**

· **A significant degree of stigma may attach to some diseases, such as HIV, sexually transmitted infections and diabetes. Notifiable diseases legislation should require the protection of personal information, and clearly define any exceptions. Concerns about discrimination and breach of privacy may be addressed by requiring certain diseases to be reported on an anonymous or de-identified basis.**

· **In some countries, legislation or regulations may be used to establish or enhance a comprehensive public health surveillance system. In federal systems, intergovernmental agreements, federal grants and conditional funding agreements may be useful strategies for achieving an integrated system where public health surveillance is, in practice, coordinated at the regional (state or provincial) level.**

· **The cases of disease or harm captured by effective surveillance systems may reflect a wide variety of public health hazards. Countries may find it useful to establish an intersectoral committee to consider whether existing legislation, regulations and other instruments are adequate to ensure a rapid and effective public health response and to fulfil the obligations set out in the International Health Regulations (2005).**

Surveillance and monitoring are critical components of a well-functioning public health system. Public health professionals use surveillance to assist them in performing many of their key functions. These include monitoring, vector control, responding to outbreaks of infectious disease, identifying the source of foodborne illnesses, ensuring the safety of drinking water and national blood supplies,

and tracking modifiable risk factors for noncommunicable diseases in order to develop and evaluate preventive policies.

Public health laws support effective surveillance systems by identifying the diseases and conditions for which reporting is required and designating the persons to whom these reporting requirements apply – with sufficient flexibility so that these requirements can be applied rapidly to emerging diseases and conditions when appropriate. Factors that affect the design of surveillance laws include the purpose of notification requirements, the frequency and severity of disease incidence, the reliability of the diagnosis, and the need for a rapid response. This section briefly identifies different kinds of surveillance strategies, and gives examples of how public health law can establish and maintain these systems. The collection of health information that identifies individuals carries the risk of discrimination and loss of privacy. The management of these risks, through legal requirements to maintain the security, privacy, and confidentiality of personal information, and through legal protection from discrimination, provide the foundation for effective control of communicable diseases. This is discussed further in Chapter 10.

9.1 Clinical and laboratory-based surveillance

A critical function of clinical surveillance is to provide early warning of disease outbreaks that require rapid response at the regional, national or international level. On the front line of surveillance systems are health care providers, who examine patients and diagnose diseases based on signs and symptoms, with or without assistance from laboratory-based tests, rapid test kits or other diagnostic aids.

Public health laws typically establish a list of "notifiable diseases" and other conditions that health care providers, hospitals and/or laboratories are required to report to the relevant local or national public health authority. Notifiable diseases generally include infectious diseases that can quickly spread throughout communities and regions via water, food, contact with animals, mosquitoes, airborne droplets, or through sexual contact and other forms of human interaction. Examples of notifiable diseases include diseases preventable by vaccination (e.g. influenza, hepatitis B), sexually transmitted diseases (e.g. HIV, herpes), nosocomial infections (e.g. methicillin-resistant *Staphylococcus aureus* (MRSA)), foodborne illnesses (e.g. botulism), waterborne diseases (e.g. cholera), contagious diseases caused by airborne particles (e.g. tuberculosis), and diseases transmitted by vectors or parasites (e.g. rabies, malaria). The list of notifiable diseases mandated by legislation may vary over time, according to a country's stage of development and the capacity of its health workforce. In some countries, risk factors for noncommunicable diseases may also become notifiable (**Box 9.1**).

Box 9.1: Mandatory reporting of noncommunicable disease risk factors: an example from New York City

The surveillance of noncommunicable diseases and their risk factors tends to occur through community-based or voluntary clinical reporting systems, rather than through formal, legislative notification systems.[1] In appropriate circumstances, however, the mandatory reporting of risk factors for noncommunicable diseases may assist in identifying cases and ensuring that affected individuals are offered treatment to prevent the progression of disease. For example, in 2006, New York City expanded notifiable disease reporting obligations to include haemoglobin A1c (glycated haemoglobin), in order to create a registry to map the epidemiology of hyperglycaemia and to identify and offer treatment to the estimated one in three diabetics who are unaware of their disease.[2]

Effective surveillance systems must respond rapidly to cases of emerging epidemic diseases and ensure that they are identified and reported to authorities. Legislative drafters can facilitate this by ensuring that notifiable diseases and other conditions to which reporting obligations apply are included in the schedules or appendices of legislation, or that these can be updated rapidly by executive action. In the early stages of a new epidemic, confirmatory laboratory tests may be unavailable and the best available case definition may be both complex and nonspecific.

In addition to detecting disease outbreaks, clinical surveillance systems perform an epidemiological surveillance function by capturing vital statistics (births, deaths, causes of death), and by monitoring the incidence of other reportable conditions over time, such as perinatal deaths, deaths from specified diseases (e.g. cancer, malaria) and deaths from preventable causes (e.g. burns, drownings, road traffic injuries). Longitudinal surveillance performs a vital role in public health, informing the allocation of resources and facilitating the evaluation of community-based and population-level prevention strategies. In some cases, public health laws may require notification to be made to particular hospitals or other centres of excellence that lead national surveillance and research efforts and host disease-specific registers. Disease registers may record diagnosis, clinical data and outcomes data that facilitate the evaluation and improvement of diagnostic strategies and clinical treatments.

One limitation of clinical surveillance systems is that they are passive systems that only identify cases when patients seek medical assistance or come into contact with the health care system. In countries where large numbers of people lack affordable access to health care services, clinical surveillance systems may underestimate the burden of disease, while also failing to achieve their primary goal of identifying disease outbreaks. The goal of achieving universal access to health services therefore supports efforts to improve clinical surveillance capabilities. One legal strategy for improving surveillance capability in low-resource settings is to impose reporting requirements for suspected cases of epidemic diseases on a wider range of people, including school principals, employers, and village chiefs (**Box 9.2**). Care should be taken to ensure that suspected cases are treated with dignity, that confidentiality is respected, and that the diagnosis of suspected cases is reviewed by qualified health care workers at the earliest opportunity.

Box 9.2: Improving the front line diagnosis of acutely infectious diseases: an example from Zimbabwe

Public Health Act (Ch 15:09)[3]

Zimbabwe's Public Health Act provides that the Minister may, by statutory instrument, declare a disease to be a "formidable epidemic disease" for the purposes of the Act. Section 27 of the Act provides that:

Medical practitioners, principals of schools, heads of families or householders, employers of labour, owners or occupiers of land or premises, chiefs, headmen and others shall report to the local authority or district administrator, as the case may be, the occurrence of any case of illness or death coming to their notice and suspected to be due to any formidable epidemic disease, or with a history of presenting symptoms or post-mortem appearances which might reasonably give grounds for such suspicion.

Where available, laboratory confirmation of clinical diagnoses is important to improve the accuracy of surveillance systems. Public health laws typically impose reporting requirements on laboratories in order to confirm clinical diagnoses, or in circumstances where accurate diagnosis requires laboratory investigations. In higher-income countries, legislation may apply the same compulsory notification requirements to laboratories as to physicians; however, this may not be a cost-effective use of limited laboratory resources in lower-income countries. In cases where both clinical and laboratory reporting obligations are imposed, accurate patient identification will be necessary to avoid double counting.

A significant degree of stigma may attach to some diseases, including HIV, sexually transmitted infections, and diabetes. Diagnosis may carry the risk of discrimination, especially when there is weak protection for privacy and confidentiality. Notifiable diseases legislation should require the protection of personal information, and clearly define any exceptions. In order to reduce disincentives for testing, and to improve compliance with treatment regimes, legislation may also require the reporting of certain diseases to health authorities on an anonymous or de-identified basis. This approach may enhance rates of testing among vulnerable groups, including sex workers, injecting drug users, ethnic minorities, and, in some cases, women.

9.2 Sentinel surveillance

Sentinel surveillance provides public health authorities with data on the prevalence of a disease in a particular area or among a particular subgroup. For example, carefully chosen sentinel sites may provide early warning of disease outbreaks as well as prospective monitoring of rates of infectious disease or other health conditions, such as child malnutrition.[4] Like other passive surveillance strategies, sentinel surveillance only provides authorities with approximate figures, but may be a critical component of an early warning system that triggers an urgent response to public health events of national significance.

9.3 Community-based surveillance and investigations

Since clinical and laboratory-based surveillance is passive (identifying cases of disease only among those who present for treatment), it must be complemented by strategies to identify missing cases, confirm diagnoses and investigate outbreaks within community settings. Rare and new events may not be included in regular, clinical and laboratory-based surveillance systems. In addition, outbreaks of serious or contagious diseases require immediate investigation so that appropriate public health measures (e.g. isolation, contact tracing) can be implemented.[5]

As illustrated in **Box 9.2**, community-based surveillance may rely on non-medical personnel to identify potential outbreaks. These may include other health care workers, community groups, community services (e.g. schools, police, and religious organizations) as well as the media. In developing a reporting strategy, governments will need to identify the appropriate balance between sensitivity (identifying all important events), and sustainability (maintaining the reporting capability without undermining other public health functions).[6] Since it may have a higher error rate than other types of surveillance, community surveillance is best used where symptoms are easily recognizable and likely to clearly identify a given disease. Governments should ensure that event assessment teams responding to community reports have appropriate powers to carry out event-based surveillance in community settings, and where necessary, to implement public health measures urgently (see Chapter 11).

9.4 Comprehensive surveillance systems

Laws that establish surveillance systems may enable different kinds of surveillance strategies to be implemented simultaneously. This may help to overcome the limitations of each strategy and provide a clearer picture of the burden of disease and the extent of disease spread. For example, Argentina's Resolution no. 1715/2007, enacted in order to bring its national surveillance capabilities into conformity with the International Health Regulations (2005) (IHR), authorizes and explains the case for each surveillance strategy (**Box 9.3**). Comprehensive surveillance systems that combine multiple strategies will require coordination between local, regional and national health authorities. For example, clinician and laboratory reporting of a serious outbreak must trigger national – and, following notification to WHO – international response systems to minimize the spread of disease. The surveillance capabilities required at local, regional and national levels are not purely matters of domestic policy but are prescribed in the IHR.[7]

Box 9.3: Different surveillance strategies used to track and investigate notifiable events

Resolution 1715/2007 of the Ministry of Health of Argentina, on rules for the surveillance and control of diseases or events subject to compulsory notification[8]

3. Surveillance strategies for events subject to compulsory notification. Different strategies will be used to monitor notifiable diseases, including multiple strategies for the same event. They are:

3-1. Clinical surveillance: shall be universal. Cases are notified on the suspicion of the treating

physician, based on the corresponding definition of a suspect case. This provides the system with sensitivity and timeliness. Suspected cases are confirmed or amended upon laboratory or epidemiologic investigation. Clinical surveillance includes syndromic surveillance, in cases where a number of diseases share similar clinical manifestations.

3-2. Laboratory surveillance: is complementary to clinical surveillance, it provides specificity and supplies diagnoses of etiologic agents, natural reservoirs, and/or vectors. Its main objective is to contribute to knowledge of health events caused by the disease agent, determining the frequency of various microorganisms, their geographical and temporal distributions, and identifying patterns of behaviour of different agents.

3-3. Sentinel surveillance: three variants of this strategy have been implemented within the country: units, physicians, and sentinel groups. The sentinel site strategy is not currently in use.

3-4. Special studies: epidemiological studies are performed periodically to monitor trends in reportable events. These are generally cross-sectional studies of prevalence used to obtain baseline data and then conducted at a particular frequency to track changes in relation to implementation of control measures. Examples include a survey tracking risk factors for noncommunicable diseases, or Chagas seroprevalence in children under 5 years of age (and in other age groups), etc.

9.5 Developing integrated national capabilities for surveillance and response

The IHR[9] require countries to meet a number of "core capacity requirements" for surveillance and response at local, intermediate and national levels (**Box 9.4**). At the local community or primary public health response level, core capacity requirements include the ability to detect events involving disease or death above expected levels for the particular time and location in all areas within the territory of the country, and to report all available essential information to local community health care institutions or the appropriate health personnel, or to the intermediate or national response level, depending on organizational structures.[10] At the national level, core capacity requirements include assessing all reports of urgent events within 48 hours, and notifying WHO immediately of all events that may constitute a "public health emergency of international concern", via a national IHR focal point.[11] States Parties to the IHR must also inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by human cases, vectors carrying infection or contaminated goods that have been exported or imported by that State Party.[12]

Box 9.4: Core capacity requirements for surveillance and response under the International Health Regulations (2005)[13]

A. Core Capacity Requirements for Surveillance and Response

4. At the local community level and/or primary public health response level

The capacities:

(a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and

(b) to report all available essential information immediately to the appropriate level of healthcare response. At the community level, reporting shall be to local community health-care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed; and

(c) to implement preliminary control measures immediately.

5. At the intermediate public health response levels

The capacities:

(a) to confirm the status of reported events and to support or implement additional control measures; and

(b) to assess reported events immediately and, if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

6. At the national level

Assessment and notification. The capacities:

(a) to assess all reports of urgent events within 48 hours; and

(b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

Public health response. The capacities:

(a) to determine rapidly the control measures required to prevent domestic and international spread;

(b) to provide support through specialized staff, laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);

(c) to provide on-site assistance as required to supplement local investigations;

(d) to provide a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;

(e) to provide direct liaison with other relevant government ministries;

(f) to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;

(g) to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a

public health emergency of international concern; and

(h) to provide the foregoing on a 24-hour basis.

Ensuring an integrated, national system that meets the core capacity requirements for surveillance and response is an important part of each country's obligation to fully implement the IHR. Some countries have used legislation or executive orders to establish or to enhance a national public health surveillance system (**Box 9.5**). However, federal countries may need to ensure that the division of regulatory power between national, state and local/city governments does not create impediments to the rapid sharing of information between different levels of government, or to national coordination of surveillance activities throughout the country. Even when federal governments have adequate legislative powers that could be used, intergovernmental agreements may be a more practical way of establishing a national system in countries where public health surveillance is, in practice, coordinated at the regional (state or provincial) level.[14]

Box 9.5: Establishing Colombia's public health surveillance system

In Colombia, the public health surveillance system was established by Presidential decree. The decree identifies the Ministry of Social Protection, departmental, district, and municipal health directorates, and a number of other agencies as the entities that are responsible for the implementation and development of the system, and sets out their respective functions. The functions of the Ministry of Social Protection include analysing information from the surveillance system to identify public health priorities and to guide public health responses.[15] The functions of the municipal health directorates include ensuring the infrastructure and human resources required to carry out surveillance at the municipal level, organizing the community in appropriate community-based surveillance activities, identifying cases and contacts and investigating disease outbreaks within the municipal area.[16] The functions of reference institutions and entities generating primary data, including laboratories, blood and organ banks, and health service providers, are also set out. The decree establishes a National Intersectoral Commission for Public Health Surveillance to provide high-level guidance to national ministries overseeing the system.[17] Public health surveillance committees are also established to assist the health directorates at departmental, district and municipal levels.[18]

In some countries, the most pressing difficulty is likely to be that surveillance and response capabilities are degraded or non-functioning in particular regions of the country. Options available for federal governments include the provision of financial assistance to strengthen regional surveillance systems, or more generally, the provision of conditional funding. For example, federal grants to regional governments may contain conditions that require the harmonization of regional surveillance systems in order to meet the core capabilities set out in the IHR.[19]

The cases of disease or harm that are captured by effective surveillance systems may reflect a wide variety of public health hazards. WHO has pointed out that "different public health risks (e.g. infectious disease, food safety, risks of chemical accidents or contamination, radionuclear safety, or animal health issues which may affect humans) are addressed in different laws or regulations, and often by different ministries, departments and governmental levels".[20] For this reason, WHO has

recommended that countries establish an intersectoral committee for legislative assessment that includes representation from all government sectors and, if appropriate, other interest groups affected by the IHR.[21] The task of such a committee would be to assess whether "existing legislation, regulations and other instruments cover all the subject areas and functions of the IHR (2005)".[22] For example, identification of cases of a serious foodborne illness (e.g. botulism) through a clinical and laboratory surveillance system should trigger an urgent investigation of the likely source. In turn, this will require public health personnel to have adequate powers to enter food businesses, remove samples, recall products and require the removal of products from sale, temporarily close businesses, and issue public health alerts.

The IHR have a particular focus on the international spread of disease. They therefore require countries to meet core capacity requirements for managing international traffic and responding to potential health risks at designated airports, ports and ground crossings.[23] WHO has published a toolkit to assist countries to assess their national legislation and regulations against the specific requirements of the IHR.[24] These matters are discussed further in Chapter 11.

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Chapter 10: Controlling the spread of infectious diseases

SUMMARY POINTS

· **Minimizing the transmission of infectious diseases is a core function of public health law. The appropriate exercise of legal powers will vary according to the seriousness of the disease, the means of transmission, and how easily the disease is transmitted.**

· **Law can contribute to the prevention of infectious diseases by improving access to vaccinations and contraceptives, and by facilitating screening, counselling and education of those at risk of infection. Law also has a reactive role: supporting access to treatment, and authorizing public health authorities to limit contact with infectious individuals and to exercise emergency powers in response to disease outbreaks.**

· **Where public health laws authorize interferences with freedom of movement, the right to control one's health and body, privacy, and property rights, they should balance these private rights with the public health interest in an ethical and transparent way. Public health powers should be based on the principles of public health necessity, reasonable and effective means, proportionality, distributive justice, and transparency.**

· **Immunization is a successful and cost-effective public health strategy that saves millions of lives each year. Governments can support vaccination coverage by ensuring that vaccination is free or affordable, by ensuring that all children are vaccinated (with limited exceptions for medical or religious reasons), and that vaccinations are documented.**

· **Screening individuals to determine if they have been infected with or exposed to an infectious disease is a core public health strategy. Early treatment has important public health benefits; for example, people receiving treatment for tuberculosis and HIV infection are less likely to transmit the infection to others. Routine, voluntary HIV testing benefits both affected individuals and their intimate partners by facilitating early access to prevention, care and treatment services.**

· **Health laws can improve the success of voluntary screening programmes by including counselling requirements, ensuring the confidentiality of test results, and protecting individuals diagnosed with particular diseases from discrimination. Public health laws should protect the confidentiality of a person's HIV status, authorizing disclosure to third parties only in limited circumstances where a third party is at significant risk of HIV transmission and where other statutory preconditions are met.**

· **Governments should carefully consider the appropriate role of criminal law when amending laws to prevent the transmission of infectious and communicable diseases. For example, criminal penalties for transmission of HIV may create disincentives to individuals to come forward for HIV testing and treatment, or may provide the pretext for harassment and violence against vulnerable groups. Encouraging personal responsibility and self-protection is critical, especially in countries where rates of HIV infection are high.**

· **Public health laws should authorize compulsory treatment only in circumstances where an individual is unable or unwilling to consent to treatment, and where their behaviour creates a significant risk of transmission of a serious disease. Compulsory treatment orders should restrict individual liberty only to the extent necessary to most effectively reduce risks to public health.**

· **Public health laws may authorize the isolation of individuals and groups who may have been exposed to an infectious disease, as well as the closure of businesses and premises and the confiscation of property. The exercise of these powers must be based on public health considerations, without discrimination on grounds of race, gender, tribal background, or other inappropriate criteria. Public health laws should provide for the fair compensation of those who have suffered economic loss due to a public health order affecting their property or facilities.**

Minimizing the transmission of infectious diseases is a core function of public health law. Clearly-defined legal powers are needed to respond to outbreaks of contagious and serious diseases at national level. The appropriate exercise of legal powers will vary according to the seriousness of the disease, the means of transmission, and how easily the disease is transmitted. Some diseases are entirely preventable by vaccination (e.g. measles and polio), or by access to improved sanitation and clean drinking water (e.g. diarrhoeal and parasitic diseases). Others are treatable when detected in a timely manner (e.g. tuberculosis and malaria). The epidemic of HIV can be substantially reduced through laws supporting access to treatment, combined with measures to educate and support individuals and communities to implement proven strategies for preventing transmission. As discussed in Section 11.1, States Parties to the International Health Regulations (2005) have an obligation to assess and notify WHO of all events occurring within their territories that may constitute a public health emergency of international concern.[1] The legal framework for responding to public health emergencies is discussed further in Chapter 11.

In circumstances where a disease or infection is transmitted by sexual contact or other forms of human behaviour that are private and difficult to monitor, the priority for governments is to create an enabling legal environment that supports those behaviours that are most successful in preventing further transmission. This is the challenge of HIV and the law. High rates of infection with HIV, particularly in sub-Saharan Africa, combined with inadequate access to treatment, have resulted in a heavy burden of disease from AIDS, dramatically reducing average life expectancy, productivity, and creating major obstacles to the progressive realization of the right to health (see Section 3.2(a)). These problems have been exacerbated by a lack of resources. In 2009, the Regional HIV Prevention Experts Think Tank and Multisectoral Stakeholder meeting convened by the East African Community recommended that Partner States commit at least 15% of their national budgets to health, and 15% of the national health budget to HIV and AIDS interventions – beyond the 5% currently committed.[2] They also recommended that Partner States scale up by at least 50% the allocation of the total HIV and AIDS budget devoted to HIV prevention interventions.[3]

10.1 Building ethical principles into infectious disease legislation

Public health laws can support the control of infectious diseases in two important ways. Firstly, law has a proactive or preventive role: improving access to vaccinations and contraceptives, together with screening, education, counselling and other strategies that aim to minimize exposure to disease. Secondly, law has a reactive role: supporting access to treatment, and authorizing health departments and health care providers to limit contact with infectious individuals and to exercise emergency powers in response to disease outbreaks. Because infectious disease control and prevention laws may involve interference with freedom of movement, the right to control one's health and body, and with privacy and property rights, public health laws should embody a decision-making process that balances these personal rights with the public's health in an ethical and transparent way. **Table 10.1** identifies a set of ethical principles that are relevant and sets out what they mean in terms of the exercise of coercive power over individuals, within a legal framework for control of infectious diseases.[4]

Table 10.1: Building ethical principles into legislation that restricts personal rights and freedoms

Ethical principle	Putting the principle into practice
Public health necessity	Coercive powers should be exercised on the basis of a demonstrable threat to public health. Mandatory physical examination, treatment or isolation should require a reasonable suspicion that the person is contagious or could pose harm to others.
Reasonable and effective means	The specific measures adopted by governments must be appropriate to prevent or reduce the threat. Governments should monitor the effectiveness of public health interventions and ensure that they are based on sound science.
Proportionality	Governments must strive to ensure that there is a reasonable fit between the coercive measures imposed on individuals, and the public health benefit that they seek to achieve. Governments should adopt the least burdensome measure from among the measures that are available and reasonably appropriate to mitigate the risks in question. Restrictions that are "gratuitously onerous or unfair" may "overstep ethical boundaries".[5]
Distributive justice	The risks, benefits and burdens of public health interventions should be shared fairly. For example, vulnerable populations should not be targeted with restrictive measures, nor excluded or given lower priority in the allocation of treatment, vaccines, or other benefits.

Trust and transparency	The public should have an opportunity to participate in the formulation of public health policies, and governments should give reasons for policies and decisions that restrict individual freedoms. Openness and accountability are essential to generating public trust, and are likely to improve public health decision-making. Without public trust and voluntary cooperation, governments will find it harder to achieve their goals and to act in the public interest.

10.2 Preventing the transmission of infectious diseases

(a) Immunization

"Overwhelming evidence demonstrates the benefits of immunization as one of the most successful and cost-effective health interventions known".[6] Immunization avoids about 2–3 million deaths each year, as well as serious disability from vaccine-preventable diseases including Yellow fever, diphtheria, tetanus and pertussis, rubella, rotaviruses, polio, pneumococcal diseases, mumps, measles, human papillomavirus, polio, hepatitis B, and *Haemophilus influenzae* type b.[7] To maximize immunization coverage, national vaccination plans should provide for free or affordable immunizations that are available from most health care providers, public education campaigns to illustrate the importance and safety of vaccinations, monitoring of vaccination rates and their impact on health outcomes, and limited exceptions for individuals who for medical or religious reasons wish to avoid vaccinations.

Belize's Public Health Act 2000 illustrates some important features of a national vaccination strategy: all children are to be vaccinated, vaccinations are to be documented, any person (including any adult) may be vaccinated free of charge, and public health officials may require any person to be vaccinated or revaccinated if an outbreak occurs (**Box 10.1**). Governments may determine that certain highly infectious diseases warrant compulsory vaccination, although such a requirement may be subject to constitutional protections relating to the right to be free from non-consensual medical treatment, or to freedom of religion.

Box 10.1: National requirements for child vaccination in Belize

Public Health Act[8]

Section 150. Child to be vaccinated within three months.

(1) Every parent of a child in Belize shall, within three months after the birth of the child, or within three months after receiving into custody the child, take or cause the child to be taken to a public vaccinator of the district in which such child is then resident, to be vaccinated according to this Act, unless the child has been previously vaccinated by a [medical practitioner].

Section 151. Inspection after vaccination.

(1) On the eighth day after the vaccination, the parent shall again take or cause the child to be taken to the public vaccinator for inspection at such time and place as may have been appointed by him at the time of vaccination.

(2) If on inspection it is ascertained that the vaccination has been unsuccessful, the parent shall, if the vaccinator so directs, cause the child to be forthwith again vaccinated and afterwards inspected as on the previous occasion.

(3) If the vaccination has been successful the public vaccinator or surgeon forthwith shall give to the parent a certificate ... and within seven days shall transmit a certified copy of the certificate to the Registrar of the district within which the child's birth was registered ... or if the birth of the child has not been registered, then he shall give it to the Registrar of the district where the child resides.

Section 152. Where child is unfit

(1) If any public vaccinator or surgeon is of opinion that the child is not in a fit and proper state to be successfully vaccinated, he shall forthwith deliver to the parent a certificate under his hand according to the form of the Sixth Schedule or to the like effect, that the child is then in a state unfit for successful vaccination, which certificate shall remain in force for two months only but shall be renewable for a like period from time to time, until a public vaccinator or surgeon thinks the child to be in a fit state for successful vaccination, when the child shall with all reasonable dispatch be vaccinated and a certificate of successful vaccination according to the form of the Fifth Schedule duly given if warranted by the result and a certified copy sent to the Registrar of the district where the child resides.

S 154. Public Vaccination gratis.

(1) Any public vaccinator shall, on application, vaccinate or re-vaccinate without charge any person at any time and place appointed for the attendance of such public vaccinator, and on the performing of the same the public vaccinator shall appoint a time and direct such person to attend at the same place, the time being as far as practicable the eighth day after vaccination.

National vaccination strategies should include contingency plans for outbreaks of highly contagious or serious diseases (e.g. pandemic influenza). In these circumstances, shortages of vaccine may occur. Priority of access to limited supplies of vaccine should occur in accordance with regulations developed through a transparent process that provides the opportunity for meaningful public discussion about the principles of fair allocation. In many cases, priority is likely to be given to health care workers, emergency responders (e.g. fire and police personnel) and others responsible for ensuring the continuation of key services and societal functions.[9]

(b) Screening

Screening individuals to determine if they have been infected with or exposed to an infectious disease is a core public health strategy. Screening enables health care providers to begin treatment in a timely manner, to manage co-morbidities more effectively, to encourage patients to reduce high-risk behaviour and, in certain cases, to identify the need for compulsory treatment. In addition to reducing the severity of illness, early treatment may also reduce transmission rates. For example, early treatment with antiretroviral drugs lowers the viral load of people with HIV and significantly

reduces the risk of sexual transmission.[10] WHO supports the expansion of HIV testing and counselling in order to identify people with HIV early on in their infection and to "link them successfully to prevention, care, and treatment services".[11]

In addition to authorizing screening, including mandatory screening in appropriate circumstances, public health laws can improve the success of screening programmes by including counselling requirements, by ensuring the confidentiality of test results, and by protecting individuals diagnosed with particular diseases (e.g. HIV) from discrimination. Laws drafted in accordance with human rights principles increase the likelihood that individuals will voluntarily seek out testing and treatment services.[12]

Global strategies for controlling infectious diseases advise against placing heavy reliance on criminal laws and penalties. For example, the Joint United Nations Program on HIV/AIDS has advised against the criminalization of unintentional HIV transmission and non-disclosure of HIV infection to sexual partners,[13] and the HIV and AIDS Prevention and Management Bill, passed in 2012 by the East African Legislative Assembly, integrates human rights principles into law in the region[14] (**Box 10.2**).

Box 10.2: Incorporating human rights principles into infectious disease screening policies in the East African Community

The East African Community HIV and AIDS Prevention and Management Bill[15]

9. HIV and AIDS education and information as a health care service.

(1) The provision of HIV and AIDS education and information shall form part of the delivery and health care services by all health care providers at public and private health care facilities.

15. Prevention of mother-to-child transmission. In order to prevent or reduce the risk of mother-to-child transmission of HIV, the Minister shall ensure that –

…

(b) HIV counselling and testing is made available and offered to all pregnant women and their partners, as part of ante-natal care services.

19. Contents of post-test counselling.

…

(3) Where the result of a test is HIV positive, a counsellor shall –

(a) provide post-test counselling which shall include at a minimum –

(i) the medical consequences of living with HIV;

(ii) the modes of prevention and transmission of HIV and other opportunistic infections;

(iii) the importance of disclosure of the person's status to the person's spouse or spouses or sexual partner or partners;

(iv) the medical treatment and other social facilities available;

(v) the need to continuously seek professional services relating to HIV; and

(b) refer the tested person to an appropriate health service provider for follow up testing or treatment.

21. Provision of testing facilities. The Minister shall ensure that facilities for HIV testing are made available –

(a) free of charge, to persons who voluntarily request an HIV test in respect of themselves; and

(b) to persons who are required to undergo an HIV test under this Act or any other written law.

22. Prohibition of compulsory testing.

(1) Subject to this Act, no person shall compel another person to undergo an HIV test.

(2) Unless otherwise provided under this Act, every HIV test shall be confidential.

(3) Without prejudice to the generality of subsections (1) and (2), no person shall compel another to undergo an HIV test as a precondition to, or for continued enjoyment of –

(a) any employment;

(b) marriage;

(c) admission into any educational institution;

(d) entry into or travel out of a Partner State; or

(e) the provision of health care, insurance cover or any other service.

23. Consent to testing.

(1) Unless otherwise provided by this Act, the informed consent of the person to be tested shall be obtained prior to any HIV test.

Under the East African Community law, which applies within Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania, HIV screening remains voluntary and routine, meaning that all patients are offered an HIV test when they come into contact with the health system. This approach has become the norm within infectious disease control strategies and settings where antiretroviral drugs are available and accessible,[16] and is a proven way of both increasing uptake of screening and increasing the number of women who are aware of their HIV status and receive interventions to reduce mother-to-child transmission.[17] Where access to treatment is limited, HIV screening policies should not require routine testing, but rather require health care providers to screen symptomatic patients, patients who request testing, and all blood collected for transfusion or for the manufacture of blood products.[18] The East African Community bill provides that the results of HIV tests shall be confidential and encourages persons diagnosed with HIV to voluntarily disclose their status to spouses or sexual partners. The disclosure of a person's HIV status to a third party without consent is authorized in strictly limited circumstances where a third party is at significant risk of HIV transmission and where other statutory preconditions are met (**Box 10.3**).

Box 10.3: HIV test results, post-test counselling and disclosure of HIV status in the East African Community

The East African Community HIV and AIDS Prevention and Management Bill[19]

Section 24. HIV test results.

(1) Subject to subsection (3) and (4), the result of an HIV test shall be confidentially and directly communicated to the person concerned ...

(2) A person providing treatment, care or counselling services to a person living with HIV shall encourage that person to inform the person's spouse ... or sexual partner or partners or any other third party who is at significant risk of HIV transmission from the person living with HIV, of the person's HIV status.

(3) Except where subsection (4) is applicable, a person providing treatment, care or counselling services to a person living with HIV may notify a third party of the HIV status of that person only where the notifying person is requested by the person living with HIV to do so.

(4) A person providing treatment, care or counselling services to a person living with HIV may notify a third party of the HIV status of that person if –

(a) In the opinion of the person providing treatment, care or counselling services, after discussion of the matter with the person living with HIV, that person is not at risk of serious harm from the third party or from other persons as a consequence of such notification;

(b) The third party to be notified is at significant risk of HIV transmission from the person living with HIV;

(c) The person living with HIV, after appropriate counselling, does not personally inform the third party at risk of HIV transmission; and

(d) The person providing treatment, care or counselling services has informed the person living with HIV of the intention to notify the third party;

or

(e) The person living with HIV is dead, unconscious or otherwise unable to give consent to the notification and is unlikely to regain consciousness or the ability to give consent; and

(f) In the opinion of the person providing treatment, care or counselling services, there was a significant risk of transmission of HIV by the person living with HIV to the third party.

Routine HIV testing services are likely to be most effective when combined with outreach programmes that target those populations most at risk of transmission. These include sex workers, men who have sex with men, injecting drug users, military personnel, transport workers, and prisoners. For example, Thailand's National AIDS Committee adopted a strategy targeting commercial sex workers, which resulted in an increase in condom use by sex workers by over 70% in three years[20] and a fivefold decrease in new HIV infections.[21]

(c) Criminal law and mandatory disclosure laws

The appropriate role of criminal law in national efforts to prevent transmission of HIV and other sexually transmissible infections is often controversial. Public health laws often contain penalties for failing to comply with public health orders made by authorities, or for engaging in behaviours that place public health at risk. However, policy-makers should not ignore the potential for unintended consequences arising from laws that create criminal offences for recklessly exposing another person to HIV, or for failing to disclose one's HIV status to a sexual partner (mandatory disclosure laws).[22]

Laws like these may be intended to encourage personal responsibility in the hope that individuals will modify their behaviour in order to avoid criminal penalties. They may also be motivated by the belief that those who fail to protect others from HIV transmission, or from the risk of transmission, deserve punishment. On the other hand, the broader impact of these laws on transmission rates and public health can be negative. The final report of the Global Commission on HIV and the Law pointed out that criminal laws against HIV in many countries are overly broad, carry draconian penalties, and are "virtually impossible to enforce with any semblance of fairness".[23] For example, sex workers and women in abusive relationships may face violence if required to disclose their HIV status to sexual partners.[24] To the extent that criminal penalties have any effect on sexual behaviour at all,[25] they may create disincentives to individuals to come forward for HIV testing and treatment, for fear of criminal penalties or official investigation. This is counter-productive, since it is important to encourage individuals to monitor their HIV status and to seek treatment as soon as they are diagnosed, both because those who acquired the virus recently will have a higher viral load and will be more likely to transmit it,[26] and because effective treatment with antiretroviral therapy lowers viral load and makes it less likely that HIV positive individuals will pass on the virus to others.[27]

An additional concern that relates to mandatory disclosure laws is the potential for such laws to subtly undermine disease control efforts by weakening the assumption that individuals are primarily responsible for protecting themselves from the risks of transmission of HIV and other sexually transmissible diseases. In countries where large numbers of the population are infected, relying on voluntary disclosure by sexual partners is unrealistic. Individuals may not know their status, or may be ashamed, fearful, or otherwise unwilling to reveal information about themselves. In these circumstances, personal responsibility and self-protection remain critical.

The Joint United Nations Programme on HIV/AIDS (UNAIDS)[28] and, more recently, the Global Commission on HIV and the Law, have recommended that countries should only prosecute HIV transmission in cases of intentional and actual transmission, and require a high standard of evidence and proof. The Global Commission recommended that countries repeal provisions that explicitly criminalise HIV transmission, and rely on existing laws against assault, laws against causing bodily harm, or laws that permit public health officials to intervene when a person's behaviour creates a serious risk of transmission of communicable disease.[29]

10.3 Compulsory treatment orders

Although the right to consent to medical treatment is a fundamental individual human right, there are circumstances in which public health authorities may be justified in ordering the compulsory

diagnosis and treatment of individuals. Public health laws should authorize compulsory treatment orders only in circumstances where the person in question is unable or unwilling to consent to a diagnostic procedure or treatment, and where their behaviour creates a significant risk of transmission of a serious disease. For example, South Africa's National Health Act states that a health service may not be provided to a user without the user's informed consent, unless "failure to treat the user, or group of people which includes the user, will result in a serious risk to public health".[30]

A treatment order should clearly state the grounds on which it has been made, should set out any restrictions or limitations on behaviour, and should take into account the principle that individual liberty should only be restricted to the extent necessary to most effectively reduce risks to public health (see Section 10.1). Public health laws should also include procedural rights to protect the interests of individuals subject to treatment orders. This may include the requirement for a court to review each compulsory treatment order within a defined period of time. Public health officials must ensure that laws authorizing treatment without consent are never used to discriminate against or to marginalize vulnerable individuals and groups.

10.4 Limiting contact with infectious persons

Isolating persons who have or may have been exposed to a serious contagious disease, in order to prevent transmission, is a long-established public health strategy that may be applied to both individuals and groups. Where an outbreak of a serious, contagious disease occurs, it will often be impractical or impossible to accurately identify cases and carriers of disease. For this reason, public health laws should authorize officials to evacuate or to order the closure of premises (e.g. markets, schools and movie theatres) and to prevent access to public spaces where people would otherwise gather. Since the closure of premises can affect businesses and livelihoods, it is important for the operation of public health orders to be reviewed regularly and to be based on public health considerations, without discrimination on grounds of race, gender, tribal background or other inappropriate criteria.

Public health orders for the evacuation or closure of premises may be coupled with orders to disinfect and decontaminate premises, or to remove noxious articles (including objects, birds and animals) that are contaminated with an infectious agent. Where the confiscation or destruction of private property causes more than trivial economic loss, public health laws should require reasonable compensation to be paid to the owner. This principle can have an important benefit for public health: laws that provide for just compensation are more likely to secure the trust and voluntary cooperation of those who are poor and economically vulnerable, and who for that reason are most likely to be adversely affected by a public health order.

Public health laws should authorize public health officials to make orders for the isolation of infected individuals, and the quarantine of those who have been exposed to a serious contagious disease. As with treatment orders, however, these restrictions on autonomy should only be used as a last resort and should be minimally restrictive (see Section 10.1). For example, an infectious individual who does not require medical attention may be effectively quarantined within his or her home, rather than being confined in a hospital or other facility used as a detention centre. Laws authorizing

mandatory confinement must also ensure that basic needs are met, including adequate shelter, food, water and sanitation. They should also provide for appropriate treatment and health care, and respect the cultural or religious expectations of quarantined or isolated individuals to the greatest possible extent (**Box 10.4**). National laws should also include procedural safeguards, by giving individuals who are the subject of a quarantine or isolation order the right to seek review by a court within a reasonable time.

Box 10.4: Incorporating human rights protections into quarantine and isolation laws: an example from the United States

Model Public Health Act[31]

Section 5-108: Quarantine and Isolation.

(a) Authorization. A state or local public health agency may isolate or quarantine an individual or group of individuals pursuant to rules or regulations promulgated by the state public health agency consistent with the provisions of this section.

(b) Conditions and Principles. The state or local public health agency shall adhere to the following conditions and principles when isolating or quarantining individuals or groups of individuals:

(1) Isolation and quarantine must be by the least restrictive means necessary to prevent the spread of a contagious or possibly contagious disease to others and may include, but are not limited to, confinement to private homes or other private and public premises.

(2) Isolated individuals must be confined separately from quarantined individuals.

(3) The health status of isolated and quarantined individuals must be monitored regularly to determine if they continue to require isolation or quarantine.

(4) If a quarantined individual subsequently becomes infected or is reasonably believed to have become infected with a contagious or possibly contagious disease he or she must promptly be removed to isolation.

(5) Isolation and quarantine must be immediately terminated when an individual poses no substantial risk of transmitting a contagious or possibly contagious disease to others.

(6) The needs of individuals who are isolated or quarantined shall be addressed in a systematic and competent fashion, including, but not limited to, providing adequate food, clothing, shelter, means of communication with those in isolation or quarantine and outside these settings, and competent medical care.

(7) Outside premises used for isolation and quarantine shall be maintained in a safe and hygienic manner and be designed to minimize the likelihood of further transmission of infection or other harms to individuals isolated and quarantined.

(8) To the extent possible, cultural and religious beliefs shall be respected in addressing the needs of individuals, and establishing and maintaining isolation and quarantine premises.

(c) Entry into Isolation or Quarantine Premises. The state or local public health agency may authorize physicians, health care workers, or others access to individuals in isolation or quarantine

as necessary to meet the needs of isolated or quarantined individuals. Any individual entering isolation or quarantine premises with or without authorization of the state or local public health agency may be isolated or quarantined where needed to protect the public's health.

(d) Temporary Isolation and Quarantine without Notice. The state or local public health agency may temporarily isolate or quarantine an individual or groups of individuals through a written directive if delay in imposing the isolation or quarantine would significantly jeopardize the agency's ability to prevent or limit the transmission of a contagious or possibly contagious disease to others.

(e) Isolation or Quarantine with Notice. The state or local public health agency may make a written petition to a court for an order authorizing the isolation or quarantine of an individual or groups of individuals.

(f) Relief from Isolation and Quarantine. An isolated or quarantined individual or group of individuals may apply to a court for an order to show cause why isolation or quarantine should not be terminated. The court shall rule on the application to show cause within 48 hours of its filing.

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Chapter 11: Public health emergencies

SUMMARY POINTS

· **Disaster management is a core function of public health law. National laws and emergency plans must take account of international obligations for the management of public health emergencies, including the International Health Regulations (2005) (IHR). The purpose of the IHR is to prevent and manage the public health risks arising from the international spread of disease, while avoiding "unnecessary interference with international traffic and trade".**

· **Important obligations that arise under the revised IHR include the following:**

· **Each country is required to establish a National IHR Focal Point accessible at all times for communications with WHO.**

· **Each country must develop and maintain the capacity to assess health risks within its territory and to notify WHO of all events that may constitute a public health emergency of international concern. The IHR contain a decision instrument to assist countries to identify events requiring notification.**

· **The IHR impose a legal requirement on countries to strengthen and maintain their surveillance and response capabilities at local, intermediate and national levels, and at designated airports, ports and ground crossings. At national level, countries are expected to develop the capacity to assess all reports of urgent events within 24 hours.**

· **Following a determination by WHO that a public health emergency of international concern is occurring, the Director-General may issue temporary recommendations, after receiving advice from the Emergency Committee. These recommendations may include the requirement to carry out medical examinations and vaccinations, to place suspect persons under public health observation, to quarantine, isolate or require the contact tracing of contacts of affected persons, to carry out exit screening, and to refuse entry to suspect or affected persons.**

· **The IHR require countries to exercise their health powers in a transparent and non-discriminatory manner, with full respect for the dignity, human rights and fundamental freedoms of persons. When issuing temporary recommendations, the Director-General shall consider health measures that are neither more restrictive of international traffic and trade nor more intrusive to persons than reasonable and appropriate alternative measures. The IHR contain a number of more specific human rights protections that apply to the exercise of specific powers.**

· **In addition to the IHR, the Pandemic Influenza Preparedness (PIP) Framework provides guidance in relation to the sharing of influenza viruses with human pandemic potential through the WHO-coordinated Global Influenza Surveillance and Response System. The framework includes a benefit-sharing system that gives commercial entities access to PIP biological materials in exchange for providing assistance to developing countries.**

· **National authorities should develop a national emergency plan that sets out a clear chain of command and takes account of all relevant levels of government. The legal authority and roles of key officials during an emergency should be defined in legislation. These powers may include the authority to take such actions as are reasonably required to deal with a serious risk to public health. Public health laws should establish clear triggers for the application of emergency powers, with clear time limits. Disaster management laws should enable individuals to seek an**

independent review of decisions that restrict their fundamental rights.

· **In order to ensure an adequate health workforce during an emergency, public health laws may grant temporary practice licenses to health professionals who are inactive, retired or licensed in other jurisdictions.**

· **National emergency plans should establish a national stockpile of essential medicines, vaccines and medical supplies to meet emergency needs.**

· **In some circumstances, public health laws authorize government authorities to take control of premises, facilities and supplies, including health facilities and medical supplies, provided that reasonable compensation is paid.**

· **Public health laws should authorize public health officials to take such actions as reasonably necessary to investigate the causes, sources and means of transmission of disease agents, to authorize diagnostic testing, compulsory medical treatment, and to make orders for isolation and/or quarantine. These powers should not be exercised in an arbitrary or discriminatory way, and should be exercised in accordance with the principle of proportionality.**

Disaster management is a core function of public health law. Public health emergencies can arise from a wide range of causes, including outbreaks of contagious, life-threatening disease, natural disasters, as well as chemical contamination of the environment and the release of radiation. In emergencies, large numbers of people may require medical attention, health care systems may be over-stretched, and public order may be threatened. This chapter identifies some of the legal issues that may arise for national authorities in the course of responding to a public health emergency.

11.1 International management of public health emergencies

(a) The International Health Regulations (2005)

The revised International Health Regulations (2005) (IHR), adopted by the World Health Assembly in 2005, are binding on all WHO Member States and provide a regulatory framework for international management of public health emergencies.[1] The purpose of the IHR is to prevent and manage the public health risks arising from the international spread of disease, while avoiding "unnecessary interference with international traffic and trade".[2] Critical features of the IHR include:

- the legal obligation imposed on each country to notify WHO of events that may constitute a "public health emergency of international concern within its territory";[3]
- the obligation of countries to "develop, strengthen and maintain" their national capacities to detect, assess, report and respond effectively to public health risks and emergencies;[4] and
- the ability of the WHO Director-General to make non-binding, temporary recommendations to countries in whose territory a public health emergency of international concern has arisen.[5]

This report does not provide a technical review of obligations owed by countries under the IHR.[6] WHO has published a range of resources to assist countries to implement their obligations under the IHR through national legislation (**Box 11.1**).[7]

Box 11.1: Implementation of the International Health Regulations (2005): selected priority areas[8]

- National International Health Regulations (2005) (IHR) Focal Points: designation and operation
- Detection, reporting, verification and control of events, as well as related communications, domestically and internationally
- Communications and collaboration with WHO
- Implementation of IHR documents:
  - Ship Sanitation Certificate (Annex 3)
  - International Certificate of Vaccination and Prophylaxis (Annex 6)
  - Maritime Declaration of Health (Annex 8)
  - Health Part of Aircraft General Declaration (Annex 9)
- Designation of Points of Entry (ports, airports and ground crossings) for development of core public health capacities
- Identification (and informing WHO) of ports authorized to issue Ship Sanitation Certificates and provide related services.

National IHR Focal Points

In order to facilitate global surveillance and response capabilities, the IHR require each country to establish a National IHR Focal Point. The Focal Point shall be accessible at all times for communications with corresponding WHO IHR Contact Points, established by WHO to assist communications with each country.[9] The IHR envisage a number of important forms of communication between national focal points and WHO; in addition, the focal points are expected to function as coordinating centres for surveillance and reporting within their countries, and for communications between government departments.[10] Countries must ensure that telecommunications systems enable the focal point to be contacted and to communicate with WHO at all times.

Reporting obligations

The IHR require each country to assess health risks within its territory and to notify WHO of all events that may constitute a public health emergency of international concern, together with the health measures it has taken in response to those events.[11] Following notification, each country shall continue to provide timely, accurate and detailed information about the notified event, including (where possible), "case definitions, laboratory results, source and type of risk, number of cases and

deaths, conditions affecting the spread of the disease and the health measures employed", and any difficulties faced and support needed in order to respond effectively.[12]

The concept of a "public health emergency of international concern" is not limited to epidemic-prone diseases, but extends to biological, chemical and nuclear hazards, including the chemical or nuclear contamination of the environment, and contaminated food and pharmaceuticals.[13] The IHR contain a decision instrument to assist countries to identify events requiring notification (**Box 11.2**). Countries are required to notify WHO within 24 hours (or immediately in the case of nuclear-related events), through their National IHR Focal Point.[14] Prior to this point, countries are encouraged to consult with WHO about emerging health threats and the appropriate health response.[15] Determining the existence of a public health emergency of international concern under the IHR is the prerogative of the Director-General, who acts on the advice of Emergency Committees.[16]

Box 11.2: Notification of events that may constitute a public health emergency of international concern under the International Health Regulations (2005)

Article 6 of the International Health Regulations (2005) (IHR) imposes an obligation on countries to notify WHO, via the National IHR Focal Point, of "all events which may constitute a public health emergency of international concern within its territory".[17] The IHR define a "public health emergency of international concern" as an extraordinary event that is determined to "constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response".[18] The algorithm in Annex 2 of the IHR identifies two categories of reportable events.[19] Under the first category, countries are required to assess domestic public health events against the four criteria below and to notify WHO when at least two of the four criteria are met:

- Is the public health impact of the event serious? (yes/no)
- Is the event unusual or unexpected? (yes/no)
- Is there any significant risk of international spread? (yes/no)
- Is there any significant risk of international travel or trade restrictions? (yes/no)

Under the second category, one or more cases of the following four specific diseases are considered by definition to constitute a public health emergency of international concern:

- smallpox;
- severe acute respiratory syndrome (SARS);
- human influenza caused by a new subtype;
- poliomyelitis due to wild-type poliovirus.

WHO has published guidance to assist countries to identify events that are reportable under Annex 2 of the IHR.[20]

Surveillance and response capabilities

The IHR impose a legal requirement on countries to strengthen and maintain their surveillance and response capabilities at local, intermediate and national levels, and at designated airports, ports and ground crossings.[21] At the local community level, this includes the capacity to identify outbreaks of disease or death above expected levels for the particular time and place and for all areas within that country.[22] At national level, countries are expected to develop the capacity to assess all reports of urgent events within 24 hours. In addition, countries are required to inform WHO of public health risks identified outside their territory that may result in the international spread of disease, as manifested by human cases, vectors for infection or contaminated goods.[23] Countries are expected to establish and maintain core capacities for responding to the risks presented by ill travellers who present at designated airports, ports and ground crossings. These include providing prompt medical assessment of those who are ill, transporting ill persons to appropriate medical facilities, and assessing and if necessary imposing quarantine restrictions on persons who may have been exposed to disease.[24]

Temporary recommendations

Following a determination by WHO that a public health emergency of international concern is occurring, the Director-General may issue temporary recommendations, after receiving advice from an Emergency Committee.[25] These recommendations may include health measures for implementation both by countries experiencing the public health emergency, and other countries. Depending on the circumstances, the recommendations may include the requirement to carry out medical examinations and vaccinations, to place suspect persons under public health observation, to quarantine, isolate or require the contact tracing of contacts of affected persons, to carry out exit screening and to refuse entry to suspect or affected persons.[26]

Human rights protections within the IHR

Countries are required to implement the IHR with "full respect for the dignity, human rights and fundamental freedoms of persons",[27] and to exercise their health powers "in a transparent and non-discriminatory manner".[28] When issuing temporary recommendations, the Director-General shall consider health measures that are neither more restrictive of international traffic and trade, nor more intrusive of persons than "reasonably available alternatives that would achieve the appropriate level of health protection".[29] More specific human rights protections are summarized in **Box 11.3**.

Box 11.3: Protecting human rights under the International Health Regulations (2005)

- Countries may require travellers, on arrival or departure, to provide information about their destination and itinerary, and may conduct a "non-invasive medical examination which is the least intrusive examination that would achieve the public health objective". On the basis of this assessment, countries may also require a suspect or affected traveller, on a case-by-case

basis, to undergo a medical examination, provided it is the "least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease".[30]

- Countries may require travellers to undergo invasive medical examinations, vaccination or other prophylaxis and deny entry to a traveller who refuses to consent to such a measure. However, where there is evidence of an imminent public health risk, travellers may be compelled to undergo "the least invasive and intrusive medical examination that would achieve the public health objective". In these circumstances, countries may also require vaccination or other prophylaxis, and impose additional health measures in order to control the spread of disease, including isolation, quarantine and public health observation.[31]
- Countries shall treat all travellers with "respect for their dignity, human rights and fundamental freedoms". In order to minimize discomfort or distress associated with public health measures (including medical examinations, quarantine, and isolation), countries shall:
  - take into consideration the "gender, sociocultural, ethnic or religious concerns" of travellers; and
  - provide adequate food and water, accommodation and clothing, protection for possessions, appropriate medical treatment and linguistic assistance.[32]

(b) Pandemic Influenza Preparedness Framework

The Pandemic Influenza Preparedness Framework ("PIP Framework") adopted by the World Health Assembly in 2011 provides important international guidance in relation to H5N1 and "other influenza viruses with human pandemic potential".[33] Negotiation of the PIP Framework was precipitated by the decision of Indonesia in January 2007 to withhold H5N1 influenza virus samples from WHO for surveillance or vaccine development purposes, following advice that samples were provided to pharmaceutical companies without its consent. Indonesia's position was that efforts to develop patentable diagnostics, vaccines and therapeutic drugs derived from use of biological samples sourced from Indonesia, without its consent, reflected the inequity of global arrangements for virus sharing, which benefit richer countries that can afford to pay for patented products at the expense of those which cannot.[34]

The PIP Framework encourages WHO Member States to share PIP biological materials from influenza viruses with human pandemic potential in a "rapid, systematic and timely manner" through the WHO-coordinated Global Influenza Surveillance and Response System (GISRS).[35] In doing so, countries are taken to consent to the onward transfer and use of PIP biological materials to other institutions, organizations and entities, subject to the terms of two standard material transfer agreements. These agreements apply to transfers of viruses and PIP biological materials within the GISRS system, and outside the GISRS system, respectively.[36]

The framework requires WHO to establish an electronic traceability system to enable the tracking in real time of all PIP biological materials. Under the first material transfer agreement, between providers and recipient laboratories within the GISRS, both parties are encouraged not to seek to obtain any intellectual property rights in the materials.[37] The second material transfer agreement,

between WHO and recipients outside the GISRS, creates a benefit-sharing system that gives commercial entities access to PIP biological materials in exchange for assistance to developing countries (**Box 11.4**). Among other provisions, the PIP Framework commits the Director-General to work with multilateral agencies and donors to establish stockpiles of vaccines and antivirals, and asks countries to urge manufacturers to implement tiered pricing in order to increase the affordability of influenza vaccines and antivirals in developing countries.[38] Manufacturers of influenza vaccines, as well as diagnostic and pharmaceutical manufacturers receiving samples through the GISRS system are also required to pay annual contributions equivalent to half the running costs of the GISRS network.[39]

Box 11.4: Benefit-sharing provisions applicable to commercial entities receiving influenza viruses under the Pandemic Influenza Preparedness Framework

A. Benefit-sharing options for manufacturers of vaccines and/or antivirals. Manufacturers shall commit to at least two of the following:

- donate 10% or more of real-time pandemic vaccine production to WHO;
- reserve 10% or more of pandemic vaccine production for WHO at affordable prices;
- donate at least X [amount to be negotiated] courses of antiviral treatment for the pandemic to WHO;
- reserve at least X courses of antiviral treatment for the pandemic at affordable prices;
- grant licences to manufacturers in developing countries on fair and reasonable terms for products in which the recipient holds intellectual property rights (influenza vaccines, adjuvants, antivirals, and/or diagnostics);
- grant royalty-free licences to manufacturers in developing countries, or alternatively, royalty-free licences to WHO for production of pandemic influenza vaccines, adjuvants, antivirals and diagnostics;

B. Benefit-sharing options for manufacturers of products other than vaccines or antivirals. Manufacturers shall commit to at least one of the following:

- donate to WHO at least X [amount to be negotiated] diagnostic kits for use in a pandemic;
- reserve at least X diagnostic kits for use in a pandemic, at affordable prices;
- in coordination with WHO, support the strengthening of influenza specific laboratory and surveillance capacity in developing countries;
- in coordination with WHO, support the transfer of technology and know-how for pandemic influenza preparedness to developing countries.

C. In addition to the above commitments, recipients shall consider contributing to the following measures:

- donations of vaccines;
- donations of pre-pandemic vaccines;
- donations of antivirals;
- donations of medical devices;

- donations of diagnostic kits;
- affordable pricing;
- transfer of technology and processes;
- granting of sublicences to WHO;
- laboratory and surveillance capacity-building.

(c) Strengthening WHO's emergency response capacity

The Ebola virus disease outbreak in 2014–2015, which resulted in the establishment and deployment of the United Nations Mission for Ebola Emergency Response (UNMEER),[40] has been a catalyst for a number of developments in the global management of public health emergencies. These include the establishment of a global health emergency workforce, and a contingency fund to support WHO's emergency response capacity.

National governments bear the primary responsibility for developing their domestic health systems and establishing an effective health emergency workforce. However, in order to support national efforts, WHO has committed to scaling up the global health emergency workforce, both by expanding partnerships with United Nations agencies, funds and programmes, and by improving the coordination of other international responders, including through its leadership of the Global Health Cluster of international humanitarian health organizations.[41] The process of operationalizing the global health emergency workforce includes developing processes for pre-deployment (establishing rosters, quality assurance and training), deployment (including logistic planning and medical evacuation), and decommissioning of personnel, together with governance and finance arrangements. In order to support its role in coordinating the global response to public health emergencies, WHO has established a contingency fund with a target capitalization of US$ 100 million.[42] Financed through voluntary contributions, this fund can support all aspects of WHO's emergency response work, including the mobilization of the global health emergency workforce, and surveillance in high-risk areas.

11.2 National public health emergency plans

The following sections identify some of the legal issues that countries may face during the process of strengthening their national laws and operational plans for responding to public health emergencies. Countries should prepare and regularly review a national emergency plan that sets out a clear command structure for decision-making and for activating and coordinating resources. Emergency plans should specify the officials and agencies that will have operational control during the emergency, and identify relevant advisory bodies, such as national emergency councils and standing committees advising in specialist areas. The roles and powers of officials performing key operational or executive roles during an emergency, including the health minister, chief health officer, director of human biosecurity (and similar officials), should be defined in legislation.

Since overlapping authority, and gaps in authority may cause uncertainty and disputes during an emergency, national emergency plans should take account of all levels of government (national, state/regional/provincial, and local/city), ensuring that the response to localized emergencies can be scaled up as required.[43] In order to ensure that countries meet their obligations under the IHR, national governments may need to formalize agreements about operational control and chains of command through memoranda of understanding. Similarly, the roles and responsibilities of different ministries, as well as statutory and executive bodies, should be considered and specified.[44]

Public health laws contribute to effective disaster management by authorizing rapid and decisive government responses, and by temporarily suspending the operation of laws and processes that would otherwise disrupt an effective emergency response. Public health laws should establish clear triggers for the application of emergency powers, such as the scale or seriousness of the emergency, or a formal declaration of emergency as well as a specific time period for the application of these powers (e.g. 30 days, renewable if necessary). Since the emergency powers required for disaster management may require interferences with individual human rights, disaster management laws should include accountability mechanisms, such as the right to seek review of decisions that affect a person's fundamental rights by an independent, external body, within a time frame that is reasonable in the circumstances.

Emergency powers may include the power to rapidly marshal the physical and human resources that are needed to provide health care and other services. As discussed in the following sections, public health laws may authorize public health officials to:

- expand the health care or disaster management workforce by co-opting personnel from other agencies and jurisdictions under a unified command structure;
- seize property in order to establish emergency response centres and to ensure the availability and rapid distribution of pharmaceuticals and supplies; or
- conduct surveillance and mandate vaccinations, treatment, isolation or quarantine of infected or potentially infected individuals.

11.3 Emergency health workforce

Health care workers may be in short supply following a natural disaster or event causing mass casualties. Public health laws may provide that health professionals must assist in the provision of emergency assistance, grant temporary practice licences to medical professionals and nurses who are inactive, retired, or licensed in other countries or jurisdictions, or allow health professionals to perform functions beyond their licensed scope of practice (**Box 11.5**). The United States Model State Public Health Act illustrates how emergency health care workers may be protected from civil lawsuits that arise from treatment provided during an emergency in a given jurisdiction, except in circumstances where their actions or omissions demonstrated a reckless disregard for the life and health of the patient.

Box 11.5: Maintaining the health care workforce during a public health emergency: an example from the United States

Model State Public Health Act[45]

Section 6-104. Protection of individuals.

(d) Licensing and appointment of health personnel. During a state of public health emergency, the state or local public health agency is authorized:

(1) Health care providers. To require in-state health care providers to assist in the performance of vaccination, treatment, examination, testing, decontamination, quarantine, or isolation of any individual as a condition of licensure, authorization, or the ability to continue to function as a health care provider in this state.

(2) Health care providers from other jurisdictions. To appoint and prescribe the duties of out-of-state emergency health care providers (with proof of current licensure in their state) as may be reasonable and necessary to respond to the public health emergency.

(i) The appointment of out-of-state emergency health care providers shall not exceed the termination of the declaration of a state of public health emergency. The state or local public health agency may terminate the out-of-state appointments at any time or for any reason provided that any such termination will not jeopardize the health, safety, and welfare of the people of this state.

(ii) The state public health agency may waive any or all licensing requirements, permits, or fees required by state code and applicable orders, rules, or regulations for health care providers from other jurisdictions to practice in this state.

(iii) Any out-of-state emergency health care provider appointed pursuant to this Section shall not be held liable for any civil damages as a result of medical care or treatment related to the response to the public health emergency unless such damages result from providing, or failing to provide, medical care or treatment in the event of gross negligence or willful misconduct.

Colorado State Governor's Expert Emergency Epidemic Response Committee Draft Executive Order 5.0, United States of America[46]

Authorizes Colorado licensed physician assistants and emergency medical technicians to practice outside of their normal supervision but under the supervision of another physician to meet the emergency epidemic.

11.4 Control of premises, facilities and supplies

Natural disasters as well as emergencies resulting from human actions, may create dangerous or contaminated areas that present a risk to public health and must be immediately closed off to the public. Public health laws may authorize public health authorities to compel the evacuation and closure of any premises or public area, and include the power to enter premises and private property in order to dispose of infectious waste or contaminated material (**Box 11.6**).

A public health emergency may create an urgent need for vaccinations, treatments and emergency response sites. Emergency plans should provide for the stockpiling of essential pharmaceuticals and medical supplies, and should consider the logistics of distributing essential supplies to areas of greatest need following an emergency event. For example, in the United States, federal law requires the Centers for Disease Control and Prevention (CDC), in coordination with the Secretary of Homeland Security, to maintain a strategic national stockpile of essential medicines, vaccines, medical devices and other supplies "in such numbers, types and amounts" as the Secretary determines to be necessary.[47] The contents of the stockpile are required to be kept within their shelf-life limits and made available, free of charge, to meet the needs of states and communities within 12 hours of determination of emergency need.[48] The Secretary is required to review the contents of the stockpile and to make plans for the management of the stockpile in consultation with federal, state and local officials.[49] In 2009, the stockpile was used to assist state health departments to respond to the H1N1 influenza outbreak (antiviral drugs such as oseltamivir and zanamivir were distributed to states to replenish supplies).[50] Public health laws can support these plans by authorizing public health officials to purchase or acquire essential medicines, vaccines and other medical supplies from public or private sources, on reasonable terms (**Box 11.6**). In addition to authorizing the specific actions set out in **Box 11.6**, public health laws may contain general authorizing provisions permitting government officials to exercise executive powers following the declaration of an emergency, and authorizing health departments to take such actions as are reasonably required to deal with the risk to human health.

Box 11.6: Laws authorizing the emergency use of facilities and pharmaceuticals: an example from the United States

Model State Public Health Act[51]

Section 6-103. Management of property.

(a) Emergency Measures Concerning Facilities and Materials. During a state of public health emergency, the state or local public health agency is authorized:

(1) **Close facilities.** To close, direct, and compel the evacuation of, or decontaminate or cause to be decontaminated any facility of which it has reasonable cause to believe that it may endanger the public's health.

(2) **Use of materials and facilities.** To procure, by condemnation or otherwise, construct, lease, transport, store, maintain, renovate, or distribute materials and facilities as may be reasonable and necessary to respond to the public health emergency, with the right to take immediate possession thereof. Such materials and facilities include communication devices, carriers, real estate, fuels, food, and clothing.

(3) **Use of health care facilities.** To require a health care facility to provide services or the use of its facility if such services or use are reasonable and necessary to respond to the public health emergency as a condition of licensure, authorization or the ability to continue doing business in the state as a health care facility. The use of the health care facility may include transferring the management and supervision of the health care facility to the state or local public health agency for a limited period of time.

(4) **Destruction of materials.** To decontaminate or cause to be decontaminated, or destroy, any material of which it has reasonable cause to believe that it may endanger the public's health.

(5) **Control of materials.** To inspect, control, restrict, and regulate by rationing and using quotas, prohibitions on shipments, allocation, or other means, the use, sale, dispensing, distribution, or transportation of food, fuel, clothing and other commodities, as may be reasonable and necessary to respond to the public health emergency.

(e) Control of Health Care Supplies.

(1) **Procurement.** During a state of public health emergency, the state or local public health agency may purchase and distribute anti-toxins, serums, vaccines, immunizing agents, antibiotics, antidotes, and other pharmaceutical agents, medical supplies, or personal protective equipment to prepare for or control a public health emergency.

(2) **Rationing.** Where a state of public health emergency results in a state-wide or regional shortage or threatened shortage of any product under subsection (1), whether or not such product has been purchased by the agency, the agency may control, restrict, and regulate by rationing and using quotas, prohibitions on shipments, allocation, or other means, the use, sale, dispensing, distribution, or transportation of the relevant product. In making rationing or other supply and distribution decisions, the agency may give preference to health care providers, disaster response personnel, and mortuary staff.

(3) **Distribution.** During a state of public health emergency, the agency may store or distribute any anti-toxins, serums, vaccines, immunizing agents, antibiotics, antidotes, and other pharmaceutical agents, personal protective equipment, or medical supplies located within the state as may be reasonable and necessary to respond to the public health emergency, with the right to take immediate possession thereof….

Section 6-106. Compensation

(a) **Just Compensation.** The State shall pay just compensation to the owner of any facilities or materials that are lawfully used or appropriated by a state or local public health agency for its temporary or permanent use during a state of public health emergency according to the procedures and standards set forth in this Article.

11.5 Health care services during a public health emergency

In order to deal effectively with a public health emergency, emergency powers can include the power to authorize compulsory medical treatment, and to make orders for isolation and quarantine. However, laws that directly restrict the freedom of individuals during a disaster or public health emergency should comply with the human rights protections set out in the IHR (see Section 11.1(a)), with the United Nations' Siracusa Principles (see **Box 11.7**),[52] and with any domestically applicable fundamental rights protection regime.

Box 11.7: Requirements for laws directly restricting individual freedom during a public health emergency: the Siracusa Principles

Emergency laws that place limitations on individual freedoms must:

(1) Respond to a pressing public or social need;

(2) Pursue a legitimate aim;

(3) Be proportionate to the legitimate aim; and

(4) Be no more restrictive than required to achieve the purpose sought by restricting the right.[53]

Laws that restrict rights should not be applied or implemented in an arbitrary or discriminatory manner.[54] Furthermore, where limitations are placed upon fundamental rights, such as freedom of movement, they must be substantiated by scientific evidence and implemented in ways that take account of the values of participation, transparency and accountability.[55]

In addition to authorizing medical treatment, emergency powers should authorize urgent investigations to determine the causes, sources and means of transmission of disease agents. Conducting swift and accurate surveillance during a public health emergency enables authorities to design and implement effective responses. Public health laws can authorize state or local health departments to enter premises, to collect specimens and perform diagnostic tests on living or deceased persons, and to access previously collected samples or test results as necessary in order to respond effectively.

Disasters may threaten public order and public health due to violence and crime. Reproductive health needs are often especially great in the aftermath of a disaster. Displaced women are often victims of rape and sexual violence, and may have an urgent need for emergency contraception and treatment for sexually transmissible infections. WHO's Interagency Emergency Health Kit,[56] which includes emergency contraception and midwifery supplies, and WHO's Model List of Essential Medicines,[57] can serve as a benchmark in operational planning for a public health emergency.

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Chapter 12: Enabling environments to support healthy and safe behaviours

SUMMARY POINTS

· **Noncommunicable diseases (NCDs) kill more than 38 million people every year. Three quarters of these deaths occur in low- and middle-income countries, entrenching poverty, cutting into the productive years of life and undermining the benefits of the lower dependency rates enjoyed by developing countries with younger populations.**

· **Members of the World Health Assembly have committed to a 25% relative reduction in premature mortality from cardiovascular diseases, cancer, diabetes and chronic respiratory diseases by 2025, and to a set of supporting targets covering key risk factors: harmful use of alcohol, physical inactivity, salt intake, tobacco use, raised blood pressure, and overweight and obesity. The WHO Global Action Plan for the Prevention and Control of NCDs identifies a suite of policy options to assist countries to meet these targets.**

· **Many of WHO's recommended "best buys" for reducing risk factors for NCDs will require legal and regulatory controls for effective implementation. To ensure that these measures are implemented, with adequate budgets for monitoring and enforcement, high-level leadership will be required from presidents, prime ministers, health ministers and other senior cabinet ministers. The involvement of non-health ministries is vital, since many of the most important interventions will be implemented outside the health sector. Examples include raising taxes on alcohol and/or unhealthy food and beverages, reducing the amount of smuggled and counterfeit tobacco products, and restricting the marketing of unhealthy foods to children.**

· **When implementing effective measures to prevent and control NCDs, governments can expect resistance from manufacturers and retailers of tobacco, alcohol and unhealthy foods, and their allies. The tobacco and alcohol industries should have no role in the formation of tobacco and alcohol control laws and policies.**

· **Where voluntary partnerships with the food industry are ineffective in achieving national targets, governments may consider strengthening their level of oversight of the industry, and implementing a co-regulatory approach.**

· **Governments have a responsibility to disseminate accurate information about health risks to their populations and to promote healthy lifestyles. Independent health promotion agencies, established by legislation, are one model for providing national leadership in health promotion.**

· **Injuries claim nearly 5 million lives each year and are a neglected global health priority. Ninety per cent of fatal injuries occur in low- and middle-income countries.**

· **Law has an important role to play in reducing road traffic injuries, including through setting and enforcing speed limits on roads, regulating the licence system, implementing drink-driving counter-measures (e.g. random breath testing), and requiring seat belts to be used by all occupants of motor vehicles and helmets to be worn on motorcycles and bicycles.**

Introduction

Enabling individuals to make healthy choices and to engage in safe behaviours is a core function of public health law. Individual behaviour is a significant contributor to avoidable death and disability, both from noncommunicable diseases (NCDs) and injuries. The most prominent NCDs (cardiovascular disease, cancer, diabetes and chronic respiratory diseases) are linked to a cluster of behavioural risk factors including tobacco use, harmful use of alcohol, unhealthy diets and lack of physical activity. In 2012, NCDs caused 38 million deaths. Nearly three quarters of these deaths (28 million), and over 80% of premature deaths, occurred in low- and middle-income countries.[1] Injuries and violence accounted for a further 5 million deaths.[2]

To the extent that they have the knowledge and resources to do so, individuals share responsibility for the choices they make about their health and lifestyles. At the same time, governments have an over-riding responsibility to seek to realize the right to health for the populations they represent (see Section 1.1). Public health laws can significantly reduce the occurrence of injuries and the preventable component of NCDs by helping to create environments that are safer and that support healthier behaviours. This section identifies priority areas where law can support governments and individuals to reduce risks from NCDs and injuries.

12.1 Enabling behaviours that reduce risks for NCDs

WHO has identified four modifiable behavioural risk factors that are responsible for most NCDs: tobacco use, lack of physical activity, unhealthy diet and harmful use of alcohol.[3] These risk factors contribute to metabolic and physiological risk factors including raised blood pressure (which alone was responsible for over 9 million deaths in 2010),[4] overweight and obesity, high blood glucose levels (hyperglycaemia), and high cholesterol. NCDs and their risk factors occur at higher rates among those with lower levels of income and education,[5] entrenching poverty,[6] cutting into the productive years of life and undermining the benefits of the lower dependency rates enjoyed by developing countries with younger populations.[7]

NCDs impose heavy economic costs on households, health systems and economies due to a range of factors including reduced labour supply, reduced productivity, higher demand for medical treatments, and higher social welfare expenditures.[8] According to a study prepared for the World Economic Forum, under a "business as usual" scenario, NCD morbidity and mortality will cost low- and middle-income countries US$ 500 billion per year over the period 2011–2025 (roughly 4% of average gross domestic product).[9] On the other hand, cost-effective interventions are available. WHO has estimated that the cost of implementing a core set of population-level and individual-level interventions for preventing and treating NCDs (including the cost-effective "best buys" indicated in **Table 12.1**), would require an annual investment of US$ 1 per person in low-income countries, US$ 1.50 in lower middle-income countries, and US$ 3 in upper-middle-income countries.[10]

(a) Global targets for reducing mortality from NCDs

In 2012, at the World Health Assembly (WHA), WHO Member States adopted a global target of a 25% relative reduction in mortality from cardiovascular diseases, cancer, diabetes and chronic respiratory diseases by 2025.[11] In 2013, the WHA adopted a global monitoring framework that included eight additional voluntary targets for reducing risk factors and improving the response of national health systems, and 25 indicators for measuring progress towards each target.[12] These targets include a 10% relative reduction in the harmful use of alcohol; a 10% relative reduction in the prevalence of insufficient physical activity; a 30% reduction in mean population salt intake; a 30% relative reduction in prevalence of current tobacco use; and a halt in the rise of diabetes and obesity. A progress report was submitted to the WHA in 2015, and further reports will be submitted in 2020 and 2025.[13]

Following the high-level meeting on the prevention and control of NCDs held by the United Nations General Assembly (UNGA) in September 2011,[14] the UNGA has also become a forum for global action on NCDs. For example, in 2014, members of the UNGA made a number of time-bound commitments; these included the commitment to consider setting national targets and process indicators, taking into account the nine voluntary targets adopted by the WHA, and to consider developing or strengthening a national multisectoral coordinating mechanism to achieve these national targets.[15] Members of the UNGA have also assumed reporting obligations to facilitate the preparation, by WHO, of reports to the UNGA on progress achieved in the prevention and control of NCDs.[16] Separately, members of the UNGA have adopted 17 Sustainable Development Goals (SDGs) and 169 supporting targets in order to accelerate sustainable development over the period 2015–2030. The Sustainable Development Goals include the following target: to "reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being" (Target 3.4).[17]

(b) Implementing "best buys" for NCDs

The WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020 identified a suite of policy options to assist countries to meet these targets. A number of these policies are "best buys", meaning that they are very cost-effective and affordable in low- and middle-income countries.[18] As **Table 12.1** illustrates, the implementation of priority actions for the prevention and control of NCDs may require fiscal policies by governments (e.g. raising taxes) or new legislation or regulations that prescribe standards, mandate required actions and authorize government agencies to carry out monitoring and enforcement.[19] Specific legal strategies for reducing tobacco use and obesity are discussed in Chapters 13 and 16 of this report.

Fully implementing the legal and regulatory priorities included in **Table 12.1** is likely to be challenging in some countries, due to the political influence of tobacco, alcohol and processed food manufacturers and retailers. In order to secure the passage of the laws, policies and budgets that are needed, high-level leadership will be needed from presidents, prime ministers, health ministers and other political leaders.[20] While leadership within the health ministry will be vital, the involvement of other ministries is also necessary, since many of the priority interventions will be implemented outside the health sector. Governance processes will be required to coordinate the work of all

relevant ministries, including health, agriculture, finance and taxation, education, recreation and sport, media and communications, transport and urban planning. Coordinating mechanisms are necessary to mediate tensions between ministries and to ensure that all ministries work constructively towards common goals (see Section 6.3).[21]

Table 12.1 Selected legal and regulatory priorities for reducing risk factors for NCDs[22]

(Best Buy = ✓)

Tobacco	Comprehensive implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC),[23] especially:
	● Reducing the affordability of tobacco products by increasing tobacco excise taxes (WHO FCTC, Article 6) ✓
	● Banning smoking in in public places, including workplaces, public transport, bars and restaurants (WHO FCTC, Article 8) ✓
	● Health warnings on tobacco products, and at point of sale; labelling controls (WHO FCTC, Articles 11 and 12) ✓
	● Comprehensive bans on all forms of tobacco advertising, promotion and sponsorship, including in all media, in community settings, and in retail establishments (WHO FCTC, Article 13) ✓
	● Bans on sales of tobacco by and to persons under the age of 18 years, or the age set by domestic law, with monitoring and enforcement (WHO FCTC, Article 16)
	● Penalties for smuggled and counterfeit tobacco, with adequate resources for monitoring and enforcement (WHO FCTC, Article 15; Protocol to Eliminate Illicit Trade in Tobacco Products)[i]
	● Affordable treatment for tobacco dependence: supporting interventions for smoking cessation in primary care; affordable pharmacological therapies (WHO FCTC Article 14)
Alcohol	Implementation of the WHO Global Strategy to Reduce the Harmful Use of Alcohol,[24] especially:
	● Increasing excise taxes on alcoholic beverages (paras 32–34) ✓
	● Strengthening tracking systems for illicit alcohol, with penalties for smuggled and informal alcohol, and adequate resources for monitoring and enforcement (paras 37–39)
	● Restricting or banning alcohol advertising and promotion through the media, including social media, in community settings and retail establishments; restrictions on alcohol sponsorship of cultural and sporting events (paras 29–31) ✓
	● Controls on access to retailed alcohol, including minimum age purchasing laws, licensing and other controls on days and hours of retail sale, location and density of retail outlets (paras 27–28) ✓
	● Health warnings on alcohol products and at point of sale; enforce laws against serving to intoxication, and legal liability for harm that results from intoxication following the service of alcohol (paras 19 and 36)
	● Drink-driving counter-measures, including random breath testing, a maximum 0.5 g/l blood alcohol concentration limit for adult drivers, with a reduced or zero limit for younger drivers (paras 24–26)

[i] The Protocol was adopted on 12 November 2012 at the fifth session of the Conference of the Parties to the WHO FCTC, but at the time of writing had not yet entered into force.

	Building on the WHO Global Strategy on Diet, Physical Activity and Health:[25]
Diet, and physical activity	● Institutional and governance reform to enable development of a comprehensive and multisectoral approach to policy development for diet, nutrition and physical activity, with input from key sectors (agriculture, transport, education, environmental and urban planning, sport, youth, industry, finance, and media and communications). City and local governments should have a legal mandate to play a leading role (paras 38–44)
	● Review agricultural policies to ensure they contribute to a healthy and sustainable food supply (para. 41)
	● Encourage or require food reformulation in order to reduce levels of salt ✓, saturated fat and added sugar (para. 41)
	● Requiring food manufacturers to replace trans-fats with polyunsaturated fats (para. 41) ✓
	● Place restrictions on the marketing of foods and beverages high in salt, sugar and fats (especially to children): WHO, resolution WHA 63.14 (adopted in May 2010) on marketing of foods and non-alcoholic beverages to children)
	● Implement a framework for food labelling and health claims on food products to support healthy choices and to prevent misleading claims about food (para. 40)
	● Manage food taxes and subsidies to encourage a healthy diet; for example, by imposing higher taxes for foods and beverages to be consumed in lower quantities, and consider using revenues to support greater access to healthy foods among disadvantaged communities (para. 41)
	● Legislation to protect women's right to breastfeed, without harassment or discrimination
Other strategies	● Hepatitis B vaccination

(c) Engaging with the private sector

The implementation of legal and regulatory priorities for NCDs will necessarily affect the interests of the private sector, including manufacturers and retailers of tobacco products, alcoholic beverages, and nutritionally-poor foods and beverages. As discussed in Section 13.6, Article 5.3 of the Framework Convention on Tobacco Control (WHO FCTC) requires parties to protect the setting and implementation of their tobacco control policies from the commercial and vested interests of the tobacco industry.[26] The Conference of the Parties to the WHO FCTC has issued guidelines to assist parties to implement their recommendations under Article 5.3.[27]

Similarly, in light of evidence that the alcohol industry seeks to use partnerships to weaken national policies for alcohol control,[28] WHO has emphasized that "the development of alcohol policies is the sole prerogative of national authorities"[29] and that governments should take care to "protect the formulation of health policies from distortion by commercial or vested interests".[30]

In some countries, food manufacturers, retailers, government and public health stakeholders are engaged in voluntary partnerships to reformulate food products and to reduce levels of salt, saturated fat and sugar over time.[31] In circumstances where voluntary processes fail to make timely progress towards public health goals and targets, governments may consider adopting a responsive regulatory approach that includes strengthening their level of oversight of the industry, "scaffolding"

voluntary processes with formal targets, or supplementing voluntary standards with legislation (see Section 2.1(c)).[32]

(d) Supporting health promotion

Health promotion campaigns to build adult literacy and public awareness about healthy behaviours are an important component of a comprehensive response to NCDs and their risk factors. The right to health imposes a duty on states to disseminate "appropriate information relating to healthy lifestyles and nutrition, harmful traditional practices and the availability of services", and to support people in making informed choices about their health.[33] Similarly, the WHO Global Strategy on Diet, Physical Activity and Health encourages governments to develop national dietary and physical activity guidelines and to ensure the availability of health promotion and education programmes.[34] Evidence-based recommendations include the following:

- limit energy intake from total fats and shift fat consumption away from saturated fats to unsaturated fats and towards the elimination of trans-fatty acids;
- increase the consumption of fruits and vegetables, and legumes, whole grains and nuts;
- limit the intake of free sugars;
- limit salt (sodium) consumption from all sources and ensure that salt is iodized; and
- engage in at least 30 minutes of regular, moderate-intensity physical activity on most days.[35]

Independent agencies dedicated to health promotion can provide an important institutional base for national campaigns to quit smoking, reduce the harmful use of alcohol, reduce dietary risk factors and promote physical activity. For example, in 2007, in response to a rapidly escalating NCD crisis, Tonga passed legislation to establish a national Health Promotion Foundation (also known as TongaHealth).[36] The Foundation is an independent body that works with communities, nongovernmental organizations and government departments to promote healthy lifestyle changes throughout Tonga. It acts as a catalyst for the development of new policies, programmes and environments, designs and conducts social marketing campaigns, and administers a competitive grant scheme that funds research, programmes and facilities to promote health and reduce NCD risk factors.[37] Members of the Board of the Foundation are appointed by an appointment committee that consists of the Minister for Health, the Chair of the National Noncommunicable Diseases Committee and its sub-committees.[38] The existence of an independent statutory agency may be helpful in ensuring that health promotion receives the budgetary resources it needs within the overall health portfolio. Tonga's example has been helpful in influencing other South Pacific countries to establish similar agencies.

12.2 Discouraging behaviour that contributes to injuries

Injuries claim nearly 5 million lives each year: around 9% of global deaths. One quarter of these deaths are caused by road traffic injuries, the ninth leading cause of death in 2012, and the leading cause of death for people aged 15–29 years.[39] Road traffic injuries cost low- and middle-income countries over US$ 100 billion annually (between 1% and 2% of gross national product), and are increasing in many countries due to rapid motorization coupled with the failure to invest in proven road safety interventions. [40]

WHO has recommended that countries develop national strategies for preventing road traffic injuries, and designate a single agency or focal point with responsibilities in this area. These responsibilities should include collaborating with other ministries and stakeholders, including transport companies and the community.[41] Law plays an important role in improving road safety. Key areas for law reform may include: setting and enforcing speed limits on roads, introducing traffic-calming measures, introducing and enforcing offences for driving while intoxicated, introducing a graduated licensing system (with mandatory speed restrictions) for novice drivers, prohibiting drivers from using hand-held electronic devices while driving, requiring motorcycles to use running lights during daytime, and mandating the use of seat belts and child restraints in cars, and helmets by people using motorcycles and bicycles.[42] In countries where alcohol use is not condoned, significant hidden consumption may nevertheless occur, and paradoxically there may be limited public awareness of the hazards of drink-driving.

The Islamic Republic of Iran experienced a significant decline in fatal traffic accidents and injuries between 1997 and 2007, following the passage of a law that required the government to develop road safety legislation within a period of six months (see **Box 12.1**).[43] Laws requiring the use of safety belts for drivers and all passengers of four wheeled vehicles save lives during traffic accidents, are highly cost-effective, and can be successfully implemented in rapidly motorizing low and middle-income countries.[44]

Box 12.1: Reducing the risk to health from traffic accidents: an example from the Islamic Republic of Iran

Law of the Fourth Economic, Social, and Cultural Development Plan: Enhancement of Health and Improvement of the Quality of Life.[45]

The Government is charged with preparation of a bill for protection and enhancement of health of the individual members of society and reduction of the risks to health, including through the following points, and to present the said bill to the Islamic Consultative Assembly for approval, within six months of enactment of this law:

- Reducing traffic accidents, through reconnaissance of accident-generating points and axes along roads and highways … and reducing the number of such points by 50% by the end of the fourth plan.
- Placing emphasis on the principles of safety and safe driving regulations.

- Regulating and completing the pre-hospital and hospital medical emergency networks of the country and reducing the death tolls resulting from traffic accidents by 50% by the end of the fourth plan.
- Enhancing the safety plan for motor vehicles and enforcing human and safety engineering standards.

In one intervention carried out in the Chinese city of Guangzhou, four strategies for reducing road traffic injuries were implemented over a 12-month period. These included enhanced police training, highly visible police patrols, as well as static, covert operations at different locations throughout the city and social marketing (radio and television commercials, billboards, bus signs). Courses or materials concerning the requirement to fit and use seat belts, and the safety benefits, were provided to taxi company managers, instructors in driving schools and primary school teachers. Over the period of the intervention, the prevalence of seat-belt use by drivers and passengers increased by 12%, reducing serious injuries and fatalities by 7%.[46] Interventions like this are highly cost-effective in reducing the cost of road traffic accidents in rapidly motorizing societies.

Among motorcyclists, research shows that mandatory helmet laws are highly effective in reducing deaths from traffic accidents as well as non-fatal traumatic brain injury. In Viet Nam, a national helmet law in effect from December 2007 increased helmet use up to 99% and avoided 1557 deaths and 2495 serious injuries in its first year of operation (**Box 12.2**).[47] In Romagna, Italy, hospital admissions for traumatic brain injury decreased by 31% in the year following introduction of the mandatory motorcycle helmet law.[48] Experience has shown that the repealing of mandatory motorcycle helmet laws is associated with sharp increases in rates of motorcycle fatalities.[49]

Box 12.2: Reducing death and disability from motor vehicle accidents in Viet Nam through a national motorcycle helmet law

Reasons for the success of Viet Nam's law included the following:

- Significant penalties were set for failing to wear a helmet;
- Public education and social marketing increased public awareness prior to the introduction of the new law. Civil service employees and members of the armed services wore helmets three months before the law took effect;
- The law was strictly enforced from the date it came into effect;
- The obligation imposed was simple to understand: the helmet law applied to all motorcycle riders and all passengers on all roads;
- Supported by government product standards to prevent substandard products entering the market, high-quality, climatically appropriate helmets were widely available for sale at an affordable price, and 50 000 helmets were distributed to low-income families;
- The mandatory helmet law was issued by the Prime Minister. This ensured the highest level of political support. A multisectoral National Traffic Safety Committee, chaired by the Minister of Transport, with representatives from 15 ministries, led the development and implementation of the law on behalf of the Vietnamese government.

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Chapter 13: Tobacco control

SUMMARY POINTS

· **The foundation for effective national tobacco control policies lies in comprehensive implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC).**

· **Once it enters into force, the Protocol to Eliminate Illicit Trade in Tobacco Products could provide a comprehensive framework for national legislation to eliminate smuggled, counterfeit and illicit tobacco products that increase the accessibility and affordability of tobacco and undermine government revenues.**

· **The Conference of the Parties to the WHO FCTC has issued detailed guidelines to assist Parties to implement specific provisions of the WHO FCTC in an effective, evidence-based manner.**

· **In entering trade and investment agreements, countries should ensure that they do not unduly restrict their health sovereignty or unduly diminish their capacity to implement and enforce effective tobacco control measures.**

· **Countries should coordinate the activities of their health, trade and finance ministries in order to ensure that they do not undertake trade and investment obligations that unduly conflict with their health goals, including their capacity to effectively regulate tobacco, alcohol and unhealthy food products.**

· **Tax policy is a powerful instrument for raising the price and reducing the affordability of tobacco products. Uniformly high tobacco prices help to discourage initiation, encourage quitting, and reduce the amount of tobacco consumed by those who do not quit. Countries can use tobacco excise tax increases, applied to all brands and forms of tobacco, whether imported or locally produced, to achieve the public health goal of reducing the death and disease caused by tobacco use.**

· **Other priority policies for implementing the WHO FCTC at national level include large, text-based and graphic health warnings on tobacco packages, comprehensive bans on all advertising, promotion and sponsorship of tobacco products, and legislative measures to ensure protection from exposure to tobacco smoke, including in all workplaces, public transport and indoor public places.**

· **The interests of the tobacco industry are in irreconcilable conflict with public health. Governments should limit their interaction with the tobacco industry, ensure that any interactions that do occur are transparent, avoid conflicts of interest and ensure that the industry is excluded from law reform and law-making processes.**

Introduction

There are currently around 1.3 billion smokers in the world, mostly living in low- and middle-income countries. Unless they quit, up to half of them will die prematurely from tobacco-related diseases, including lung cancer, heart disease and stroke and chronic obstructive pulmonary disease.[1] Tobacco killed 100 million people during the twentieth century, and currently causes around 6 million deaths each year, including over 600 000 deaths among non-smokers that are attributable to exposure to

second-hand tobacco smoke.[2] Globally, tobacco is responsible for 12% of all male deaths and 6% of all female deaths.[3] Due to population growth, and the aggressive marketing activities of tobacco companies, tobacco-related deaths are projected to increase, rising from 6 million deaths to around 12 million deaths per year for the period 2025–2050.[4]

13.1 Global tobacco control

(a) The Framework Convention on Tobacco Control

Tobacco use is an "industrially created epidemic" that is sustained by the activities of the tobacco industry.[5] The burden of death and disease caused by tobacco is preventable, but preventing them requires governments to honour their commitments to implement evidence-based and cost-effective legal measures to regulate the tobacco industry.[6] The foundation for effective national tobacco control policies lies in comprehensive implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC).[7] The WHO FCTC was adopted by the World Health Assembly in 2003 and entered into force in 2005. It requires Parties to implement measures to reduce both demand for, and supply of, tobacco products (**Box 13.1**). The Conference of the Parties to the WHO FCTC has issued detailed guidelines to assist Parties to implement specific provisions of the Convention in an effective and evidence-based manner.[8] Under Article 2.1, Parties are encouraged to implement tobacco control measures that go beyond the requirements of the Convention and its protocols and that are consistent with international law.[9]

In many countries, significant law reform efforts are still needed in order to fully implement the provisions of the WHO FCTC. For example, in 2015, 103 countries (and nearly 2.8 billion people) were fully covered by at least one or more tobacco control measures as recommended by WHO in the MPOWER package of recommendations for countries implementing the WHO FCTC. These measures include tobacco taxes, tobacco advertising bans, warning labels and smoke-free controls. Nevertheless, only 49 countries (with 20% of the global population) were covered by two or more such measures.[10]

Box 13.1: Using public health law to reduce supply of and demand for tobacco: the WHO Framework Convention on Tobacco Control

Supply reduction provisions:

- Enact legislation to reduce illicit trade in tobacco products (including for offences in relation to counterfeit and contraband cigarette and authorizing seizure of illicit tobacco and of proceeds derived from commerce in illicit tobacco products) (Article 15).
- Implement legislative or other measures to prevent sales of tobacco to and by minors. These measures may include: prohibiting the manufacture and sale of sweets or other objects in the form of tobacco products that may appeal to minors, prohibiting the distribution of free tobacco products to the public, prohibiting the sale of cigarettes individually or in small packets, ensuring that tobacco vending machines are not accessible to minors, and banning the sale of tobacco products in ways that make them directly accessible to members of the

public (Article 16).

- Provide support for economically viable alternative activities for tobacco workers, growers, and sellers (Article 17).
- Demand reduction provisions:
- Adopt tax and/or price policies aimed at reducing consumption of tobacco (including restrictions on tax- and duty-free tobacco products) (Article 6).
- Ban smoking in indoor workplaces, public transport, indoor public places, and as appropriate, other public places (Article 8).
- Adopt measures for the testing, measuring and regulation of the contents and emissions of tobacco products (Article 9).
- Require tobacco manufacturers and importers to disclose to governmental authorities information about the contents and emissions of tobacco products. Implement measures for the public disclosure of information about the toxic constituents of tobacco products, and the emissions they produce (Article 10).
- Prohibit false, misleading and deceptive labelling and advertising of tobacco products, including descriptors, trademarks or other signs suggesting that a particular product is less harmful than others (e.g. labelling products as “low tar”, “light”, “ultra-light”, or “mild”) (Article 11.1(a)).
- Require each tobacco package to include clearly visible and rotating warnings about the harmful effects of tobacco use, approved by a competent national authority. Warnings should cover 50% or more of the principal display areas, but shall be no less than 30% of the principal display areas (Article 11.1(b)).
- Implement public awareness campaigns to promote access to information regarding the addictive nature of tobacco use, the health effects of smoking and of second-hand smoke, the benefits of tobacco cessation, and the economic and environmental consequences of tobacco production and consumption (Article 12).
- To the extent permitted by each country’s constitution, ban or restrict all tobacco advertising, promotion, and sponsorship. Subject to the legal environment and technical means available to each Party, this shall include a comprehensive ban on cross-border advertising, promotion and sponsorship of tobacco originating from its territory (Article 13).
- Promote cessation of tobacco consumption and treatment for tobacco dependence. This shall include the diagnosis and treatment of tobacco dependence within national health and education programmes (Article 14).

Some countries, particularly those with limited capacity, may find that the most rapid way to make progress in combating the tobacco epidemic is to prioritize the implementation of their obligations under the WHO FCTC in a stepwise manner. WHO’s MPOWER package[11] is not a substitute for the obligations that countries have assumed under the WHO FCTC. However, it may assist Parties to prioritize their actions towards full implement the WHO FCTC by identifying six priority areas for policy action and by explaining their rationale and evidence base. These six areas are:

1. monitor tobacco use and prevention policies;
2. protect from tobacco use;

3. offer help to quit tobacco use;
4. warn about the dangers of tobacco;
5. enforce bans on tobacco advertising and sponsorship; and
6. raise taxes on tobacco.

In 2012, Turkey became the first country in the world to protect its entire population with all six of the MPOWER measures implemented at the highest level of achievement.[12] After ratifying the WHO FCTC in 2004, the Ministry of Health formed a National Tobacco Control Committee to prepare a national implementation plan. Between 2008 and 2012, larger, pictorial warning labels were introduced on tobacco packs, taxes on tobacco increased to in excess of 80% of the retail price, a total ban on all tobacco advertising, promotion and sponsorship was implemented, and smoke-free laws were strengthened to cover restaurants, bars and cafés.[13] During this four-year period, smoking rates fell from 30.1% to 25.7% – a reduction of 14.6%.[14] Turkey's achievement illustrates how rapid changes are possible through sustained political commitment to implementing the core obligations of the WHO FCTC.

The comprehensive tobacco control law passed in 2013 by the Russian Federation illustrates the kind of urgent action still needed in many countries.[15] The law established smoke-free environments in medical, educational, sports and cultural facilities, government buildings, public playgrounds, beaches, apartment stairwells, airports and public transportation. From June 2014, smoking bans were extended to cover hospitality venues including hotels, cafés, bars and restaurants.[16] The retail sale of tobacco products is also banned in many of these places.[17] The law bans retail cigarette displays and prevents retailers from displaying price lists containing colours or logos.[18] Television programmes and movies depicting smoking must also broadcast a public service announcement warning viewers about the health risks of smoking.[19]

During the period of economic transition that occurred in the Russian Federation between 1990 and 2000, cigarette consumption increased by 81%.[20] The Global Adult Tobacco Survey, conducted in 2008–2010, found that 40% of Russians smoke, including 60% of Russian males, giving Russia the highest smoking rates in Europe.[21] Russia's comprehensive approach could dramatically reduce the future burden of tobacco-related disease, and provide an important model for other countries to follow.

A major obstacle to the implementation of effective tobacco control laws at national level is the influence and activities of transnational tobacco companies.[22] As discussed below, two of the major strategies used by transnational tobacco companies are the use of international trade rules and commitments to challenge national tobacco control laws and to gain access to markets, and the use of smuggling and other forms of illicit trade in tobacco products.[23] Like all forms of illicit tobacco trade, smuggling reduces government revenues from the taxing of legitimately produced and imported products. By reducing government revenues, illicit trade in tobacco may also undermine spending on social programmes, including tobacco control programmes.[24]

(b) The Protocol to Eliminate Illicit Trade in Tobacco Products

In 2007, the Conference of the Parties to the FCTC established an Intergovernmental Negotiating Body to negotiate a protocol on illicit trade in tobacco products.[25] Following several years of negotiations, the Protocol to Eliminate Illicit Trade in Tobacco Products was adopted by the Parties to the WHO FCTC in 2012. The Protocol aims to eliminate all forms of unlawful activity relating to the production, shipment, receipt, possession, distribution, sale or purchase of tobacco products.[26] The Protocol requires ratification or formal acceptance by 40 Parties before it enters into force.[27]

Illicit production and smuggling of tobacco products encourage tobacco use and undermine public health policies by reducing prices and increasing access. In turn, lower prices encourage smoking initiation and higher levels of tobacco consumption, particularly among young people, the poor and low-income groups.[28] Illicit trade in tobacco deprives governments of taxation revenues, while also undermining tobacco control laws and policies such as large pictorial warnings and retail controls. The smuggling of tobacco may also threaten national security by providing a lucrative source of income for criminal groups, providing financing for terrorist acts and by facilitating other forms of criminal activity such as money laundering and smuggling of weapons, drugs and counterfeit goods.[29]

The key provisions of the Protocol require Parties to take measures to improve their control of the tobacco supply chain. The Protocol requires Parties to prohibit the manufacture, import or export of tobacco products and manufacturing equipment except in accordance with a licence granted by a national authority.[30] To the extent that it is appropriate, Parties must also licence persons engaged in growing, wholesaling, warehousing, distribution and retailing tobacco products and manufacturing equipment. Parties must establish a designated national authority to administer tobacco licences,[31] and within five years must establish a tracking and tracing system to permit Parties to trace the origin, movement and legal status of all tobacco products within their territory.[32]

National and regional tracking systems provide the basis for a global tracking and tracing regime and global information-sharing focal point (located at the Secretariat of the WHO FCTC) which Parties have agreed to establish within the same five-year period. The obligations of Parties to establish a national tracking system must not be delegated to the tobacco industry, although Parties may require the industry to bear the costs of its administration.[33] The Protocol requires each Party to consider banning retail sales of tobacco products over the Internet or using telecommunications devices.[34] In some countries, including the United States, legislation restricts the retail sale of tobacco through the mail, since mail-order sales may evade excise taxes and make it easier for children and adolescents to purchase tobacco.[35]

(c) World Trade Organization agreements and domestic tobacco control laws

In many countries, the implementation of obligations under the FCTC takes place against the backdrop of the obligations they have assumed as members of the World Trade Organization (WTO). WTO Agreements of potential relevance to domestic tobacco control laws include the General Agreement on Tariffs and Trade (GATT),[36] as well as the Agreement on Technical Barriers to Trade (the TBT Agreement),[37] and the Agreement on Trade-Related Aspects of Intellectual Property Rights

(TRIPS).[38] In implementing all such agreements, countries should ensure that they do not unduly restrict their health sovereignty or unduly diminish their capacity to implement and enforce effective tobacco control measures.

Trade agreements seek to foster a predictable, competitive global marketplace that eliminates discriminatory practices and reduces unnecessary regulatory obstacles to international trade in goods and services and to the global protection of intellectual property rights.[39] These goals are not inherently opposed to the protection of public health. For example, where trade liberalization measures result in economic growth, this may reduce poverty and raise living standards, permitting higher levels of spending on health, education and social services. On the other hand, governments should ensure that the implementation of trade liberalization measures takes account of public health considerations, and that governments preserve the policy space to adopt policies that will best protect the health of the population.[40]

Some aspects of trade agreements require particular scrutiny in terms of their potential impact on public health. For example, reductions in tariffs (customs duties) and the elimination of non-tariff barriers, such as quotas, licences and monopolies, may help to create a more contestable market for tobacco products, increasing the availability of global brands, reducing prices and stimulating demand. Complaint mechanisms in trade agreements provide opportunities for national governments to challenge domestic tobacco control laws in other countries, including import bans, labelling requirements and product regulation. Bilateral and regional investment agreements may also give tobacco companies the right to make complaints against national governments for harm to the value of their investment in a host country. Transnational tobacco companies strongly support trade liberalization agreements giving them greater access to developing country markets, and have lobbied national governments to support investor–State dispute settlement rights in regional trade and investment agreements.[41]

In addition to defining the obligations that countries owe under international law, trade and investment agreements can have a broader, political function, as tools used by transnational tobacco companies to place pressure on national governments to weaken their domestic tobacco control laws. The risks are greatest for smaller countries, and for developing and least developed countries, which may lack the financial resources to defend complaints, or the human resources to provide accurate advice about the scope of global trade laws and global trade and investment agreements.[42] Article 5.3 of the FCTC states that "In setting and implementing their public health policies with respect to tobacco control, Parties should act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law".[43] It is clear from this article that the tobacco industry is not a trustworthy or reliable source of information for governments about the scope of their obligations under the FCTC, under WTO Agreements or any other trade or investment agreement.[44]

WTO Agreements impose several different kinds of obligations on WTO members. Firstly, under the GATT, WTO members must not impose customs duties that exceed the "bound" tariff rates set out in each member's GATT schedule.[45] The aspiration of the WTO system is for countries to eliminate non-tariff barriers, and to progressively lower their tariff barriers.[46] Although lower tariffs may result in cheaper tobacco imports, greater competition and increased domestic consumption, national authorities are not precluded from raising taxes on both imported and domestic tobacco products in

order to counter this effect. On the other hand, since the WTO Agreements prohibit the discriminatory treatment of imports, the risk remains that high domestic tax rates applied equally to both imported and domestic goods will be difficult to achieve in political terms.[47] Thailand's remarkable achievement in progressively raising tobacco taxes until they reached 71.5% of retail price in 1999 was an important factor in enabling it to reduce smoking rates, despite an adverse WTO ruling in 1990 that required it to wind back its government monopoly on tobacco and to permit tobacco imports.[48]

Secondly, a core principle underlying the WTO Agreements is trade without discrimination.[49] WTO members are prohibited from adopting laws and policies that have the effect of treating imported goods less favourably than "like" domestically produced goods (the principle of national treatment), and from discriminating between "like" goods imported from third countries (principle of most favoured nation treatment). These principles are reflected in Articles I and III of the GATT,[50] which applies to international trade in tobacco products, and in Article 2.1 of the TBT Agreement),[51] which applies to tobacco product requirements, such as tobacco packaging and labelling requirements, and restrictions on flavoured tobacco products.[52]

In circumstances where a WTO member's tobacco control laws are considered to have a discriminatory effect, that member may nevertheless seek to justify them on the basis of Article XX(b) of GATT, which provides an exception for measures that are "necessary to protect human, animal or plant life or health". Article XX(b) provides that such measures must not be applied in a manner that constitutes unjustifiable discrimination between countries, or a disguised restriction on international trade.[53]

In contrast to GATT, there is no human health exception for measures that are considered to be in breach of the principles of national treatment and most favoured nation treatment under Article 2.1 of the TBT Agreement. However, in the United States – Clove Cigarettes case, the Appellate Body drew attention to the sixth recital to the TBT Agreement, which recognizes that no country should be prevented from taking measures necessary "for the protection of human, animal or plant life or health, of the environment or for the prevention of deceptive practices, at the levels it considers appropriate", provided that they are not applied in a way that constitutes discrimination or are a disguised restriction on international trade.[54] A tobacco control measure that has a negative impact on the competitive opportunities for tobacco exports of another member is not, for that reason, prohibited, provided that the detrimental impact "stems exclusively from a legitimate regulatory distinction".[55]

Thirdly, Article 2.2 of the TBT Agreement requires WTO members to ensure that their technical domestic regulations do not have the effect of creating "unnecessary obstacles to trade".[56] Article 2.2 clarifies this obligation by stating that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create".[57] Article 2.2 acknowledges that the "protection of human health or safety, animal or plant life or safety" is a legitimate objective that members can seek to fulfil, provided that in doing so, the technical regulations are not more trade-restrictive than necessary.

Scholars working in the field of international trade regulation and health have pointed to the considerable degree of deference shown by WTO panels and the Appellate Body towards the

legitimate policy objectives of members.[58] For example, in the United States – Clove Cigarettes case, the WTO Panel found that United States legislation banning the production and sale of clove-flavoured cigarettes[59] was not more restrictive than necessary to fulfil the legitimate objective of reducing youth smoking, under Article 2.2 of the TBT.[60] The Panel referred to the *Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC*, which recommend that "Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products".[61] The Panel noted that these guidelines "show a growing consensus within the international community to strengthen tobacco control policies through regulation of the content of tobacco products, including additives that increase the attractiveness and palatability of cigarettes".[62]

On the other hand, in the same case, the Appellate Body found that by exempting menthol cigarettes from the legislative ban that applied to all other flavoured cigarettes, the legislation gave less favourable treatment to clove cigarettes imported from Indonesia than it did to American-produced menthol cigarettes, in breach of the national treatment principle in Article 2.1.[63] The prohibition on discriminating between different imports, and between imports and domestic goods, contained in both Article 2.1 of the TBT and in the GATT, applies only to "like products". As the Appellate Body pointed out, the concept of "like products" "serves to define the scope of products that should be compared to establish whether less favourable treatment is being accorded to imported products".[64] According to the Appellate Body, menthol and clove cigarettes were both like products, since both were in a competitive relationship for the purposes of satisfying smokers' addition to nicotine, and both flavourings had the capacity to mask the harshness of tobacco smoke.[65]

As pointed out above, a tobacco control law that has a detrimental impact on the competitive opportunities of imported tobacco products in the marketplace will not be inconsistent with Article 2.1 provided that this detrimental impact stems exclusively from a legitimate regulatory distinction.[66] The regulatory purpose of legislative provisions is therefore central to determining what constitutes less favourable treatment under Article 2.1.[67] In United States – Clove Cigarettes, the Appellate Body decided that the distinction drawn under the United States legislation between menthol and other flavourings (including cloves) could not be sustained, since both menthol and cloves mask the harshness of tobacco and make initiation easier for young people – factors which undermined the legitimacy of the exemption for menthol under this legislation.

The immediate lesson to draw from United States – Clove Cigarettes is that national authorities should take care, in framing their tobacco control laws, to ensure that product bans are applied equally to all imported and domestic tobacco products that are considered to be "alike". The broader lesson is that, as with the impact of the TRIPS Agreement on national policies for providing universal access to essential medicines (see Chapter 15), countries will need to increase their familiarity with WTO obligations in order to frame and implement their national policies effectively. It may be helpful to coordinate the provision of expert assistance to governments of small and low-income countries at the regional level, including through regional organizations. WHO and the Secretariat of the WHO FCTC may also be able to provide assistance to national authorities that are considering or drafting tobacco control laws. At the national level, countries will need to coordinate the activities of their health, trade and finance ministries in order to ensure that they do not

undertake trade and investment obligations that conflict with their health goals, including their capacity to effectively regulate tobacco, alcohol and unhealthy food products.

(d) Bilateral and regional investment agreements and domestic tobacco control laws

This report does not provide a technical review of key obligations under WTO Agreements, nor of the obligations that may arise under bilateral or multilateral trade and investment agreements.[68] Trade and investment agreements cover a wide spectrum. They include investor-State contracts (for example, between a country and a transnational tobacco company), customs agreements, bilateral investment treaties, and regional trade and investment agreements, including the Transatlantic Trade and Investment Partnership (under negotiation at the time of writing),[69] and the Trans-Pacific Partnership (concluded in 2015).[70] While the GATT and TBT provisions described above prohibit discriminatory and trade-restrictive domestic regulations that place imports at a disadvantage, investment agreements protect the investments of foreign investors within the host country. In many cases, they also give the foreign investor standing to seek compensation if a dispute arises under the agreement.[71]

Contracts entered into between a foreign tobacco company and a host State, as well as joint ventures between State-owned tobacco companies and foreign investors, may cause serious harm to tobacco control efforts when they contain freezing and stabilization clauses that provide the investor with an assurance that the regulatory environment will not change within the host State, or that the foreign investor may be compensated if it does.[72] In circumstances where tax holidays are given to tobacco investors, this will reduce government revenues and undermine the capacity of the government to support worthwhile programmes in health and other sectors. Similarly, where the excise rate on tobacco products is frozen for the benefit of the tobacco investor, a country will deprive itself of the most powerful tool that can be applied to reduce tobacco consumption – that is, high rates of internal taxation applied to both imported and domestically produced tobacco products. Guidelines adopted by COP under Article 5.3 of the WHO FCTC recommend that Parties should not to give preferential tax treatment or other privileges to the tobacco industry, and should treat State-owned tobacco companies no differently to other members of the tobacco industry.[73]

In addition to non-discrimination, international investment agreements typically require the host State to provide fair and equitable treatment to the investor, and to protect the investor against measures that effectively expropriate their investment. Recent challenges brought by tobacco companies under bilateral investment agreements illustrate how these agreements may be used as a weapon to resist implementation of the WHO FCTC and effective tobacco control laws. For example, in 2012, Philip Morris Asia brought a claim against Australia arguing that Australia's tobacco plain packaging legislation represented an expropriation of its investment in Australia.[74] In 2015, this claim was unanimously dismissed.[75] In 2010, Philip Morris companies began a claim for US$ 25 million compensation under its bilateral investment agreement with Uruguay.[76] Uruguay's legislation prevents the use of "brand families" as a marketing tool by restricting tobacco brands to one variant only, and requires health warnings to cover 80% of the front and back of the pack.[77] Although foreign investment may assist a country with its economic development, there is no health benefit in reducing the cost of tobacco products, less still in giving transnational tobacco companies

the right to seek compensation for the economic impacts of laws and policies that are designed to reduce tobacco consumption within that country. Scholars have pointed to a range of mechanisms that could be adopted by countries involved in the negotiation of trade and investment agreements in order to protect the policy space of governments seeking to implement the right to health. These include excluding tobacco products from all trade and investment agreements, or recognizing clear exceptions for measures that seek to protect human life and health.[78] Other options include side letters acknowledging a shared understanding that certain measures shall not constitute a breach of the agreement.

13.2 Pricing and taxation

This report now turns to consider core obligations under the WHO FCTC whose implementation into domestic law will usually require legislation, executive orders and other forms of legal regulation. The WHO FCTC recognizes that tax and price measures are a powerful, cost-effective tool for reducing tobacco consumption, particularly among young people.[79] Article 6 of the WHO FCTC calls on Parties to implement tax policies (and where appropriate, pricing policies) in order to reduce tobacco consumption, and to prohibit or restrict the availability of tax- and duty-free tobacco products.[80]

Uniformly high tobacco prices achieved through high specific excise taxes, based on weight or amount of tobacco, help to prevent tobacco initiation, encourage quitting (rather than switching to cheaper brands), and to reduce the amount of tobacco consumed by those who do not quit.[81] Excise taxes should be applied equally to the tobacco in all brands and forms of tobacco, whether imported or domestically produced. Low specific excise taxes in low-income countries are a substantial reason for the significant price differences between tobacco products in many low- and high-income countries.[82] In addition, rapid economic growth and rising incomes have also contributed to an increase in the relative affordability of tobacco products in many low- and middle-income countries.[83] Excise taxes should take account of inflation; for example, in Australia, the federal excise on tobacco is adjusted twice each year in line with average weekly earnings.[84] An excise tax that comprises at least 70% of the retail price is a useful benchmark for countries where excise taxes are currently much lower; in addition to saving lives, and reducing the burden on national health systems, this benchmark will generate substantial tax revenues that governments may use to fund tobacco control and other health programmes.[85]

The reduction in tobacco consumption that results from higher tobacco prices affects populations differently depending on their income levels. In high-income countries, evidence suggests that a 10% increase in the price of tobacco results in an average reduction in tobacco consumption of around 4%.[86] In low- and middle-income countries, the reduction in demand is significantly higher. WHO has published guidance to assist countries to develop effective and efficient tobacco taxation policies.[87]

In low-income populations, tobacco consumption entrenches poverty and undermines health in other ways; for example, by diverting spending from necessities like food, education and health care.[88] For example, in Indonesia, households with smokers spend an average 11.5% of household expenditure on tobacco, compared with 2.3% on health, 3.2% on education, and 11% on meat, fish, eggs and milk.[89] There is evidence that low-income smokers, and youth smokers, are more price

sensitive and more likely to quit or to reduce their level of consumption when tobacco becomes more expensive. Reducing the relative affordability of tobacco products may therefore be an important way of reducing health inequalities between higher and lower income groups within a country.[90]

Some countries have passed laws that dedicate a proportion of tobacco tax revenues to smoking cessation programmes, or to health and welfare programmes targeting low-income groups.[91] By ensuring sustainable funding for health and social welfare programmes, governments may find that tobacco taxes receive a higher level of public support.[92] To ensure that their impact is not eroded over time, governments should create a legislative mechanism to adjust excise taxes upwards to keep pace with inflation and real income growth. As discussed Section 13.1(d), entering into agreements with tobacco manufacturers or other entities to limit tax increases for imported or domestically produced tobacco products harms tobacco control efforts by undermining the most powerful tool in tobacco control: increasing the retail price of tobacco products.

13.3 Labelling and packaging of tobacco products

High rates of tobacco use are partly a result of lack of knowledge about the addictive nature and health risks of tobacco use. In China, for example, fewer than one out of every four adults are aware that tobacco use can cause stroke, heart disease and cancer.[93] Prominent health warnings on tobacco packages are an important tool for communicating the specific risks of tobacco use which – in combination with other measures to reduce tobacco consumption – can encourage quitting.[94] Article 11 of the WHO FCTC requires Parties to implement laws to ensure that tobacco labelling is not false, misleading or deceptive. For example, for many decades tobacco companies have manufactured and advertised tobacco brands that are described as "light", "mild", and "low tar", despite knowing that these products are no less harmful than regular products.[95] Many smokers persist with the false belief that "light" cigarettes are less likely to cause them harm.[96] Evidence also indicates that smokers of "light" cigarettes are less likely to quit.[97]

Article 11 of the WHO FCTC requires Parties to implement effective measures to ensure that all tobacco products and packages carry health warnings describing the harmful effects of tobacco use. These warnings should cover 50% or more (and must cover 30%) of the principal display areas of each tobacco package. *Guidelines for the implementation of Article 11* urge Parties to the WHO FCTC to use colour pictorial warnings to emphasize text-based warnings and to rotate health warnings periodically to ensure that their impact does not diminish over time.[98] Furthermore, as experience in New Zealand illustrates, pictorial warnings should be culturally appropriate and should reflect the different concerns of smoker subgroups, as well as being well integrated into mass media campaigns.[99]

The guidelines on Article 11 also recommend that Parties adopt "plain tobacco packaging" measures that restrict the use of trademarks, logos, brand colours and images, other than brand and product names in a standard colour and font.[100] In 2011, Australia became the first country to pass plain tobacco packaging legislation embodying these characteristics,[101] followed by the United Kingdom[102] and Ireland[103] in 2015. In 2016, the Court of Justice of the European Communities upheld the right of Member States of the European Union to pass plain packaging laws that exceed the requirements

for the standardization of tobacco packaging contained in the European tobacco products directive.[104] These requirements include mandatory health warnings, comprising text and colour photographs, covering 65% of the back and front of tobacco packages.[105] Studies published since the introduction of Australia's plain tobacco packaging legislation illustrate that these restrictions are not only associated with lower smoking appeal and more frequent thoughts about quitting,[106] but also with more frequent requests for quitting assistance. For example, in Australia, one study reported a 78% relative increase in requests for quitting assistance four weeks after the new legislation took effect. This increase in requests for quitting assistance persisted over a significant period of time (43 weeks).[107] Another study found that one year after implementation, there was no evidence of the catastrophic, unintended consequences predicted by the tobacco industry, including a rise in the use of unbranded, illicit or contraband tobacco.[108]

13.4 Advertising, promotion and sponsorship

Comprehensive bans on tobacco advertising can significantly reduce demand. Article 13 of the WHO FCTC requires Parties to implement a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship, to the extent that this is possible under their national constitutions.[109] Article 13 emphasizes that this includes "a comprehensive ban on cross-border advertising, promotion and sponsorship" originating from the territory of each Party. [110] Parties must implement these requirements through appropriate legislative, executive or administrative measures within five years. Guidelines for the implementation of Article 13 emphasize that a comprehensive ban on advertising, promotion and sponsorship would extend not only to traditional forms of media, such as television, radio and print media, but to digital technologies (such as mobile phones and other devices connected to the Internet), and to advertising in cinemas prior to feature films.[111] Such a ban would also extend to all forms of commercial communication and to all forms of contribution to individuals, activities and events that have the aim or likely effect of promoting tobacco products or tobacco use[112] (**Box 13.2**).

A comprehensive ban on tobacco advertising should include a ban on all retail advertising of tobacco products, including cigarette pack displays at point of sale, since these stimulate unplanned purchases, especially among smokers who are those trying to quit.[113] The *Guidelines for the implementation of Article 13* state that Parties to the WHO FCTC should only permit "the textual listing of products and their prices" at points of sale, "without any promotional elements".[114] They also state that a comprehensive ban, as required by Article 13, should include a ban on both incoming and outgoing forms of tobacco-related advertising, promotion and sponsorship that cross the borders of a Party to the Convention.[115] One benefit of implementing a comprehensive ban on all tobacco advertising and promotion is that it reduces the influence of the tobacco industry over the media, and over entertainment, cultural and sporting organizations which would otherwise become proxies for the tobacco industry in resisting other tobacco control laws and policies.[116]

Box 13.2: Key features of a comprehensive ban on tobacco advertising, promotion and sponsorship under Article 13 of the WHO Framework Convention on Tobacco Control

A comprehensive ban on tobacco advertising, promotion and sponsorship would apply to:

- All kinds of tobacco products, as well as tobacco use generally;
- Any tobacco brand names, trademarks, logos, and all other corporate promotion of tobacco manufacturers and tobacco businesses;
- All forms of media advertising, regardless of the medium involved (including online interactive marketing), as well as retail sales promotions, direct marketing, billboard advertising, and public relations;
- All forms of contribution and financial support to events, activities, individuals and organizations where the aim or likely effect is to promote tobacco use, tobacco products or tobacco businesses either directly or indirectly;
- Cross-border advertising, that is, tobacco-related advertising, promotion and sponsorship that enters into, or which originates from, a country's territory;
- Any person or organization who is involved in producing, placing, organizing or disseminating tobacco advertising, promotion and sponsorship;
- Entities responsible for tobacco advertising, promotion and sponsorship should be defined widely in order to cover the entire marketing chain.
- In addition, the ban should extend to retail tobacco displays, vending machines, and to Internet sales of tobacco products.
- Parties should consider plain tobacco packaging requirements that suppress the advertising of brand logos and design elements.
- Promotion to the public of activities undertaken as part of "corporate social responsibility" programmes by tobacco companies should be prohibited. Financial contributions made by tobacco companies to community, welfare and arts organizations should also be prohibited.
- Legislation should not include any list of prohibited activities which is understood to be exhaustive.
- A comprehensive ban must be supported by public education programmes, and effective monitoring, enforcement, and penalties for breach.

In some countries, the majority of spending on tobacco advertising and promotion takes the form of price discounts paid by tobacco manufacturers to create incentives for retailers to stock their brands, to lower the retail price of specific brands, and to stimulate competition based on price.[117] For example, in the United States, in 2013, US$ 7.6 billion (more than 85% of total tobacco advertising expenditures in that year) were spent on various kinds of incentive payments to wholesalers and retailers.[118] Evidence suggests that these payments may cushion the impact of price rises on price-sensitive adolescents, resulting in higher rates of initiation to regular smoking.[119] Legislative responses to these forms of tobacco promotion and price manipulation include

mandatory reporting of all advertising and promotional payments by tobacco companies, bans on wholesale and retail price discounting, and minimum price laws that prohibit retailers from selling below a statutory minimum.[120] In addition, WHO has recommended prohibiting tobacco manufacturers or retailers from claiming these payments as business tax deductions.[121]

In many countries, smoking remains common in high-grossing movies and in popular television programmes.[122] Smoking in films and interactive games, and the promotion of tobacco products through entertainment products has a powerful impact on young people.[123] Guidelines for the implementation of Article 13 recommend that Parties prohibit the depiction of tobacco brand images in entertainment products and require entities involved in the production or distribution of those products to certify that no money, gifts, interest-free loans or other assistance have been given in exchange for this form of publicity.[124] The guidelines recommend that Parties implement a classification or ratings system that takes account of tobacco use, and requires the display of anti-tobacco advertisements at the beginning of any entertainment product that depicts tobacco products or tobacco use.[125] In 2012, India implemented regulations that make television broadcasters and cinema and theatre owners responsible for broadcasting anti-tobacco messages to counteract the depiction of smoking and other forms of tobacco use in films and television programmes.[126] These requirements are summarized in **Box 13.3**.

Box 13.3: India's law to counteract the depiction of tobacco use in films and television programmes[127]

"Old" films and television programmes:

- Since 2012, Indian regulations require 30-second anti-tobacco messages to be screened at the beginning and during the middle of all "old" films and television programmes that display tobacco products. An old film or television programme refers to a film that was certified or a television programme that was produced before the regulation took effect.
- In the case of television programmes, a health warning must also be displayed at the bottom of the screen during the period that tobacco products are visible.
- The anti-tobacco messages and health warnings must be in the same language used in the film or television programme (in the case of dubbed or subtitled programmes, the language of dubbing or subtitle). This language requirement applies to both new and old films and programmes.
- Penalties for failure to comply with these requirements may include the suspension or cancellation of the licence of the broadcaster or cinema owner.

"New" films and television programmes:

- A 30-second anti-tobacco message must also be screened at the beginning and during the middle of all new films and television programme that display tobacco products or show them being used.
- A health warning must also be displayed at the bottom of the screen during the period that tobacco products are visible in all new films and television programmes.
- An audiovisual disclaimer warning of the harms caused by tobacco use (with a minimum

duration of 20 seconds) must be shown at the beginning and during the middle of all new films and television programmes that display tobacco products or their use.

- New films that do not meet these requirements may not be certified for public exhibition.
- Failure to comply with these requirements may result in cancellation or suspension of the licence of the broadcaster or cinema owner.

13.5 Second-hand tobacco smoke

Article 8 of the WHO FCTC requires Parties to implement legislative, executive and administrative measures that provide protection from exposure to tobacco smoke in "indoor workplaces, all public transport, indoor public places and, as appropriate, other public places".[128] Reducing exposure to second-hand tobacco smoke benefits health in many ways, such as by significantly reducing tobacco consumption[129] and by reducing the likelihood that young people will progress to established smoking.[130] For example, the Turkish Tobacco and Alcohol Market Regulatory Agency reported that tobacco sales fell by 16% in the year following the implementation of Turkey's indoor smoking ban in 2009.[131] Smoke-free legislation is also associated with significant reductions in hospital admissions for myocardial infarction precipitated by exposure to tobacco smoke,[132] and with significant reductions in both premature birth and paediatric hospital admissions for asthma.[133] The obligation to provide protection from tobacco smoke is grounded in fundamental human rights and freedoms.[134] Failure to provide protection from exposure to tobacco smoke not only undermines the right to health, but may violate a range of other human rights obligations that, in many countries, are enforceable by individuals through the courts.[135]

The *Guidelines for implementation of Article 8*, adopted by the COP, confirm that there is no safe level or threshold value for exposure to tobacco smoke.[136] National laws should therefore insist on a complete ban on smoking in order to create 100% smoke-free environments. The guidelines emphasize that "ventilation, air filtration and the use of designated smoking areas (whether with separate ventilation systems or not), have repeatedly been shown to be ineffective and there is conclusive evidence ... that engineering approaches do not protect against exposure to tobacco smoke.[137] Effective protection from second-hand tobacco smoke requires legislation, since voluntary smoke-free policies based on accommodation of smokers' needs have repeatedly been shown to be ineffective.[138]

The *Guidelines for the implementation of Article 8* provide advice on the definition of key terms in domestic legislation implementing this Article. For example, smoking bans operating in "indoor public places and, as appropriate, other public places" should apply to "all places accessible to the public… regardless of ownership or right of access".[139] This would include schools, hospitals and health care establishments, restaurants, bars, shops, train and bus stations, and airports. Since even small levels of exposure to tobacco smoke create a risk to health, lawmakers in some States and provinces have implemented smoking bans on public beaches, in and around playgrounds, sporting facilities and picnic areas, and in cars carrying children.[140]

Contrary to claims by the tobacco industry, evidence suggests that smoke-free laws do not reduce business profitability.[141] Compliance with smoking bans can be encouraged by imposing monetary fines on both individuals and businesses, although enforcement efforts should focus on the latter.[142] Over time, smoke-free laws will increasingly be enforced by public convention, as cultural norms change and both smokers and non-smokers develop a preference for smoke-free environments. Governments may also consider extending smoke-free laws to smokeless forms of tobacco, and electronic cigarettes, in countries where either of these are commonly used. For example, the use of electronic cigarettes in smoke-free environments may undermine the denormalizing effects of smoke-free laws, reduce quitting incentives and expose bystanders to exhaled aerosol toxicants.[143] In August 2014, Maharashtra became the first state in India to ban the use of smokeless tobacco in a range of public places, with penalties for those caught chewing or spitting tobacco.[144] In 2016, the state of California extended the smoke-free laws that apply to cigarettes to electronic cigarettes, and raised the minimum purchasing age for all forms of tobacco, including electronic cigarettes, to 21 years.[145]

13.6 Resisting industry interference in tobacco control laws and policies

Tobacco control laws and policies in many countries are vulnerable to the influence of tobacco companies and other business groups that benefit economically from high rates of tobacco use. Article 5.3 of the WHO FCTC requires Parties, in setting and implementing their public health policies with respect to tobacco control, to protect these policies from "commercial and other vested interests of the tobacco industry in accordance with national law".[146] Similarly, the Protocol to Eliminate Illicit Trade in Tobacco Products requires that national authorities responsible for tracking and tracing tobacco products should interact with the tobacco industry "only to the extent strictly necessary" to administer that system.[147]

The *Guidelines for implementation of Article 5.3* point to the "irreconcilable conflict between the tobacco industry's interests and public health interests".[148] Accordingly, the guidelines urge Parties to limit their interactions with the tobacco industry and to ensure that any interactions that do occur are transparent. For example, the Russian Federation's tobacco control law requires all correspondence between government agencies and the tobacco industry to be made publicly available on the Internet.[149] Partnerships, memoranda of understanding and other non-binding or non-enforceable agreements with the tobacco industry should be rejected.[150] Tobacco companies should not be involved in the drafting of tobacco control laws, nor should government accept voluntary codes of conduct drafted by the tobacco industry as a substitute for legally enforceable standards.[151] Members of Parliament and government staff should resist any attempts by the tobacco industry to influence legislative and executive processes during the passage of tobacco control laws (this may extend to direct tampering with the wording of draft legislation during the legislative process).[152]

The *Guidelines for the implementation of Article 5.3* point out that "corporate social responsibility" activities undertaken by the tobacco industry should be recognized as marketing activities that are in conflict with the goals of tobacco control; accordingly, Parties should not endorse or support such

activities.[153] Tobacco companies should not be involved in the design or implementation of any public education programmes related to tobacco control:[154] this extends to industry support or involvement in youth non-smoking programmes. Parties should not give incentives (including tax incentives) to the tobacco industry to establish or run businesses, and State-owned tobacco enterprises should be treated no differently to other participants in the tobacco industry.[155]

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Chapter 14: Migration and retention of health care workers

SUMMARY POINTS

· **The WHO Global Code of Practice on International Recruitment of Health Personnel sets out voluntary principles for ethical international recruitment of health care workers, and is intended to improve the legal and institutional framework for recruitment practices at the country level.**

· **The Code encourages Member States to scale up the training of health personnel, to consider measures to address the geographical misdistribution of health workers in underserved areas, and to monitor the national health labour market.**

· **Member States should consider establishing or designating a national authority responsible for the exchange of information regarding health personnel migration and the implementation of the Code.**

· **There is a range of strategies that may assist source countries to retain and build their health workforce, while also ensuring a better distribution of health workers between urban, rural and remote areas. These include compulsory service requirements, bonding schemes, improvements in human resource management, a safe working environment, greater investment in facilities and equipment, improved pay and conditions, and career development opportunities.**

Introduction

An adequate and effective health workforce is one of the foundations of a successful health system. The health workforce includes medical practitioners (including specialist physicians), nurses, midwives, allied health care professionals, health administrators as well as other public health personnel. A country's health workforce can be expensive to train and shortages can be difficult to fill quickly, due to the lead-time in recruiting and training new staff. Some countries have no medical schools at all.[1]

Over the past 25 years, international trade in skilled services has increased dramatically. While some countries face challenges due to the migration of domestically trained health care workers,[2] other countries have experienced a rapidly growing domestic market for health care services due to "medical tourism". The 2006 World Health Report estimated that 57 countries, particularly in sub-Saharan Africa, faced critical shortages of health personnel totalling 2.4 million doctors, nurses and midwives.[3] Overall, WHO estimates that there is a global shortage of about 4.3 million health care workers, a shortfall of about 15%.[4] In France and Germany, for example, the density of physicians per 10 000 population was 32 and 39, respectively, over the period 2007–2013, whereas in a number of African countries it was less than 1 per 10 000 population.[5] Over this period, the average density of physicians, and of nursing and midwifery personnel for the WHO European Region was 32 and 80 per 10 000 population, respectively, but only 2.7 and 12.4 per 10 000 population for the African

Region.[6] These shortages are aggravated by the migration of health care workers away from the countries that most need them.

Health professionals from developing countries emigrate for a variety of reasons. They may be attracted to high-income countries by the prospect of higher income, better equipment and working conditions, better job security and opportunities for career development, or they may be discouraged by ineffective management or safety and security concerns in their home countries.[7] Migration of health workers within countries, particularly from rural to urban areas and a lack of employment opportunities for health professionals within their own country pose additional problems.

14.1 International strategies

In May 2010, the World Health Assembly adopted the WHO Global Code of Practice on International Recruitment of Health Personnel, which outlines voluntary principles for ethical international recruitment, and is intended to improve the legal and institutional framework for recruitment practices at the country level (**Box 14.1**).[8]

The Code urges all countries, in their international recruitment practices, to take into consideration the needs of source countries for a sustainable health workforce. It recognizes the benefits that opportunities to study and work abroad can provide, both to source and destination countries, and to health care workers themselves. However, it urges countries to discourage the recruitment of health personnel in countries facing critical shortages. While recognizing the benefits of circular migration, the Code encourages WHO Member States to develop a sustainable workforce that will reduce long-term reliance on migrant health workers. The Code also encourages Member States to scale up the training of health personnel, to consider measures to address the geographical maldistribution of health workers in underserved areas, and to monitor the national health labour market. All States should, as appropriate, designate a national authority responsible for the exchange of information regarding health personnel migration and the implementation of the Code.[9]

Regional and bilateral agreements provide additional tools for implementing the principles of the Code and improving health workforce labour market practices. Bilateral agreements can recognize the need for both source and destination countries to monitor the extent of migration and its impact on the source country, and to ensure adequate training and strategies for financial support to the health system in the source country. Key issues that bilateral agreements can address include: recruitment standards, employment standards, recognition of the freedom to migrate and to engage in professional development, monitoring and implementation, and dispute resolution.

Box 14.1: Key Messages from the WHO Global Code of Practice on the International Recruitment of Health Personnel[10]

3.2 Addressing present and expected shortages in the health workforce is crucial to protecting global health. International migration of health personnel can make a sound contribution to the development and strengthening of health systems, if recruitment is properly managed. ...

3.4 Member States should take into account the right to the highest attainable standard of health of the populations of source countries, individual rights of health personnel to leave any country in accordance with applicable laws, in order to mitigate the negative effects and maximize the positive effects of migration on the health systems of the source countries. ...

3.6 Member States should strive, to the extent possible, to create a sustainable health workforce and work towards establishing effective health workforce planning, education and training, and retention strategies that will reduce their need to recruit migrant health personnel. ...

3.8 Member States should facilitate circular migration of health personnel, so that skills and knowledge can be achieved to the benefit of both source and destination countries.

4.6 Member States and other stakeholders should take measures to ensure that migrant health personnel enjoy opportunities and incentives to strengthen their professional education, qualifications and career progression, on the basis of equal treatment with the domestically trained health workforce subject to applicable laws. ...

5.1 ... Destination countries are encouraged to collaborate with source countries to sustain and promote health, human resource development and training as appropriate. Member States should discourage active recruitment of health personnel from developing countries facing critical shortages of health workers.

5.2 Member States should use this Code as a guide when entering into bilateral, and/or regional and/or multilateral arrangements, to promote international cooperation and coordination on international recruitment of health personnel. ...

5.4 As the health workforce is central to sustainable health systems, Member States should take effective measures to educate, retain and sustain a health workforce that is appropriate for the specific conditions of each country, including areas of greatest need, and is built upon an evidence-based health workforce plan. All Member States should strive to meet their health personnel needs with their own human resources for health, as far as possible.

5.5. Member States should consider strengthening educational institutions to scale up the training of health personnel and developing innovative curricula to address current health needs. …

5.7 Member States should consider adopting measures to address the geographical maldistribution of health workers and to support their retention in underserved areas, such as through the application of education measures, financial incentives, regulatory measures, social and professional support.

7.3. For purposes of international communication, each Member State should, as appropriate, designate a national authority responsible for the exchange of information regarding health personnel migration and the implementation of the Code.

At the national level, both source and destination countries can develop laws and policies to reduce the loss of health personnel from developing countries and also to promote a more equitable distribution of human resources for health across rural areas – where 50% of the world lives, but only 24% of health professionals work.[11]

In the United Kingdom, for example, the Code of Practice for the International Recruitment of Healthcare Professionals regulates recruitment practices by the National Health Service.[12] Recruitment is only permitted in countries where there is an explicit government-to-government agreement that permits recruitment activities (**Box 14.2**). There is no active recruitment of health care professionals from those developing countries that are included on the Department of Health website. Any hiring of public sector health workers must occur through an approved recruitment agency that complies with the Code.[13]

Box 14.2: United Kingdom: Code of Practice for the International Recruitment of Healthcare Professionals

Guiding principles

3. Developing countries will not be targeted for recruitment, unless there is an explicit government-to-government agreement with the UK to support recruitment activities.

6. International healthcare professionals legally recruited from overseas to work in the UK are protected by relevant UK employment law in the same way as all other employees.

Best practice benchmarks for international recruitment

1. There is no active recruitment of healthcare professionals from those developing countries that are included on the Department of Health website.

- No active recruitment will be undertaken in developing countries by UK commercial recruitment agencies, or by any overseas agency sub-contracted to that agency, or any healthcare organisation unless there exists a government-to-government agreement that healthcare professionals from that country may be targeted for employment.

…

- Healthcare organizations may consider unsolicited applications direct from an individual in a developing country if that individual is making an application on their own behalf and not using a third party, such as a recruitment agency.

2. All international recruitment by healthcare employers will follow good recruitment practice and demonstrate a sound ethical approach.

…

- Any international recruitment will be sensitive to local healthcare needs so that international recruitment from any country should not destabilize local health.

3. International healthcare professionals will not be charged fees in relation to gaining employment in the UK.

14.2 Retention strategies for source countries

Countries that tend to be source countries for the migration of health care workers frequently face both critical shortages, and large disparities in access to health care workers between remote, rural, and (more developed) urban areas. Countries may consider a range of policies to address these problems including compulsory service requirements, bonding schemes, human resource management, improved pay and conditions, greater investment in facilities and equipment, and greater career development opportunities.

Compulsory service schemes may require medical practitioners to remain within the country, or to locate to rural or remote areas during their normal period of clinical residency, or for a specified period following completion.[14] In Indonesia, for example, doctors, dentists and midwives were previously required to work as contract staff during a period of compulsory service which ranged from six months to three years, depending on the remoteness of the location.[15] In 2007, this period of service became voluntary, but the contract scheme has remained popular among new graduates due to increased financial incentives, and the short length of the contract period.[16] In 2009, the Ministry of Health introduced an additional Special Assignment Programme in order to address specific shortages in "strategic health workers" including nurses, nutritionists and public health workers, in specific underserved locations.[17]

For more than four decades, Thailand has adopted a policy of compulsory rural service for early-career health workers graduating from government-funded professional schools.[18] Doctors and nurses sign a rural service contract at the commencement of their training in a public medical or nursing school. Although there are penalties for breaking this commitment (up to US$ 10 000 for physicians), some nevertheless break these contracts in order to take up more highly-paid positions in the private sector.[19] Following the introduction of Thailand's universal coverage scheme (originally known as the "30 baht" policy), demand for medical services in rural areas increased substantially. In response, the Thai Ministry of Public Health established new medical schools in rural areas and offered higher salaries to government-employed doctors in rural areas.[20] The government has also established special admission tracks for entry to medical school that target high-school graduates in particular provinces. Following graduation, these health workers are required to undertake mandatory service (for a period of three years, or 12 years, depending on the scheme) in provinces that are experiencing health worker shortages.[21] In addition, those who want to seek specialty training are required to complete one year of rural service, and those who work in a rural setting for at least three years are eligible for a full scholarship for specialty training.[22] In an effort to retain an adequate number of experienced physicians in rural areas, the government offers board certification (with an accompanying pay raise) for those who work in rural areas for over five years.[23]

Bonding schemes require health professionals who received State-funded scholarships during their period of training to fulfil public service obligations after graduation. In Australia, for example, individuals who receive government support for their medical education must perform a contracted number of years of public service, often in rural hospitals, before they can receive a billing number that allows them to be paid under the national health care system.[24] Buy-outs are not allowed, and medical practitioners who fail to complete their contract are required to wait twice the contract period before they are given a billing number (**Box 14.3**). To reduce the possibility that health

workers will seek to avoid their service obligations by migrating, the WHO Global Code of Practice encourages recruiters and employers to respect the legal obligations of health personnel that apply within their countries of origin.[25]

Box 14.3: Bonding schemes for retention of health care workers: an example from Australia

Health Insurance Act 1973 [26]

Section 19ABA. Medicare benefits not payable in respect of services rendered by doctors who breach certain contracts with the Commonwealth

(1) Despite section 19AA, a medicare benefit is not payable in respect of a professional service rendered by, or on behalf of, a medical practitioner who has breached a contract with the Commonwealth under which the practitioner agreed to work in a rural or remote area.

(2) The period during which medicare benefits are not payable under subsection (1) is a period equal to twice the length of the period that the practitioner agreed, under the contract, to work in the rural or remote area or such shorter period as is determined in, or in accordance with, the contract.

(3) Subsections (1) and (2) apply whether or not the medical practitioner referred to in those subsections was a medical practitioner at the time of entering the contract or at the time of the breach.

Strategies that rely on compulsory service and bonding schemes may be effective in dealing with urgent gaps and shortages, but may not address the underlying reasons why experienced health professionals are reluctant to settle in rural or remote areas. Policies for work retention are best coupled with human resources management strategies designed to make service in underserved areas more attractive. Important elements in an effective human resource management strategy include:

- detailed job descriptions for health workers at all levels, consistent with their training;
- defined career trajectories at all levels, with a clear explanation of what is required for advancement;
- routine performance reviews;
- on-time payment;
- a strategy to keep health professionals informed of policy changes within the health system;
- a system that is responsive to complaints by health care workers and gives reasons for decisions;
- regular contact from supervisors and the central health system, particularly in rural areas. [27]

To retain health workers, countries may also consider moving towards a performance-based reward system that rewards health workers for good performance in improving patient outcomes, or in meeting health needs at the community level. Performance-pay systems should be carefully tailored

to ensure that improvements are evidence-based, rather than based on selective reporting or choice of patients.[28] Workplace systems that take account of individual workloads in planning the distribution of health workers between facilities, which offer flexible working hours, and which encourage workers to develop their own solutions to local problems, can also contribute to a positive working environment where health workers feel supported and motivated (**Box 14.4**).[29] Strategies to reduce the time that health professionals spend on activities that do not require their professional expertise may also increase efficiency and motivation.[30]

Box 14.4: Human resource management strategies: an example from Kenya and Guinea

Decentralizing task management[31]

In 1999, Kenya and Guinea trialled a COPE (Client-Oriented, Provider-Efficient) model of human resource management within eight intervention sites in the two countries. The programme was supported by simple tools and was based on a philosophy of participation and teamwork, transferring decision-making power to the local, on-site team, maintaining a focus on clients' rights and needs, cost-consciousness and efficiency. An evaluation of the programme found that both skills and performance were enhanced through the programme, attendance at clinics increased, as well as immunization rates and quality of care. The evaluation found that local staff were able to resolve a range of problems without outside assistance, including small renovations, improving staff working conditions, and service-delivery issues – such as long waiting times, and poor record-keeping and referral systems. These improvements were validated by exit interviews with clients. Core features of the COPE model include the autonomy and independence of the local team, shared responsibility for actions, and a focus on improving systems and developing staff capacity: these helped to create an enabling environment in which local staff felt empowered to act and to assume responsibility for problems and their solutions.[32]

A safe working environment, including adequate facilities and equipment, are essential to health worker retention (**Box 14.5**). Minimum safe working conditions include clean water, a safe electricity supply, and adequate office space, equipment and supplies.[33] Physical violence may drive workers to leave their positions, particularly female nurses in rural areas.[34] National law must ensure that employers respond swiftly to reports of workplace violence and that employees who complain are protected from retribution or discrimination. Health workers require protective equipment, including gloves and containers for the safe disposal for needles and blood products.[35] Health workers should also be immunized and have access to post-exposure prophylaxis for HIV infection in case of a needle-stick injury.[36]

Sufficient pay is another factor that is essential to improving retention in the public health sector (**Box 14.5**).[37] Low wages are often a motivation for leaving the public health care sector, particularly in developing nations.[38] However, raising salaries – or seeking to compete with private sector salaries – is not the only way of increasing remuneration. Incentive programmes may include vehicle and education subsidies, hardship allowances, housing, travel allowances, paid vacation, preferential placement for advanced training opportunities and even access to good quality Internet services (**Box 14.5**).[39]

Box 14.5: Haiti: Partners in Health clinics[40]

Investing in safe working conditions

The loss of staff from public sector health clinics to the private sector has long been a problem in Haiti. However, Partners in Health (PIH) has turned its rural clinics into the most sought-after residency sites in the country despite offering lower pay than private clinics. Programme directors attribute the high retention levels in these clinics to the quality of the clinic facilities, which are stocked with essential medicines and technology so that health workers are not frustrated by their inability to provide care. Although PIH is an externally funded operation, its success in increasing retention of local workers is instructive.

Increased pay and incentives

Even with wages lower than the private sector (though higher than government positions), PIH recruits top candidates to its rural locations because it offers them transport back to cities to visit their families, and provides lodging and food. Often-cited is the satellite Internet service that PIH provides, which enables doctors to communicate with their families and professional colleagues and gives them access to extensive medical reference material and patient management systems. PIH also offers opportunities for Haitian medical professionals to collaborate with researchers worldwide, publish in academic journals and speak at conferences.

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Chapter 15: Access to essential medicines, TRIPS and the patent system

SUMMARY POINTS

· **All countries should develop a national medicines policy that includes a national list of essential medicines that takes account of national needs. In some countries, the national constitution commits governments to providing equitable access to essential medicines and health care services.**

· **A national procurement strategy may assist governments to formalize a range of measures to purchase quality medicines at cheaper prices. Addressing corruption, eliminating tariffs on imported drugs, controlling mark-ups on drugs at wholesale and retail levels, requiring or creating incentives for the supply of generic versions of drugs by pharmacists and medical practitioners, and banning or limiting direct-to-consumer advertising of medicines, are some of the strategies that may reduce prices.**

· **Most essential medicines are not under patent, and generic versions can be produced or imported without infringing patent rights.**

· **Affordable access to essential medicines that are under patent depends partly on the terms of national patent laws, and on the actions of the patent holder. The Agreement on Trade-Related Aspects of International Property Rights (TRIPS) includes a number of flexibilities that can be used to reduce the prices of essential medicines and to better meet the goal of universal access. TRIPS does not prevent national governments from issuing compulsory licences in order to meet national health objectives, from choosing an exhaustion regime that best suits national circumstances (allowing parallel importing for example), or from defining patentability criteria in national patent legislation.[1]**

· **A patent holder may enter into a voluntary licence with third parties, such as generic producers, to produce, market and distribute a particular drug within a specified territory. Royalty-free, non-exclusive licences that include a large number of countries within the licensed territory, permit sale to both the public and private sector, and permit licensees to source active pharmaceutical ingredients from anywhere in the world are more likely to encourage robust competition and the economies of scale that are needed to substantially reduce prices. Other strategies that support access to essential medicines include tiered pricing, donation of drugs, non-filing of patents in least developed countries, and non-enforcement of patents.**

Introduction

Ensuring universal access to free or affordable essential medicines is one of the "core obligations" for fulfilling the right to health.[2] WHO has encouraged countries to amend their national legislation or constitutions to provide for this specific right[3] (**Box 15.1**). For example, the Universally Accessible Cheaper and Quality Medicines Act of 2008, enacted by the Philippines, contains the following declaration of policy:

It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all. [4]

The Act also states that any doubts about the interpretation of provisions of the Act shall be resolved by adopting a construction in favour of the protection of public health.[5]

Box 15.1: Constitutional protections for access to medicines: examples from Panama and the Philippines

Political Constitution of the Republic of Panama[6]

Article 110. In matters of health, the State is primarily obligated to develop the following activities, integrating the functions of prevention, treatment, and rehabilitation:

…

5. Establish, in accordance with the requirements of each region, centres which provide comprehensive health care services and supply medicines to the population. These health services and medicines shall be given free to those who lack economic means to purchase them.

Constitution of the Republic of the Philippines[7]

Article 13.

Section 11. The State shall adopt an integrated and comprehensive approach to health development which shall endeavour to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the underprivileged, sick, elderly, disabled, women, and children. The State shall endeavour to provide free medical care to paupers.

Section 12. The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

In some countries, the treaty obligations assumed by countries are enforceable through the domestic courts, providing members of the population with a legal pathway for seeking greater access to essential medicines at affordable prices.[8] For example, Argentina's Constitution refers to a number of human rights treaties which supersede domestic law (**Box 15.2**). In 2000, the Argentinian Supreme Court ruled that the right to life enshrined in the International Covenant on Economic, Social and Cultural Rights[9] was enforceable under Argentinian law in that country's domestic courts. The ruling provided, in part, that the government had a positive duty – going beyond what was specifically required by Argentinian legislation – to provide medicine to a disabled child.[10]

Box 15.2: Using international treaties to promote access to medicines: human rights treaties that supersede domestic law in the Constitution of Argentina

> Section 75
>
> …
>
> 22. The American Declaration of the Rights and Duties of Man; the Universal Declaration of Human Rights; the American Convention on Human Rights; the International Covenant on Economic, Social and Cultural Rights; the International Covenant on Civil and Political Rights and its empowering Protocol; the Convention on the Prevention and Punishment of Genocide; the International Convention on the Elimination of all Forms of Racial Discrimination; the Convention on the Elimination of all Forms of Discrimination against Woman; the Convention against Torture and other Cruel, Inhuman or Degrading Treatments or Punishments; the Convention on the Rights of the Child; in the full force of their provisions, they have constitutional hierarchy [above national law], ... [and] are to be understood as complementing the rights and guarantees recognized herein.

15.1 Establishing a national drugs policy

In order to ensure access to essential medicines, countries need to establish a national drugs policy. WHO has released comprehensive guidance on creating these policies, which should address access to, and the quality and rational use of, medicines.[11] The WHO Model List of Essential Medicines can help to guide drug selection, although the development of a national list should take account of national priorities and disease challenges.[12] A national drug policy, including a list of essential medicines and standard treatment guidelines, can increase the use of generics, improve prescribing practices and protect against drug resistance.

For example, during the 1990s, South Africa developed a national drug policy in collaboration with WHO. The Minister for Health appointed a Drug Policy Committee to develop a pricing plan for drugs used in both the public and private sectors, to develop a plan for the evaluation of drugs for effectiveness, and to develop an essential drugs list for use in the public sector. The committee also considered strategies for increasing the use of generic drugs, and for procurement and distribution, particularly in rural areas.[13] The policy developed as a result of this process secures the right to universal access to essential medicines by committing the government to:[14]

- ensure the availability and accessibility of essential medicines to all citizens;
- ensure the safety, efficacy and quality of drugs;
- ensure good prescribing and dispensing practices;
- promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information; and
- promote the concept of individual responsibility for health, preventive care and informed decision-making.

The South African government has since established the South African Drug Action Programme within the Department of Health to implement the new policy and to support provincial strategies.

15.2 Pricing and procurement

A national procurement policy is an important tool for assisting governments to purchase quality drugs at the lowest possible prices. An effective procurement strategy must accurately estimate the drug needs of the country and select the most appropriate purchasing strategy based on resources and time. There are four general methods for procuring pharmaceuticals: open tenders, restricted tenders, competitive negotiations and direct procurement.[15] The procurement method chosen by a government should seek to achieve the following objectives: (1) to procure the most cost-effective drugs in the right quantities; (2) to select reliable suppliers of high-quality products; (3) to ensure timely delivery of essential medicines; and (4) to achieve the lowest possible total cost.[16] Countries may choose to incorporate these objectives into national legislation or administrative guidelines, as Sri Lanka has done (**Box 15.3**).

Box 15.3: Sri Lanka's National Procurement Strategy: guidelines for procurement of pharmaceuticals and medical devices[17]

Section 1.1. All pharmaceuticals procured must fulfil quality, safety and efficacy criteria. All medical devices procured should satisfy quality, safety, performance, effectiveness and efficacy criteria.

Section 1.2. The strategic objectives of procurement of pharmaceuticals & medical devices should be:

- procure the most cost-effective pharmaceuticals and medical devices in the right quantities;
- ensure supplier reliability with respect to service and quality;
- arrange timely delivery to avoid shortages and stock outs; and
- achieve the lowest possible evaluated cost.

Section 6. Pharmaceuticals and medical devices may be procured by International Competitive Bidding (ICB), National Competitive Bidding (NCB), Limited/restricted International Competitive Bidding (LIB), in accordance with the applicable provisions stipulated in [procurement guidelines], subject to any modifications contained herein.

Section 7.2. To ensure that the [procuring entity] obtains competitive prices the [procuring entity] should have reference to historical prices and may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health. [The procuring entity] may also consult with neighbouring countries on prices offered to them and inquire into the possibility of pooled procurement schemes.

Pharmaceutical drugs are estimated to account for 25% of global health spending. However, 10–25% of public spending on procurement is thought to be lost to corruption.[18] WHO has published

guidance to assist public authorities to avoid corruption.[19] Important steps include registering medicines on the national list, licensing importers of pharmaceuticals and medical equipment, licensing pharmacists and dispensers of drugs, inspecting facilities, controlling the advertising and promotion of medicines, introducing oversight mechanisms for clinical trials, and developing a comprehensive plan for selecting and procuring essential medicines.[20] In Kenya, neutral observers are invited to be present at committee meetings where large tenders are considered (**Box 15.4**). Other legal strategies include giving legislative protection to whistle-blowers, requiring members of the national drug registration committee to file a conflict of interest declaration, and prosecuting acts of corruption in a timely manner.[21]

Box 15.4: Applying good governance principles to procurement strategies in Kenya

Public Procurement and Disposal Regulations, 2006[22]

12. Procedure for tender committee meetings.

…

(8) To enhance transparency of the procurement process the procuring entity shall invite in addition to the representative of various departments, at least two observers to attend its meetings in cases where the value of the contract is estimated to be above fifty million shillings.

(9) At least one of the observers invited under paragraph (8) shall come from a duly recognized private sector organization or discipline relevant to the procurement under consideration.

In addition to minimizing corruption, a national drugs policy can reduce the systemic costs that create barriers to access to essential medicines. This can occur by eliminating tariffs on the import of drugs that are not produced domestically and by controlling the mark-ups that can be applied to drugs that are resold in the private and public sectors.[23] In South Africa, mark-ups on the prices of drugs at the wholesale and retail levels have been replaced with a fixed fee (**Box 15.5**). Programmes that create incentives for pharmacists and medical practitioners to dispense or prescribe generic versions of drugs, where available, can also reduce the price paid by patients and improve access.[24] Argentina, the Plurinational State of Bolivia, Peru and Uruguay all require physicians to use generic names when writing prescriptions: this allows pharmacists to fill orders with cheaper alternatives to brand name drugs when they are available.[25]

Box 15.5: Monitoring pharmaceutical pricing: South Africa's National Drug Policy[26]

Section 4.1. Rationalization of the pricing structure

- A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmacoeconomists, and representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure, and consumer representatives.

- There will be total transparency in the pricing structure of pharmaceutical manufacturers,

wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals.

- A non-discriminatory pricing system will be introduced and, if necessary, enforced.
- The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee. …
- A database will be developed to monitor the cost of drugs in the country in comparison with prices in developing and developed countries.
- Price increases will be regulated.
- Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well-being of any sector of the population, the State will make them available to the private sector at acquisition cost plus the transaction costs involved.

In addition, laws that ban or limit the advertising of pharmaceuticals direct to consumers can reduce patient demand for unnecessarily expensive drugs.[27] Direct-to-consumer advertising stimulates the prescribing of advertised medicines, and is rare outside the United States, where commercial free speech by pharmaceutical manufacturers is protected by the Constitution.[28] Finally, where a branded medicine has previously received regulatory approval, governments may encourage the supply of generic or bioequivalent versions of the same drug by offering a faster, preferential process for regulatory approval, together with discounted registration fees.[29]

15.3 Access to medicines, patents and TRIPS

The national drugs policy adopted by each country needs to be consistent with international law governing intellectual property rights. Medicines, as well as the processes required to produce them, are patentable under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[30] TRIPS is one of the family of agreements that Members of the World Trade Organization (WTO) are required to implement. In order to implement TRIPS, all Members of the WTO are required to enforce national legislation that recognizes and enforces pharmaceutical patents.[31] This section reviews some features of national patent laws that may influence access to medicines, and the prices at which medicines are available for purchase, within the context of countries' TRIPS obligations.

(a) The purpose of patents

A patent is an exclusive right that enables the patent holder to exclude competing suppliers during the term of the patent. In return, the patent holder publicly discloses their invention: this facilitates free use of this information when the patent expires.[32] Like any other property right, a patent may be sold, licensed or transferred. Patent laws are intended to encourage investors to make the huge investments that are required to discover, develop and deliver a new drug to market. In theory,

patent protection helps to ensure the continued development and availability of medicines in future, provided that markets can generate a return to the patent holder for their costs of research and development. When patent regimes work well, they promote technological innovation, by ensuring a return on investment for the patent holder, while also ensuring the transfer and dissemination of technology and the continued availability of generic medicines after the patent has expired.[33] However, since patents eliminate competition, they can also lead to high prices for medicines during the term of the patent.

High prices, as well as the scale of need for particular drugs, may combine to defeat the goal of providing universal access to a national list of essential medicines, especially in low-income countries. Furthermore, the incentive to invest in research and development in order to bring new medicines to market may not be present when the market value of the innovation is small. In the case of "neglected diseases" that disproportionately affect poor populations and low-income countries, patents have failed to achieve their objective as instruments of innovation since both governments and patients lack the purchasing power to create a market that justifies the necessary investment in the first place.[34] A variety of other policy instruments will be required to overcome market failure and to encourage research and development of neglected diseases.[35]

(b) The TRIPS Agreement and intellectual property rights

The TRIPS Agreement came into force on 1 January 1995. WTO Members were given different dates by which to amend their domestic laws and practices in order to protect patent rights on pharmaceuticals, according to their status as developing countries and whether or not they had any previously existing laws recognizing patents in this area.[36] Under Article 66.1, least developed countries were originally given until 2006 to recognize and enforce patents on pharmaceuticals, although this date has since been extended to 1 January 2033.[37] On two occasions, the Council for TRIPS has granted a broader extension of time to least developed countries to implement the substantive provisions of TRIPS (other than the non-discrimination provisions), most recently to 1 July 2021.[38]

Article 27 of the TRIPS Agreement states that patents shall be available for both products and processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.[39] The period of patent protection is 20 years.[40] In the case of products, Article 28 states that the rights of a patent holder include the right to prevent third parties from "making, using, offering for sale, selling, or importing" the product without the patent holder's consent.[41]

Since the majority of medicines that WHO considers to be essential medicines are not under patent,[42] it follows that the obligation of WTO Members to implement patent laws covering pharmaceuticals should not constitute a barrier to access for most drugs included in a national list of essential medicines. The extent to which patent protection for a particular medicine affects price and availability will depend upon the terms of patent laws and the patent status of that drug in each country, together with the existence of any voluntary or compulsory licences that have been issued. In cases where the period of patent protection has expired, generic versions of the drug may be produced and imported without infringing any patent rights. During the period of patent protection,

national authorities, as well as private suppliers, will need to negotiate with the patent holder on commercial terms for the price at which the medicine can be imported into that country, or alternatively, negotiate for a licence to manufacture the medicine within the country – assuming that there are no other generic medicines that are equally effective.

Article 63 of the TRIPS Agreement requires WTO Members to notify the Council for TRIPS about the national laws, regulations, and judicial and administrative decisions that affect the scope of protection for patents and other intellectual property rights, and to respond to requests from other WTO Members about the scope of their laws.[43] Disputes between WTO Members about a Member's compliance with its obligations under TRIPS are considered by a panel of experts who are appointed to hear each complaint. The panel's decision may be appealed to the WTO Appellate Body. The TRIPS Agreement provides for the imposition of trade sanctions by a Member on behalf of the patent holder in cases where another Member has failed to implement the report of the panel or Appellate Body and to act in accordance with that Member's obligations under TRIPS.[44]

Despite their obligation to implement laws granting and enforcing patents on pharmaceutical products, WTO Members retain considerable scope to adjust their patent laws in order to achieve public health objectives. For example, national laws may authorize the judiciary, the executive, or an administrative body to issue a compulsory licence to manufacture or import a patented drug without the permission of the patent holder in circumstances where licensing negotiations with the patent holder have failed or in cases of emergency or government use, in order to achieve the government's policy of providing universal access to medicines, diagnostics, vaccines or medical devices.[45] The Declaration on the TRIPS Agreement and Public Health, adopted by Trade Ministers at the Doha Ministerial Meeting in November 2001, states that "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".[46] Although the TRIPS Agreement does not refer specifically to compulsory licences, the wording of Article 31 recognizes that national patent laws may authorize public, non-commercial uses of patents by or on behalf of government, where the conditions set out in Article 31 are satisfied (**Box 15.6**).[47]

Box 15.6: Flexibilities recognized in Articles 8 and 31 of the Agreement on Trade-Related Aspects of International Property Rights (TRIPS)

Article 8

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 31

Other Use without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. …

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization…

In addition to licences issued on public interest grounds, the practice of WTO Members illustrates that national laws may authorize compulsory licences on a number of additional grounds.[48] For example, Zimbabwe's Patent Act provides that during periods of emergency (which legislators have authority to define), national laws may authorize the use of a patent without the permission of the patent holder, due to the scale of the health threat caused by a natural disaster, epidemic or security threat, as well as the physical interruption of supplies at affordable prices (**Box 15.7**). Other grounds for the issuing of a compulsory licence may arise where anti-competitive practices and pricing policies of patent holders have inflated drug prices to the point where they are no longer affordable, or where the patent holder has failed to exploit a patent or to license it within the jurisdiction.[49]

Box 15.7: Public, non-commercial (government) use of patents: Patent Act of Zimbabwe [50]

Section 34. Use of patented inventions for service of the State

(1) Notwithstanding anything in this Act, any department of the State or any person authorized in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section.

Section 35. Special provisions as to State use during emergency

(1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient—

...

(b) for the maintenance of supplies and services essential to the life of the community; or

(c) for securing a sufficiency of supplies and services essential to the well-being of the community.

At the WTO Ministerial Conference in Doha, Qatar, in 2001, WTO Ministers affirmed that TRIPS should be implemented in a way that supports the right of WTO Members "to protect public health and…to promote access to medicines for all".[51] The Declaration pointed to a number of provisions in

TRIPS that may assist Members to adjust their domestic laws to provide adequate protection to drug manufacturers and other patent holders within the territory of each Member, while acting to ensure that essential medicines remain affordable for all:

- As stated above, each Member retains the right, in accordance with their national laws, to grant compulsory licences (which authorize the use of the patent without the permission of the patent holder) and to determine the conditions to be satisfied before the compulsory licence is granted.

- In addition, each Member retains the right to determine what constitutes "a national emergency or other circumstances of extreme urgency" within the terms of Article 31. In either case, Article 31 authorizes the Member to waive the requirement to first seek a licence from the patent holder on reasonable commercial terms before issuing a compulsory licence to use the patent without the consent of the patent holder.

- Each Member also retains the right to define the circumstances in which, under their national laws, the patent holder's rights in a drug are exhausted.

The operation of these and other TRIPS flexibilities is discussed below.

(c) Awareness of TRIPS flexibilities

It is important for national health authorities to be aware of the flexibilities in the TRIPS Agreement when considering strategies to improve access to essential medicines, and to carefully consider their benefits before entering bilateral or regional trade agreements that limit any of these flexibilities.[52] By agreeing to enforce intellectual property rights that are more extensive than those recognized under the TRIPS Agreement, the cost of providing universal access to a national list of essential medicines may rise substantially. WHO, the WTO and the World Intellectual Property Organization, as well as the Commission on Intellectual Property Rights, Innovation and Public Health (established by the World Health Assembly in 2003), have published detailed guidance to assist national authorities to improve access to essential medicines.[53] The United Nations Development Programme[54] and the World Bank[55] have also published reports to assist countries to use the flexibilities in TRIPS effectively, having due regard to their obligations to respect patents and other intellectual property rights.

Article 31 requirements

Article 31 of the TRIPS Agreement states that in circumstances where the national law of a WTO Member permits a compulsory licence to be issued, the Member must first seek permission to use the patent from the patent holder on reasonable commercial terms. However, prior attempts to obtain access to the patented drug on commercial terms are not required in the case of a national emergency (which each Member is free to define), in other circumstances of extreme urgency, or in cases of public, non-commercial use – such as when a government is seeking to ensure universal access to essential drugs, or is using the patent for other government purposes (**Box 15.6**, above).

The operation of Article 31 is illustrated by the case of Thailand, which issued government use licences for seven medicines for the treatment of HIV and cancer, over the period 2006–2008.[56] Thailand's National Health Security Act of 2002 established a universal health care scheme that included a right of access to medicines on Thailand's National List of Essential Medicines.[57] In October 2003, the government declared its intention to provide universal access to triple antiretroviral therapy for people with HIV. However, the cost of providing this treatment rose rapidly, reaching nearly US$ 51 million (2.1 billion baht) in 2003.

In 2007, the Minister of Public Health, Dr Mongkol Na Songkhla, appointed two committees to support the implementation of government use licences. The first, the Committee on Price Negotiation of Patented Essential Medicines, sought to engage pharmaceutical companies in negotiations for price reductions. However, with the exception of imatinib, a cancer drug produced by Novartis, the discounts offered did not meet the Health Minister's benchmark that the discounted price should be within 5% of the price of generic versions of the medicine.[58] In the case of lopinavir/ritonavir, a fixed-dose combination used to treat HIV infection, the cost per patient for middle-income countries, including Thailand, was US$ 2967 per year, although this was reduced in August 2006 to US$ 2200 per patient per year.[59] The government issued a compulsory licence. By early 2008, the number of patients using lopinavir/ritonavir had tripled.[60]

Thailand's Minister of Public Health expressed the motivation for issuing compulsory licences for essential drugs, under Thailand's Patent Act, as follows:

> When a government such as ours declares a 'compulsory licence' to allow for public non-commercial use of patented products by the government for the greater public good, we are doing so to increase access to these essential, often life-saving, medications for the poor and marginalized members of our communities who were not consumers of these expensive, patented drugs. The more well-off members of our society continue to consult their own private physicians and continue to pay – out of their own pockets – the price of patented medications.[61]

In order to establish a clear legal basis for exercising the flexibilities that are permitted under the TRIPS Agreement, WTO Member States should enact legislation that sets out the circumstances in which the government reserves the right to issue a compulsory license. Apart from the exceptions mentioned in Article 31(b), such legislation should provide for a reasonable, yet time-limited period for negotiating with the patent holder before the designated national authority issues the licence (see **Box 15.8**). The legislation can reduce the administrative difficulty of issuing a compulsory licence by specifying which Minister or administrative body should perform this function, the approval process required, and by prohibiting patent holders from unreasonably stalling the process through litigation.[62]

Box 15.8: Legislation authorizing the issuing of a compulsory licence: Industrial Property Law[63] of Brazil

Article 68. The patent owner shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or if he uses it to abuse economic

power according to the law in force, under the terms of an administrative or judicial decision.

Article 73. An application for a compulsory licence shall set forth the conditions offered to the patent owner.

(1) After an application for a licence has been submitted, the patent owner shall be invited to submit his comments within a period of 60 (sixty) days, at the end of which, in the absence of a submission from the patent owner, the proposal shall be deemed accepted under the conditions offered.

…

(6) In the arbitration of the remunerations, the circumstances of each case shall be taken into consideration and shall include the economic value of the granted licence.

(7) Once the case has been examined, the National Institute of Industrial Property shall decide on the grant and on the conditions of the compulsory licence within a period of 60 (sixty) days.

(8) Appeals from decisions to grant a compulsory licence shall not have a suspensive effect.

In circumstances where a Member issues a compulsory licence without the authorization of the patent holder, Article 31 of the TRIPS Agreement requires the patent to be used "predominantly" in order to meet the domestic needs of the WTO Member that has authorized the licence, and "adequate compensation" (which TRIPS does not define) shall be paid to the patent holder.[64] However, in 2005, WTO Members approved an amendment to the TRIPS Agreement, which permits these requirements to be waived where certain conditions are met.[65]

WTO General Council Decision of 6 December 2005

The amendment approved in 2005 sets out a special procedure for the benefit of WTO Members whose domestic manufacturing sector lacks the capacity to manufacture the quantities of medicine that are needed. The procedure works by allowing a Member that does have adequate manufacturing capacity to issue a compulsory licence for the manufacture and export of a generic version of the patented medicine to a Member that lacks domestic manufacturing capacity. **Box 15.9** summarizes some of the key conditions that apply.[66]

Box 15.9: Key conditions that apply to compulsory licences issued under the WTO General Council Decision of 6 December 2005

- The importing Member must notify the Council for TRIPS of the names and quantities of medicines that it needs, and indicate that a compulsory licence has or will be granted for those medicines that are under patent within its territory.
- The compulsory licence issued by the exporting Member shall contain conditions restricting the manufacture of the patented medicine to the amounts that are necessary to meet the needs of the importing Member. The medicines themselves must be clearly identified as being manufactured under the scheme so that they cannot be improperly diverted to third markets. All the medicines produced in this way must be exported to the importing Member.

- The exporting Member must post the amounts being exported and the distinguishing features of the shipment on a website, and notify the Council for TRIPS about the compulsory licence and the conditions that apply to it.
- Eligible importing Members are required to take reasonable steps to ensure that medicines imported under the scheme are not re-exported.

In order to use this procedure, the importing Member must either be a least developed country or must have notified the TRIPS Council of its intention to use the procedure.[67] Countries exporting pharmaceutical products under the procedure to an eligible importing country must also notify the TRIPS Council when they do so.[68] Unless they have opted out of doing so, all WTO Members are eligible to use the procedure, whether as countries that issue a compulsory licence and manufacture medicines for export to the importing country, or as an importing country that lacks domestic manufacturing capacity of its own and seeks to import essential medicines to meet its health needs. WTO Members with established pharmaceutical industries have an important role to play in making the procedure set out in the TRIPS amendment work effectively. Patent laws in exporting countries can help to achieve this by not imposing additional conditions on licensees and importing countries above those that are already imposed by the TRIPS amendment itself. For example, the TRIPS Agreement does not require either the importing or exporting Member to engage in commercial negotiations with the patent holder in circumstances where the importing Member is facing a national emergency or using the patent for a public, non-commercial purpose; for example, in order realize a government commitment to providing universal access to essential medicines.[69] Given that the importing Member may only be capable of paying a modest price for medicines manufactured under the compulsory licence, exporting countries may also consider offering tax incentives to encourage pharmaceutical manufacturers within their territory to participate in the scheme.[70]

Exhaustion of patent rights

National patent laws dealing with the exhaustion of patent rights may also influence the price and availability of essential medicines within that country. Exhaustion governs the "extent to which a [patent] holder can prevent the resale and importation of genuine goods", once they have been placed on the market with its consent in either the same or another country.[71] For example, national patent laws may be framed so that once a patent holder has exported a drug into a national market, or licensed its manufacture within that country and received compensation for doing so, the patent holder's intellectual property rights in that drug are taken to be exhausted (so-called international exhaustion). Patents legislation that permits the resale or import of medicines that have been legitimately placed on the market by or with the consent of the patent holder in another country stimulates competition and helps to keep prices low. Medicines imported into a country in these circumstances may be unauthorized, but will not be infringing any patent rights, since the patent holder has authorized their first sale.[72]

The practice of importing genuine products that have been placed on the market by the patent holder (or authorized licensee) in another country, without the permission of the patent holder, is known as "parallel importing". By engaging in parallel importing, the importing country seeks to avoid the need to purchase the drugs at a higher price within their own domestic market, or to

negotiate with the patent holder for a licence on commercial terms. The importation of genuine pharmaceuticals from another country without the permission of the patent holder does not breach the TRIPS Agreement, since TRIPS leaves WTO Members free to establish their own laws for the exhaustion of intellectual property rights.[73]

The principle of exhaustion can be implemented at the national, regional or global levels. For example, if the principle of international exhaustion applies within the domestic law of an importing country, the patent holder's rights will be exhausted after the first sale anywhere in the world. An importing country will therefore be able to import medicines lawfully placed on the market anywhere in the world without infringing the patent holder's rights.[74] By contrast, if a principle of domestic exhaustion, or, alternatively, regional exhaustion, is applied, the patent holder would only lose the right to object to the resale of medicines within that country, or within the region, respectively.

The practice of parallel importing may constitute an infringement of the patent within countries that have adopted a principle of national exhaustion. By contrast, countries that implement a principle of regional or international exhaustion within their national patent laws may be able to resist the efforts of the patent holder to segregate markets and to insulate them from the cheaper prices that may be achieved through parallel importation from countries outside the region, or from any other country, respectively. Even in circumstances where national patent legislation adopts the principle of international exhaustion, there may be other obstacles to the practice of parallel importation. For example, if the export of medicines by an international distributor would breach a term of the distributor's licence, the result may be that within the domestic law of the importing country, parallel importation is regarded as a violation of the rights of the patent holder.[75]

As **Box 15.10** illustrates, Kenya revised its intellectual property laws in 2001 to authorize the parallel importation of pharmaceuticals that were legitimately on the market in the exporting country. As confirmed by clause 37 of Kenya's Industrial Property Regulations (2002), this would not authorize the import and sale of pirated or stolen medicines that could not lawfully be sold in the country of export.[76] On the other hand, it confirms the principle of international exhaustion by permitting Kenya to import medicines from any country in which those medicines are lawfully available for sale.

Box 15.10: Legislation authorizing parallel imports: an example from Kenya

Industrial Property Act[77]

Section 53. (1) The applicant or the owner of the invention shall have the following rights:

(a) to be granted the patent, where the relevant requirements under this Act are fulfilled;

(b) after the grant of the patent and within the limits defined in section 58 to preclude any person from exploiting the patented invention in the manner referred to in section 53; and

(c) to conclude licence contracts as provided for in Part X of this Act, and subject to the obligations referred to in subsection (2). …

Section 58. (2) The rights under the patent shall not extend to acts in respect of articles which have

been put on the market in Kenya or in any other country or imported into Kenya.

…

(5) The rights under the patent shall be limited by the provisions on compulsory licences for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions.

(6) The rights of the patent shall not extend [to] variants or mutants of living forms or replicable living matter that is distinctively different from the original for which patents were obtained where such mutants or variants are deserving of separate patents.

Industrial Property Regulations[78]

Section 37. The limitation on the rights under a patent in section 58(2) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market.

Restrictions on incremental patents

The TRIPS Agreement requires WTO Members to grant patents for all products and processes "provided that they are new, involve an inventive step and are capable of industrial application".[79] Patent holders may seek patents for minor improvements or adjustments to a drug, such as another crystalline form, an alteration of the form of delivery, a dosage form, or for new uses of an existing drug (second medical indications). While some incremental innovations can bring important benefits to patients, some of these patents may simply serve to delay the entry of cheaper, generic versions into the marketplace. While incremental patenting (also called life-cycle management or "evergreening" – depending on the point of view) may increase the return on investment for the patent holder, it may also keep prices high. National governments seeking to ensure access to essential medicines at the lowest prices may consider amending their patent laws or the guidelines for patent examiners in order to restrict the award of patents to products that can truly be said to involve an inventive step and to be "novel", resisting pressure to permit patents for small alterations, or new therapeutic uses of existing chemical compounds (**Box 15.11**).

Box 15.11: Prohibiting patentability of minor adjustments to a pharmaceutical product in the Andean Community

Andean Community Decision: Common Intellectual Property Regime[80]

Article 21. Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

India's Patents Act provides an example of national legislation intended to restrict the practice of incremental patents.[81] India amended its national patent laws in 2005 to bring them into compliance with TRIPS. In *Novartis AG v Union of India*,[82] the Supreme Court of India explained the statutory

requirements that must be satisfied. The Patents Act provides for patents to be granted for "inventions". An invention must be:

- new;
- capable of industrial application; and
- must involve an inventive step that: (i) involves a technical advance over previous knowledge or has economic significance; and (ii) makes the invention not obvious to a person skilled in the art.[83]

However, under Indian law, not all innovations will fulfil the requirements for patentability. For example, the Act provides that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not an invention within the meaning of the Act.[84] The Act also states that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".[85]

Novartis AG had applied for a patent for imatinib mesylate salt in beta crystalline form (brand name: Glivec), a drug used in treatment of leukaemia and a number of other forms of cancer. In the Novartis case,[86] the Supreme Court of India explained that the bar for patentability is set higher for pharmaceuticals and chemical substances, since in addition to being an "invention", the medicine must pass the hurdle set out in section 3(d), which excludes from patent different chemical forms of the same substance. The court accepted that "all the pharmacological effects of imatinib mesylate in beta crystalline form are equally possessed by imatinib in free base form".[87] Although Indian legislation does not exclude patent protection for incremental inventions of pharmacological substances that "lead to an enhancement of therapeutic efficacy", there was no evidence before the court that the beta crystalline form of imatinib mesylate met this requirement.[88]

Regulatory review exception

Article 30 of the TRIPS Agreement permits Members to pass legislation creating limited exceptions to patent rights, provided that they do not "unreasonably conflict with a normal exploitation of the patent".[89] This exception is generally recognized to permit national legislation authorizing researchers to conduct research on (and in some cases, research carried out using) the patented invention.[90] For example, the Common Intellectual Property Regime of the Andean Community provides that the rights of the patent holder do not extend to "acts carried out exclusively for the purposes of teaching or scientific or academic research" (**Box 15.12**).

Box 15.12: Exemptions from patent infringement liability: examples from the Andean Community and Kenya

Andean Community Decision: common intellectual property regime[91]

Article 53. A patent owner may not exercise the right referred to in the previous article with respect to the following acts:

(a) acts carried out in a private circle and for non-commercial purposes;

(b) acts carried out exclusively to experiment with the subject matter of the patented invention;

(c) acts carried out exclusively for the purposes of teaching or scientific or academic research;

…

(e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.

Kenya: Industrial Property Act[92]

Section 58(1). The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.

Another common exception permits an applicant seeking marketing approval for a generic version of a drug (and any other parties producing the active ingredient within the medicine) to use the patent for the purposes of producing the drug and meeting regulatory requirements. For example, Canada's Patent Act[93] stipulates that:

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

In 2000, a WTO Panel confirmed that the regulatory review exception, as set out in Canada's legislation, is authorized by Article 30 of TRIPS.[94] This interpretation facilitates the more rapid introduction of cheaper, generic versions of a medicine into a national market after the brand name patent has expired. However, while the patent provisions of TRIPS may not prevent an applicant from seeking marketing approval for a generic version of a drug during the patent period, the capacity to obtain early approval for generics may also be affected by legal requirements protecting the exclusivity of test data, as explained below.

Protection of test data

Irrespective of whether a drug patent has expired, the capacity of generic drug manufacturers to manufacture a particular drug may also be affected by national laws regulating the protection of test data. The process of developing a pharmaceutical drug will involve the generation of a significant amount of test data relating to the efficacy and pharmacological effects of the drug. These data will be generated through clinical trials and other tests, and are a product of the efforts of the originating company.

Not all countries will have the capacity to independently evaluate the safety, quality and efficacy of pharmaceutical products submitted for marketing approval within a national market. Some countries may simply rely on the fact that marketing approval has been granted by the United States Food and Drug Administration, or by authorities in other countries. However, in cases where a country requires the submission of test data as a condition to granting marketing approval, the TRIPS

Agreement requires WTO Members to protect such data against disclosure, except where steps have been taken to "ensure that the data are protected against unfair commercial use".[95] The requirement to protect test data only arises in circumstances where: data have not previously been published and have been generated through considerable effort, where the country reviewing a pharmaceutical product requires the submission of test data as a condition of giving marketing approval, and where the product itself utilizes "new chemical entities".[96]

The TRIPS Agreement does not define what constitutes "unfair commercial use", nor is there authoritative WTO jurisprudence that settles this issue.[97] Intellectual property laws in many developed countries recognize a fixed period of data exclusivity that disentitles regulatory authorities from relying on test data for periods of between five and 10 years from the date on which the originator product obtained marketing approval. Since the protection of test data is a distinct category of intellectual property, data exclusivity may be protected under national law regardless of whether a valid patent exists in respect of the same product in the same national market.[98]

Where national laws grant data exclusivity protection to the holder of a pharmaceutical patent, regulatory authorities will not be entitled to rely on those data when considering subsequent applications for marketing approval for generic substitutes of the brand name drug.[99] As a result, an applicant seeking marketing approval for a generic may be obliged to "duplicate tests (often involving suffering of animals) in order to reach results that are already known".[100] Data exclusivity may also interfere with the issuing of a compulsory licence, "as the entry of the generic product would be delayed for the duration of the exclusivity period or for the time it takes to undertake a new compilation of test data".[101]

Policy-makers in developing countries have considerable flexibility to define what constitutes "unfair commercial use", and to ensure that any period of data exclusivity granted in legislation is appropriately balanced with the goal of ensuring a competitive market for the supply of essential medicines. For example, national laws may grant national authorities and courts the right to declare that the use by a generic manufacturer of a patent holder's test data does not constitute "unfair commercial use" in circumstances where the government is issuing a compulsory licence to ensure wider access to essential medicines at affordable prices under a national drugs policy. To the extent that national courts and authorities give a wide interpretation to the exceptions recognized in data exclusivity provisions, they will facilitate faster access to essential medicines as soon as the patent expires, and support the efforts of national governments to realize this aspect of the right to health.[102]

(d) Voluntary licence agreements for essential medicines

Pharmaceutical companies that hold patents or other intellectual property rights over essential medicines can decide when and how to exercise their exclusive rights and as a result may choose to enter into voluntary licences with third parties, such as generic producers, to produce, market and distribute a particular drug within a specified territory. Where the licence is non-exclusive and foresees moderate royalties or is royalty-free, the licence may encourage competition between generic producers to supply the market within the authorized territory, thereby reducing the market

price.[103] Voluntary licences have been widely used by companies producing HIV medicines,[104] and could have a significant impact on the global epidemic of hepatitis C.[105] To avoid legal disputes, it is important for the voluntary licence to clearly set out the actions that licensees are permitted to take, and the territories to which the licence extends.

Voluntary licences are part of a broader set of strategies that pharmaceutical companies can use, as part of their corporate social responsibility or humanitarian programmes, to increase access to essential medicines at affordable prices. Other strategies include tiered pricing, donation of drugs, non-filing of patents in least developed countries, and non-enforcement of patents.[106] The originator company or rights owner may formalize their decision not to enforce patent rights by making a non-assert declaration, or by entering into a non-assertion covenant or immunity-from-suit agreement that sets out the conditions under which the rights owner will not enforce their patent rights.

The Medicines Patent Pool (MPP),[107] established by the International Drug Purchase Facility (UNITAID) in 2006,[108] negotiates licence agreements with patent owners and enters into sub-licensing agreements with generic companies to produce licensed drugs and drug combinations for low- and middle-income countries. For example, in 2015, AbbVie entered into an agreement with MPP to grant non-exclusive, royalty-free sub-licences for the manufacture and sale of lopinavir and/or ritonavir (LPV/r), two second-line HIV drugs, for prevention and treatment of HIV within (all) African countries.[109] This licence agreement requires sub-licensees to demonstrate their capacity to manufacture these compounds in a manner consistent with WHO prequalification standards,[110] to agree not to divert them outside African countries where this would infringe an existing AbbVie patent, and to cooperate in pharmacovigilence reporting responsibilities. In 2015 the MPP was expanded to include drugs for tuberculosis and hepatitis. The first licence issued for declatasvir, a hepatitis C drug, covers 112 countries.[111]

There are a number of variables within licensing agreements that may help to increase competition and to reduce the market price for essential medicines. For example, royalty-free, non-exclusive licences – which include a large number of countries within the licensed territory, permit sale to both the public and private sector, and permit licensees to source active pharmaceutical ingredients from anywhere in the world – are more likely to encourage robust competition and the economies of scale that are needed to substantially reduce prices. Other variables that support access include the publication of licence agreements, permitting licensees to supply countries that issue compulsory licenses in accordance with TRIPS flexibilities, and not restricting the rights of licensees to challenge the licensor's patent or to market the drug in countries where it is not under patent.[112] Where the originator company permits the licensee to rely on its pharmaceutical data, this may speed up the process of obtaining marketing approval for the drug in countries where data exclusivity provisions apply. Originator companies may also contribute to local capacity in the manufacture and distribution of essential medicines by including technology transfer components within the licence.[113] For example, the originator company may offer support to the licensee in meeting quality standards for manufacturing, packaging and storage, as well as registration requirements applicable within the authorized countries. Conversely, generic companies may also contribute expertise to the partnership with the originator company through their knowledge of registration processes and supply chain management within the authorized countries.[114]

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Chapter 16: Legal responses to poor nutrition: undernutrition, overweight and obesity

SUMMARY POINTS

· **The human right to food, as recognized in the International Covenant on Economic, Social and Cultural Rights encompasses a right to be free from hunger, and to have an adequate supply of safe and nutritious food.**

· **Many low- and middle-income countries are moving towards a "Western diet" that is higher in fats, sugars, refined carbohydrates, meat and animal products, but poorer in vegetables, legumes and coarse grains. Obesity and diet-related risk factors are contributing to the rapid rise of diabetes and other noncommunicable diseases, including in countries that continue to face a substantial burden from infectious diseases and undernutrition.**

· **Legal and regulatory policies for reducing diet-related disease cover three main policy domains: the food environment (including the retail food environment), the food production system (including regulation of the food supply chain and the nutritional content of food), and consumer behaviour.**

· **Improvements in agricultural and fiscal policies can benefit health; for example, by abolishing subsidies on sugar and other sweeteners, or by focusing investment away from the manufacture and export of oils that are high in saturated fats.**

· **Food companies use a wide variety of sophisticated advertising and promotional techniques to manipulate and shape children's food preferences. A number of countries have implemented legal controls on food advertising and promotion in order to protect children from excessive exposure to advertising and promotion of energy-dense but nutrient-poor foods, including through the media.**

· **WHO has recommended that settings where children gather (including schools, pre-schools, and playgrounds) should be free from "all forms of marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt". Governments can improve the school food environment by directly restricting the advertising and promotion of unhealthy foods in schools, and ensuring that all food sold or made available on school grounds during the school day is safe to eat and meets minimum nutritional criteria.**

· **Food labelling, including nutritional information panels, front-of-pack interpretive labelling schemes, warning labels and suitably regulated health claims, may assist consumers to choose more nutritious foods. Countries may also consider extending interpretive nutrition labelling to restaurants and food stalls.**

· **Imposing non-trivial taxes on sugar-sweetened beverages and on foods that are high in salt, saturated fat, and/or added sugar is a potential strategy for raising the prices of these products in order to reduce consumption. Quite apart from their observed impact on consumption, food and beverage taxes may encourage product reformulation by manufacturers, resulting in healthier products that can compete more effectively on price.**

· **Food and beverage taxes may also provide an additional revenue stream for governments to**

invest in health.

· **Governments may consider sales bans or mandatory food standards where there is a clear case for eliminating harmful substances from the food supply (e.g. trans-fat). Mandatory standards may also be considered appropriate where voluntary or co-regulatory processes for food reformulation are moving too slowly or have proved ineffective in meeting national nutritional goals and targets; for example, in reducing population salt intake.**

· **Governments may also adopt regulations or mandatory standards in order to implement food fortification programmes to improve micronutrient deficiencies. Examples include universal iodization of salt, and mandatory fortification of wheat flour with iron, folic acid, and/or zinc.**

· **There are many ways that law can support a healthy food and physical activity environment, including through the use of zoning and planning controls, and incentives for the establishment of stores and stalls selling healthy and fresh food.**

· **Undernutrition remains a major problem in many countries, particularly developing countries. Legal recognition of the right to adequate food and nutritional security provides the basis for holding governments accountable for policies to address hunger and micronutrient deficiencies. In some countries, this right may be enforced through national courts.**

· **As illustrated by Brazil's Bolsa Família, a cash transfer paid to the female head of household may be an effective strategy for increasing food security, and providing a flexible safety net for other needs.**

Introduction

The right to food is a human right recognized in the International Covenant on Economic, Social and Cultural Rights (ICESCR),[1] the Convention on the Rights of the Child,[2] and a number of other human rights instruments. The right to food in the ICESCR encompasses the right to be free from hunger, as well as the right of everyone to access adequate, safe and nutritious food.[3] Discharging these obligations is one of the core obligations owed by States under the right to health.[4]

Diets in low- and middle-income countries are changing rapidly. Countries that have traditionally faced problems with undernutrition and infectious diseases are now also facing a rapid upsurge in obesity and dietary risk factors, leading to diabetes and other noncommunicable diseases.[5] In 2010, dietary risk factors, combined with lack of physical activity, were responsible for 10% of the global burden of disease, and 12.5 million deaths.[6] There are many factors that are thought to be contributing to changing dietary patterns and to the burden of diet-related disease.[7] These include:

- rising incomes due to economic development (leading to diets richer in sugar and fats, and access to labour-saving technology, including motor vehicles);
- urbanization (resulting in greater access to a wider range of processed foods, greater exposure to food advertising, and reduced levels of physical activity);
- trade liberalization policies (leading to expanded international trade in food products including, for example, imports of low-quality, fatty meat products);[8]

- developments in food technology (leading to the cheap production of vegetable oils and caloric sweeteners);
- foreign direct investment in national food systems (supermarkets replacing local markets); and
- the advertising of processed, ready-made foods that are high in salt, sugar and saturated fat.[9]

These developments have hastened the convergence towards a "Western diet" that is higher in fats, sugars, refined carbohydrates, meat and animal products, but poorer in vegetables, legumes and coarse grains.

In 2013, the World Health Assembly adopted a set of voluntary global noncommunicable disease (NCD) targets, to be met by 2025, as part of the global monitoring framework on the prevention and control of NCDs.[10] These targets include a 0% increase in obesity and diabetes, a 30% relative reduction in population salt intake, and either a 25% relative reduction in the prevalence of raised blood pressure or containing the prevalence of raised blood pressure, according to national circumstances (see Section 12.1(a)).[11] Reducing salt intake, replacing trans-fats with unsaturated fats in food, and public education campaigns on diet and physical activity have also been identified as very cost-effective priorities for governments.[12]

Some scholars have emphasized the contribution that large food companies can make to reducing diet-related disease through public–private partnerships and voluntary actions; for example, by reformulating products and shifting advertising expenditure towards healthier products.[13] Others, however, have pointed to the food industry's role in undermining and weakening public health policies and programmes, and to the absence of evidence that voluntary actions are effective in achieving significant reductions in obesity or in diet-related risk factors.[14] Some have pointed to similarities between the behaviour of tobacco companies and that of food and beverage companies, arguing that the latter are vectors for the spread of dietary risk factors for NCDs.[15] Many scholars would agree that there is a need for greater accountability by the food industry for its policies and practices, and that law is an important tool for responding to diet-related disease.[16]

16.1 Food policy domains

Legal and regulatory policies for reducing diet-related disease can be categorized in a variety of ways.[17] Governments can adopt laws that seek to improve nutrition and to reduce obesity by creating healthier food environments that offer easier access to healthy foods at affordable prices. Secondly, they can impose standards to specify or improve the nutritional content of food itself, and to regulate the food supply chain and the systems responsible for production and distribution of food. Thirdly, governments can pass laws that seek to assist consumers to make healthier choices. This categorization draws attention to three overlapping policy domains:

- the food environment, including the food retail environment;

- the food production system, including the food supply chain and food content regulation; and
- consumer behaviour.

These domains by no means exhaust the range of legislative actions that governments may take in support of obesity prevention and better nutrition. For example, governments have used legislation to establish health promotion agencies, prevention councils and other processes to better coordinate government efforts to improve food and physical activity environments. Spain's law on food safety and nutrition commits the government to establishing an intersectoral strategy on nutrition, physical activity and prevention of obesity, to be reviewed every five years, and also prohibits discrimination on grounds of overweight or obesity.[18]

Laws that shape the broader environment in order to encourage healthier lifestyles and access to healthy and affordable food cover a broad area. They include nutrition support programmes for low-income and disadvantaged groups, laws imposing nutritional requirements on foods sold or made available in schools, zoning and licensing controls affecting retail food businesses, and efforts to create walk-able, more physically active neighbourhoods through investment in infrastructure. Laws that target the food production system include laws removing agricultural subsidies for the production of cheap fats and sweeteners (including sugar and high-fructose corn syrup),[19] and laws restricting or banning the sale of foods containing harmful ingredients (e.g. trans-fats).[20] For example, in its 2014 budget, Malaysia abolished its subsidy on sugar, removing a costly source of government expenditure that also contributes to over-consumption of sugar-sweetened products.[21] Laws encouraging healthier choices by consumers include labelling laws that require food manufacturers to list the ingredients of food products and their nutritional value on food packages, tax rebates for the purchase of exercise or fitness equipment, controls on the kind of health claims that can be made in relation to food, and laws restricting the advertising of certain foods, particularly to children.

The WHO Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 recognizes that a range of policy changes will be required, across a number of government sectors, in order to make progress.[22] Laws and regulations do not exist in isolation, but should be included, where appropriate, as part of broader strategies to promote the benefits of a healthy diet, to reduce poverty, to increase food security, and to ensure an environmentally sustainable diet. The following sections give examples of legal and regulatory actions that governments might consider, acknowledging that the context and exact form of these interventions may vary substantially between countries.

16.2 Economic instruments

The WHO Global Strategy on Diet, Physical Activity, and Health recognizes that fiscal policies, including taxes and subsidies, can play a role in fighting obesity and poor nutrition.[23] Imposing non-trivial taxes on sugar-sweetened beverages, and on foods that are high in saturated fat, added salt and/or added sugar, is a potential strategy for raising the prices of these products in order to reduce consumption.[24] Quite apart from their observed impact on consumption, tax increases may also

encourage food reformulation by manufacturers, resulting in healthier products that can compete more effectively on price. Since taxes are unlikely to cause consumers to avoid the taxed foods entirely, taxes may also generate additional revenues for government, and possibly fund social welfare programmes giving low-income groups better access to healthier foods.

Food and beverage taxes need to be designed carefully. Assuming that the tax is entirely passed on to the consumer, the overall health effects of the tax will depend, firstly, on how the price increases that result from the tax alter levels of consumption of the affected foods. To achieve a beneficial health effect, governments need to adopt a tax rate that is high enough to change consumption patterns, and to target the tax effectively so that it applies to the appropriate category of unhealthy foods, or alternatively, to over-consumed ingredients or nutrients. Given the persistence of demand for certain foods despite a higher price (inelasticity of demand), one review suggests that food taxes need to be substantial (at least 20%) in order to have a significant health impact.[25]

The health impact of a tax will also be affected by the substitution effects of the tax (for example, whether there are cheaper and healthier products that can be substituted for the taxed product), and by income effects (for example, whether price increases for more highly taxed products mean that consumers have less income to purchase healthy food).[26] Since those with lower incomes are likely to be most sensitive to price increases that result from the tax,[27] governments should carefully consider the nutritional consequences of food substitution resulting from the tax,[28] especially in settings where over- and under-nutrition coexist.[29] In October 2011, Denmark introduced a tax on foods containing more than 2.3% saturated fat, although it was repealed a year later due to concerns about administration costs, its impact on employment, and concerns that consumers were avoiding the tax altogether by making shopping trips to Germany and Sweden.[30] In 2013, Tonga – which has an obesity rate of nearly 60%[31] – introduced an excise tax of 50 cents per litre for sugar-sweetened beverages, and T$ 1 per kilogram for a range of animal fats, in order to discourage consumption of fatty meat, including mutton flaps and turkey tails.[32]

Sugar-sweetened beverages (SSBs) have been suggested as an appropriate candidate for taxation, since they have no nutritional benefits, are a major source of calories in many countries and are associated with weight gain and diabetes,[33] and since people do not compensate for the calories they consume from sweetened beverages by reducing their intake of other foods.[34] One study estimates that 184 000 deaths per year are attributable to consumption of SSBs, due to diabetes, cardiovascular disease and cancer.[35] In January 2014, Mexico introduced a tax of one peso per litre (about 10%) on SSBs.[36] During that year, the rate of reduction in consumption of SSBs increased, reaching 12% on average, and 17% among the lowest socioeconomic group.[37]

Evidence suggests that demand for SSBs is highly elastic. For example, the pooled price elasticity from one meta-analysis of nine studies suggested that a 10% increase in the price of SSBs could result in a reduction in consumption of around 13%.[38] The authors of this study also conclude that taxes on SSBs may result in modest reductions in obesity within the population.[39] Scholars have pointed out that a tax on the added sugar content on SSBs, regularly indexed, would prevent substitution in favour of other products with high sugar that were not taxed, and also provide an incentive for manufacturers to reduce the added sugar in SSBs.[40] By reducing sugar intake, a tax on SSBs may also improve dental health, particularly in children.[41]

In addition to taxing over-consumed foods or nutrients, governments may consider subsidizing less energy-dense foods, such as fresh fruit and vegetables, especially among low-income groups.[42] Governments can support the price and availability of healthier foods in a variety of ways, including through production subsidies, quotas, payments to reduce the retail price of fruit and vegetables, or by providing cash vouchers directly to eligible low-income and disadvantaged recipients.[43] Indonesia transitioned from a fiscally unsustainable universal rice subsidy to targeting low-income individuals with ration cards in 1997, reaching 85% of eligible persons within a year.[44] Governments may consider production subsidies where market prices are too low to encourage sufficient production, or in order to encourage the fortification of foods with essential micronutrients. These may take a variety of forms, including tax exemptions, import preferences, assistance with start-up, and training.[45] Governments can also reduce tariffs on healthy foods, which may be administratively simpler and align with trade liberalization priorities.[46]

To achieve their intended effect, food subsidies should be targeted appropriately, avoiding foods with minor health benefits and foods that exacerbate existing dietary imbalances such as the over-consumption of saturated fats and caloric sweeteners. Food subsidies are unlikely to be sustainable if spread across too many food products, and their impact on the target (poor) population group should be carefully monitored.[47]

16.3 Food advertising controls

Laws that restrict the advertising and promotion of foods that are high in saturated fat, salt or added sugar – particularly to children – may be an effective way of moderating demand for foods that are over-consumed, and which contribute little to a healthy diet.[48] One model predicts that eliminating food marketing targeting children in the United States might have prevented obesity in up to one third of obese children.[49] In the United Kingdom, restrictions on food advertising to children were implemented in 2005 as part of a co-regulatory approach to advertising regulation (see **Box 2.1**). Between 2005 and 2009, this resulted in a 37% decline in advertisements aimed at children for products high in fat, salt, or sugar (see **Box 16.1**).[50]

Box 16.1: Restricting food advertisements that target children: the Code of Broadcast Advertising, United Kingdom

In the United Kingdom, broadcast advertising is regulated by the UK Code of Broadcast Advertising (BCAP Code),[51] which was written and is reviewed by an industry body, the Broadcast Committee of Advertising Practice (BCAP) under delegation from Ofcom, the government telecommunications regulator. The BCAP Code, revised in 2010, includes a ban on the advertising of high fat, high salt or high sugar foods to children:

Section 32.5. These products may not be advertised in or adjacent to programmes commissioned for, principally directed at, or likely to appeal particularly to audiences below the age of 16:

Section 32.5.1 food or drink products that are assessed as high in fat, salt or sugar (HFSS) in accordance with the nutrient profiling scheme published by the Food Standards Agency (FSA) on 6 December 2005.

In Quebec, commercial advertising directed at persons under 13 years of age has been banned since 1980.[52] The ban covers all advertising – including food advertising – and applies to both electronic and print media.[53] The legislation specifies criteria to be used in determining whether an advertisement is directed at persons under 13 years, including the nature and intended purpose of the goods advertised, the manner of presentation, and the time and place the advertisement is shown.[54] According to one study, the ban resulted in a reduction of US$ 88 million spent on fast food during 2010, and a reduction of 13.4–18.4 billion fast food calories consumed by French-speaking households.[55]

For broadcast media, scholars have pointed out that if the purpose of regulation is to reduce children's overall exposure to unhealthy food advertising, this is more likely to be achieved by using the time of day as the basis for defining the obligations of advertisers. Since large numbers of children watch television programs that are primarily intended for older audiences, restrictions that apply to children's programming alone may have limited impact.[56]

Food companies use a wide variety of sophisticated advertising and promotional techniques to manipulate children's food preferences and to attract them to unhealthy foods, including through television, websites, and mobile electronic communications, product placement, sponsorship, point-of-purchase displays, competitions and prizes, and by including toys and other incentive items in restaurant meals.[57] In some countries, unhealthy food is systematically promoted and sold in schools.[58]

In the Republic of Korea, the Special Act on Safety Control of Children's Dietary Life, introduced in 2009, prohibits the advertising of free, non-food items such as toys, in the course of an advertisement for "children's preferred foods" (as defined in the enforcement decree).[59] These preferred foods cover a range of processed and prepared foods including confectionary, bakery foods, chocolates, ice-cream, noodles, hamburgers, pizza and deep-fried foods.[60] The Special Act, as amended, also empowers the Minister for Food and Drug Safety to limit the advertising time or to prohibit the advertising of high-calorie, nutrient-poor foods.[61]

In Chile, a Presidential decree issued in 2015 (which implements a national law passed in 2012[62]) prohibits food advertising directed at children aged less than 14 years where the food exceeds specified limits for energy, sodium, sugar or saturated fat.[63] The decree defines advertising directed at children with reference to the use of characters and figures, cartoons, toys, games, music and animals attracting the interest of children, as well as children's language and expressions and the depiction of children's daily life. The ban applies to broadcast programmes and websites where more than 20% of the audience is under 14 years of age, and extends to advertising before, during or after the broadcast of programmes or web content. It also extends to interactive games. In addition to the ban on advertising of foods that fail to meet the nutritional limits, the decree prohibits the use of accompanying promotional strategies directed at children under 14 years, including free offers, toys and stickers. These advertising controls also apply within pre-schools, primary and secondary schools.[64]

WHO has produced recommendations on the marketing of food and non-alcoholic beverages to children,[65] and a framework to assist countries to implement these recommendations.[66] The recommendations state that settings where children gather should be free from "all forms of

marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt".[67] These settings include schools, pre-schools, playgrounds, family and child clinics and paediatric services, and during sporting and cultural events. Since both in-flowing and out-flowing cross-border marketing can undermine national controls on food marketing to children, WHO has recommended that Member States reach agreement on minimum standards for marketing having cross-border effects, in order to "achieve the highest possible impact of any national policy".[68]

16.4 Nutrition labelling laws

Food labelling laws can support healthier food choices by informing consumers of the ingredients of food products, by presenting basic nutritional information about the food in a readable format, and by ensuring the accuracy of nutrient claims about the food.[69] Labelling requirements should be uniform and sufficiently detailed to prevent confusion among consumers.[70] For example, the European Union's food labelling law, revised in 2011, requires a mandatory nutrition declaration on most packaged foods that are sold commercially, with certain exemptions.[71] The regulation sets out the nutrition information that must appear in the nutrition panel, including the energy value of the food, and the amounts of fat, saturated fat, carbohydrate, sugars, protein and salt it contains.[72] Very similar requirements are imposed by the Food Standards Code, which applies within Australia and New Zealand (**Box 16.2**).[73]

It is preferable for regulations to require manufacturers to list the nutrients in a standardized unit or quantity of the food (for example, grams of fat per 100g), rather than allow the manufacturer to list the amounts of nutrients in a serving size of their own choice. Standardized quantities enable consumers to make comparisons between foods based on nutrient amounts, and to choose products containing lower levels of over-consumed nutrients. The European Union law confirms that the mandatory nutrition declaration should refer to 100g or 100ml amounts, while allowing additional, portion-based declarations as appropriate.[74]

Box 16.2: Labelling requirements for packaged food: the Australia New Zealand Food Standards Code[75]

Standard 1.2.8 – Nutrition Information Requirements

Section 1.2.8-6 What must be on a nutrition information panel

(1) A nutrition information panel must include the following information:

(a) the number of servings in the package, expressed as either

(i) the number of servings of the food; or

(ii) if the weight of the volume of the food as packaged is variable – the number of servings of the food per kilogram, or other unit as appropriate;

(b) the average quantity of the food in a serving expressed in:

(i) for a solid or semi-solid food – grams; or

(ii) for a beverage or other liquid food – millilitres;

(c) the unit quantity of the food

(d) for a serving of the food and a unit quantity of the food:

(i) the average energy content expressed in kilojoules or both in kilojoules and in calories or kilocalories; and

(ii) the average quantity of:

(A) protein, carbohydrate, sugars, fat, and

(B) subject to subsection (4), saturated fatty acids, expressed in grams; and

(iii) the average quantity of sodium, expressed in milligrams or both milligrams and millimoles; and

(iv) the name and the average quantity of any other nutrient or biologically active substance in respect of which a nutrition claim is made, expressed in grams, milligrams, micrograms and other units as appropriate…

(2) A nutrition information panel must be set out in the format in section S12-2, unless this Code provides otherwise.

(a) Front-of-pack nutrition labelling

Nutrition labels on the front of a food package are a highly visible way of informing consumers of the nutritional characteristics of food products, and assisting them to make healthy choices rapidly. For example, European Union law recognizes the potential benefits of repeating the most important elements of the nutrition declaration "in the principal field of vision" (the front of the pack).[76] The "traffic light" food labelling system, originally developed by the Food Standards Agency in the United Kingdom, uses colour-coded labels to indicate whether foods have low, medium or high levels of sodium, saturated fat and added sugars.[77] Food labelling systems like the "traffic light" system are known as "interpretive" systems, since they interpret the nutritional characteristics of the food. This allows consumers to compare different foods and to make healthier choices, while also creating incentives for food and snack manufacturers to reduce unnecessary levels of salt, saturated fat and added sugars in their products.[78] In 2011, the Republic of Korea became the first Asian country to introduce voluntary traffic light labelling for "children's preferred foods".[79]

Apart from traffic lights, other interpretive front-of-pack nutrition labelling systems that may assist consumers to choose healthier foods include "star rating" systems that award stars to food, based on an overall assessment of its nutritional content.[80] In the United States, the Institute of Medicine has advocated a system that awards zero to three nutritional points to food, based on the level of saturated and trans-fat, sodium and added sugars. However, nutritional points are only awarded where the food does not exceed a threshold limit for these nutrients.[81]

(b) Nutrition warning labels

In Finland, salt labelling legislation was introduced in 1993 to support national efforts to reduce population salt intake. High salt and low salt limits were set for a basic range of foods that are major sources of dietary salt in Finland. Relevant foods that exceed the upper limit, based on the percentage of salt in the fresh weight of the product, must carry a "high salt content" label.[82] Manufacturers are also permitted to label foods as "reduced salt" if the salt percentage falls below the low salt limit. For example, breads with salt levels exceeding 1.3% must be labelled as high salt, but may be labelled as low salt if they do not exceed 0.7%. The "high salt" labelling requirement encouraged manufacturers to reformulate their products; as a result, a variety of high salt products disappeared from the market.[83]

In some countries, lawmakers have debated the introduction of mandatory health warnings on sugary drinks, and other products that are nutritionally poor or which contribute nothing to a healthy diet.[84] In Chile, a Presidential decree requires packaged food products that exceed limits set per 100 g/100 ml for energy, sodium, sugar or saturated fat, respectively, to be prominently labelled as "high in" each of the relevant nutrients. The decree contains detailed requirements for the size and placement of these warnings. The cut-off points that trigger the warnings are to be implemented incrementally with annual reductions over a three-year period.[85]

(c) Preventing misleading and deceptive health claims

In order to prevent misleading and deceptive health claims, national governments may consider introducing laws that only permit manufacturers and advertisers to make health claims about foods that satisfy minimum criteria for good nutrition. This would prevent food manufacturers from advertising that a product that was high in added sugars, saturated fats or salt was healthy merely because it contained added vitamins. Indonesia has introduced legislation that permits nutrition claims, health claims and glycaemic index claims to be made about processed foods, but restricts these claims to foods that do not exceed limits for total fat, saturated fat, cholesterol and sodium.[86]

The International Code of Marketing of Breast-milk Substitutes also contains provisions designed to prevent misleading and deceptive practices by manufacturers and distributors of infant formula and breast-milk substitutes. The Code states that infant formula should contain a clear statement of the superiority of breastfeeding, and a statement that the product should only be used following advice from a health worker. The container and labels should not contain pictures of infants, or include pictures or text that "may idealize the use of infant formula".[87]

(d) Menu labelling

In countries where chain restaurants are common, and where an increasing proportion of meals are eaten outside the home, nutrition labelling laws can be extended beyond pre-packaged foods to the standard menu items sold in chain restaurants.[88] In the United States, federal law requires calorie counts to be shown beside standard food items that appear on the menu for at least 60 days per year in retail food chains with 20 or more locations.[89] Consumers routinely underestimate the number of calories in food items, particularly as portion sizes increase.[90] Restaurant labelling laws

requiring disclosure of calories, and potentially other nutrients, including saturated fat, trans-fat and salt, could serve dual purposes, assisting consumers to make healthier choices, while increasing the incentives for food manufacturers to improve the nutritional quality of products on the menu.[91]

Other options for identifying healthier foods include Singapore's "Healthier Choice" logo, administered by the Health Promotion Board, which enables manufacturers to obtain a renewable two-year licence to use the logo on their products if they meet nutritional guidelines set for over 60 food categories.[92] Singapore's approach has enabled the Board to update the nutritional criteria over time, and to permit different health claims to be made in conjunction with the logo, such as "lower in sodium", and "lower in saturated fat".[93] The Board has adapted the healthier choice symbol to healthier snacks, healthier ingredients and healthier hawker food. Under the Board's healthier dining programme, grants are also available to restaurants to expand their healthier menu options.[94]

16.5 The school environment

Governments and school authorities can use a variety of legal tools to ensure that healthier foods are sold or made available on school premises. For example, governments that subsidize school meals can impose conditions on their provision of financial support, requiring schools and educational authorities to ensure that school food complies with criteria on safety and good nutrition. The use of conditional grants is a powerful strategy in countries where there is fiscal inequality between national and regional governments, and where regional governments are responsible for the provision of services but rely on grants from national governments to supplement their budgets. School authorities – including government, private sector and not-for-profit entities – can also use their contracting powers to ensure that food businesses that are permitted to sell foods and beverages on school premises, or to supply snacks and meals to schools, meet nutritional standards. Governments can also mandate that education on nutrition is included in the school curriculum in order to lay a foundation for health literacy in later life.

In many countries, school lunch programmes provide an important opportunity for children to receive sufficient nutrients, particularly children from poor and disadvantaged backgrounds. For example, in the United States, the Department of Agriculture oversees a national school meal programme that provides low-cost or free breakfasts, lunches and afterschool snacks to children from low-income families.[95] Federal food assistance programmes for schools, and for low-income families, are periodically re-authorized by Congress.[96] Under the Healthy, Hunger-free Kids Act of 2010, schools that provide meals that comply with updated nutritional guidelines became eligible to receive additional reimbursement.[97] The Act also required that all other food sold on the school campus, outside the school meal programmes, must comply with national dietary guidelines.[98] Legislatures in some states have also imposed minimum nutritional criteria for all food sold in schools. For example, in 2005, the State of Kentucky restricted the sale of fast foods in school cafeterias to once per week, and introduced minimum nutritional standards for all foods and beverages available on public school campuses during the school day (**Box 16.3**). In the same year, France banned all vending machines selling snacks and drinks in schools.[99]

Box 16.3: Laws regulating the sale of snacks and drinks in schools: examples from the State of Kentucky, United States

Conduct of Schools – Special Programs[100]

Section 158.850 Limitation on sale of retail fast foods in school cafeteria.

[E]ach school shall limit access to no more than one (1) day each week to retail fast foods in the cafeteria, whether sold by contract, commercial vendor, or otherwise.

Administrative Regulations[101]

Minimum nutritional standards for foods and beverages available on public school campuses during the school day; required nutrition...

Section 1. Beverages... a beverage offered for sale through a vending machine, school store, canteen, or fundraiser on school property shall:

(1) Be a:

(a) Fluid unflavored or flavored milk that is no more than one (1) per cent milk fat;

(b) Plain or flavored, non-caloric, noncarbonated water;

(c) 100% fruit or vegetable juice or any combination of both totaling 100%; or

(d) Any other beverage that contains no more than ten (10) grams of sugar per serving, except this limit shall not apply to 100% fruit or vegetable juice or any combination of both equaling 100%; and

(2) (a) ... not exceed a volume size of seventeen (17) ounces, except for plain or flavored, non-caloric, noncarbonated water

Section 2. Food ... a food item offered for sale through a vending machine, school store, canteen, or fundraiser on school property shall meet the requirements established in this section.

(1) Calories from fat shall not exceed thirty (30) per cent, excluding reduced fat (two (2) per cent milk-fat or less), cheese, nuts, seeds, and nut butters.

(2) Calories from saturated fat shall not exceed ten (10) per cent.

(3) Calories from sugar shall not exceed thirty-two (32) per cent by weight….

(b) The grams of sugar shall not exceed fourteen (14) grams.

(c) The limit established in this section shall not apply to fresh, frozen, canned, or dried fruits and vegetables.

(4) (a) Chips, cereals, crackers, baked goods, and other snack items shall not contain more than 300 milligrams of sodium per serving.

(b) Pastas, meats, and soups shall not contain more than 450 milligrams of sodium per serving.

(c) pizza, sandwiches, and main dishes shall not contain more than 600 milligrams of sodium per serving.

(5) The portion or pack size for chips, crackers, popcorn, cereal, trail mix, nuts, seeds, or jerky shall not exceed two (2) ounces.

(6) The portion or pack size for cookies shall not exceed one (1) ounce.

(7) The portion or pack size for cereal bars, granola bars, pastries, muffins, doughnuts, bagels, or other bakery-type items shall not exceed two (2) ounces.

(8) The portion or pack size for non-frozen yogurt shall not exceed eight (8) ounces.

(9) The portion or pack size for frozen dessert items... shall not exceed four (4) ounces.

In Costa Rica, the Ministries of Health and Education proposed regulations, issued in 2012, which restrict the use of added sugars, oil, butter, margarine, cream, mayonnaise and cream cheese in food prepared in school cafeterias. Deep-frying of foods, and foods containing trans-fatty acids, are prohibited.[102] The same decree also prohibits the sale or distribution of pre-packaged foods and drinks that exceed limits for fat, saturated fat, sodium, sugar and energy. The sale of energy drinks, and carbonated drinks (including "light" and "diet" drinks) is not permitted. All foods sold must have labels that indicate their nutritional content.[103] These regulations, which are mandatory for all public schools, and recommended for private schools, were implemented incrementally over a period of three years, in order to permit manufacturers to reformulate their products.[104]

School authorities should carefully consider the potential risks of accepting payments from food and beverage manufacturers in return for the exclusive right to market brand-name foods within schools.[105] Pre-packaged food may be high in sugar, salt and saturated fat, and advertising in schools affects student choices not only in the cafeteria but also outside school hours, often resulting in increased consumption of sugar and fats.[106] As noted previously, WHO has recommended that schools, pre-schools, playgrounds and other settings where children gather should be free from "all forms of marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt".[107]

In the Republic of Korea, the Special Act on Safety Control of Children's Dietary Life introduced a number of innovative controls to improve children's nutrition and to prevent obesity. For example, the Act authorized the head of each self-governing city or local government to designate areas within 200 metres of schools as "green food zones".[108] Local governments are authorized to appoint managers to assist local food stores within the green zone to improve the nutritional quality of the foods they make available for sale to children.[109] Local food businesses that comply with minimum nutrition standards that apply to a range of children's preferred foods may apply for designation as exemplary stores.[110] Children's preferred foods that do not comply with these criteria may not be sold in schools or in the designated stores.[111] The creation of green food zones around schools is one example of how the regulation of the built environment may support improvements in nutrition (see Section 16.7, below).[112] The Special Act also authorized the head of self-governing local districts to establish centres to support the safety and nutritional quality of meals provided by children's meal services to nurseries, kindergartens and schools.[113]

16.6 Mandatory food standards, and restrictions on sale

In some countries, governments have used sales bans and other legal restrictions to support national nutritional objectives. For example, between 1987 and 1992, Mauritius imposed restrictions on the amount of palm oil in the cooking oil ("ration oil") commonly used in that country, replacing it with soya bean oil. This substitution led to a reduction in the saturated fat content of ration oil, resulting in an average 15% reduction in cholesterol among adults over this five-year period.[114] Similarly, Ghana has implemented a food standard which prevents the import or sale of fatty cuts of meat that exceed the prescribed percentage of fat: poultry (15%), beef (25%), mutton (30%), and pork (25%).[115]

This section considers mandatory food standards in three areas. Firstly, sales bans and mandatory standards that apply to food manufacturers and retailers may be an appropriate strategy where there is a clear case for eliminating a harmful substance from the food supply.[116] Conversely, governments may use mandatory fortification laws to require nutrients to be added to food, in an attempt to reduce micronutrient deficiencies in the population. Thirdly, governments may introduce regulatory measures to reduce consumption of over-consumed nutrients in the population, in circumstances where the regulatory goal is moderation, rather than elimination. For example, governments may consider mandatory standards where voluntary or co-regulatory processes for food reformulation have proved ineffective in meeting national nutritional goals; for example, in reducing average consumption of salt.[117]

(a) Eliminating harmful substances from the food supply: trans-fats

In some cases, substances contained in or added to food may cause such harm that governments may seek to eliminate them from the food supply, as distinct from warning consumers of their presence through mandatory labelling requirements. WHO has identified the elimination and replacement of trans-fats with unsaturated fats as a cost-effective priority for reducing cardiovascular diseases, diabetes, and other conditions associated with trans-fat intake.[118] Bans on the use of industrially produced, partially hydrogenated vegetable oils in food are the most effective way to achieve this, since they are likely to lead to product reformulation.[119] Such bans should be applied to trans-fats in all foods, rather than simply restaurant foods, as occurs in some jurisdictions.[120]

In 2015, the United States Food and Drug Administration (FDA) issued a final determination that partially hydrogenated oils, the principal source of trans-fat, are not "generally recognized as safe" (GRAS) under the Federal Food, Drug, and Cosmetics Act.[121] The classification of a food ingredient as GRAS under the Act excludes it from the definition of a "food additive"[122] and enables a food manufacturer to avoid the pre-market approval processes that would otherwise require them to petition the FDA and to demonstrate with reasonable certainty that the additive is not harmful under the conditions of intended use.[123] Federal regulations authorize the FDA to contest the pre-existing GRAS status of a food ingredient through a public process that involves making a preliminary determination, making the supporting evidence publicly available and considering public comments.[124] Thereafter, if the Commissioner concludes that there is a lack of convincing evidence

that the ingredient is GRAS, the Commissioner may ban the use of the additive, or alternatively issue regulations setting out the levels for the safe use of the additive in food.[125] The process of reviewing the GRAS status of a substance in food therefore provides a mechanism for removing it from the food supply, as the FDA is unlikely to grant approval for its use as a food additive.

In Canada, the province of British Columbia used its statutory power to regulate "health impediments" in order to issue regulations that require restaurants to ensure that the trans-fat content of partially hydrogenated oil or margarine used in restaurant food is less than 2%, and in any other case, is less than 5% of the total fat content of the food (**Box 16.4**).

Box 16.4: Regulating trans-fat in British Columbia

Public Health Impediments Regulation 2009[126]

Section 3 (1) In this section:

"food" means food

(a) located on the premises of, or prepared, served or offered for sale in, a food service establishment, other than food that is

(i) required under the **Food and Drugs Act** (Canada) to be labelled with a nutrition facts table, or

(ii) not intended for public consumption, or

(b) used on the premises of a food service establishment as an ingredient in the preparation of a food or beverage served or offered for sale in the food service establishment;

(2) Food is deemed to contain trans fat if:

(a) under the heading "Fat" on the nutrition facts table with which the food is labelled, it is indicated that the food contains more than 0 grams of trans fat, or

(b) an ingredient of the food is partially hydrogenated

(i) vegetable shortening,

(ii) margarine, or

(iii) vegetable oil.

(3) Subject to subsection (4), an operator of a food service establishment must ensure that the trans-fat content of food is,

(a) in the case of a partially hydrogenated vegetable oil or soft, spreadable partially hydrogenated margarine, 2% or less of the total fat content of the oil or margarine, and

(b) in any other case, 5% or less of the total fat content of the food.

(4) The limit set out in subsection (3) (b) does not apply in respect of a food in which the trans-fat comes from dairy products or ruminant meat only.

(b) Mandatory food fortification

Governments may also adopt regulations or mandatory standards in order to implement food fortification programmes to improve micronutrient deficiencies. Examples include laws or standards requiring the universal iodization of salt, and the fortification of flour with iron, folic acid, and/or zinc.[127] For example, Nigeria dramatically reduced iodine deficiency disorders through an effective, multisectoral approach.[128] In Nigeria, most salt for domestic consumption is imported through four major ports, creating a favourable environment for regulation. In 1992, the Standards Organization of Nigeria (SON) mandated that all food-grade salt must be iodized with potassium iodate. In 2002, a multisectoral taskforce was formed to improve and sustain universal salt iodization in Nigeria. It included salt producers, the federal Ministries of Health and Education, SON (which carries out inspections at ports, and at salt companies), and the National Agency for Food and Drug Administration and Control (NAFDAC), which is responsible for enforcement of SON standards at retail level. Household surveillance also occurs through primary schools, with children bringing salt samples to school for testing. In 2004, NAFDAC was reported to have destroyed more than 10 000 20 kg bags of non-iodized salt since it joined the taskforce.[129] Through product registration, education, and comprehensive inspection and surveillance at factory, distributor, retailer and household level, the taskforce has achieved impressive levels of compliance with universal salt iodization standards,[130] providing a benchmark for salt iodization programmes elsewhere.

(c) Regulatory measures to reduce over-consumed nutrients

Regulatory efforts to moderate the consumption of over-consumed nutrients, including salt, sugar and saturated fat, can take many different forms. These include food laws that require the elimination or reduction of particular nutrients as a precondition to using specific descriptors in relation to that food. For example, European Union law defines “fruit juice”, as well as the ingredients and substances that may be added to it, and provides that fruit juices may not contain added sugar.[131] Alternatively, governments may adopt voluntary or statutory targets for reductions in salt, saturated fat and/or sugar levels in food and require food manufacturers to meet them over a defined period of time (usually several years).

Salt reduction measures

In 2010, global average salt consumption was estimated to be around 9.9 g/day (3.95 g/day sodium), nearly twice the WHO recommended limit of 5 g/day.[132] Excess salt consumption has been estimated to cause over 3.1 million deaths each year.[133] For this reason, reducing average salt intake has been identified by WHO as a cost-effective priority for reducing diet-related disease.[134] A number of countries have implemented legislation, including mandatory, maximum salt levels either for particular products (e.g. bread), or for a wider range of food categories that contribute large amounts of salt to the diet.[135] In 2013, South Africa introduced regulations that impose maximum salt levels for 13 food categories, including bread, breakfast cereals and porridges, butter and fat spreads, processed meat, dry soup and stock powders, ready-to-eat savoury snacks and potato crisps.[136]

Argentina's salt reduction law sets maximum sodium limits for a wide range of meat products, flour and bakery products (including crackers and cookies), and soups, dressings and canned foods.[137] The law authorizes the Ministry of Health to set maximum salt values for additional food categories. In addition, it authorizes the Ministry to require restaurant menus and products containing sodium to include warning messages about the risks of excess sodium consumption, to require restaurants to offer menu options without added salt, and to set new norms and defaults for low-sodium salt and for the availability of salt shakers and salt packets in restaurants.[138] In 2013, Uruguay banned salt shakers in public and private high schools throughout the country,[139] while the capital city, Montevideo, passed a municipal law that requires bars and restaurants to withdraw condiments that exceed sodium limits, and to make salt shakers available only upon request.[140]

Mandatory salt reduction standards may be a useful option for governments to consider, particularly in countries where many people with hypertension are never diagnosed nor treated, where stroke victims are often left disabled and impoverished, and where nutritional literacy is low.[141] Governments may also consider mandatory standards in countries where industry-led salt reduction programmes have failed to reach agreement on an adequately ambitious set of salt reduction targets, or where a significant number of major food companies fail to reformulate their products in order to achieve them (see Section 2.3).[142] For example, governments may specify national goals for reductions in salt intake and require industry to revise targets for a sufficiently broad range of food categories to enable the goal to be achieved within a defined time frame. Governments may also make participation in food reformulation programmes mandatory for larger food companies, require companies to submit annual reports of their progress, and require independent audits of progress.

16.7 Regulating the built environment

Regulation of the physical and built environment provides opportunities to improve nutrition and reduce overweight and obesity, by: improving access to healthier foods, facilitating greater daily physical activity, and removing other disincentives to a healthy lifestyle.[143] Zoning and development regulations control the kinds of land use that are permissible in a local area, including local design features, the infrastructure that must accompany new residential and commercial developments, as well as transport options and the kinds of activities that are available.[144] These laws are not directed at individuals, but can influence patterns of behaviour within the population over a longer timescale, both by changing the conditions for approval to carry out new developments, and by gradually altering the character of existing neighbourhoods.

The development processes that govern approvals for new developments and urban renewal projects provide opportunities to introduce new land-use patterns, and to significantly reduce or reverse those features of a neighbourhood that work against an active lifestyle and a healthy diet. For example, this can occur through the requirement for public or private developers to improve public infrastructure: creating new street layouts, widening and improving sidewalks, creating dedicated bike lanes, parkland, children's playground areas and community space to promote social interaction and opportunities for physical activity. Although improvements in neighbourhood infrastructure can create an "enabling environment" for more physically active lifestyles, their impact will not be automatic. In addition, local governments and other responsible authorities will

need to meet community expectations about the safety and amenity of the local environment. Issues to consider include measures to calm traffic and to protect pedestrians from exhaust fumes and risks of motor vehicle injuries, adequate lighting and visibility to reduce security concerns, removal of rubbish and other hazards (e.g. discarded needles), protection from toxic exposures, control of pets, feral animals and animal droppings, and the maintenance of a clean and attractive environment.[145]

Zoning regulations can also alter the character of existing neighbourhoods in ways that support healthier lifestyles.[146] In many cities, local government zoning controls have segregated businesses from residential areas, schools and restaurants, encouraging automobile use while neglecting public transport options.[147] Zoning laws that encourage higher density, mixed use development along transport corridors have the capacity, over time, to bring private residences, centres of employment, small businesses, shops and places of recreation into closer proximity. Active transport options (e.g. walkways, cycle lanes), together with efficient and well-run public transport systems, can encourage incidental physical activity while reducing greenhouse gas emissions.

Zoning and development regulations, and economic policies, can also alter the character of the local food environment.[148] Evidence suggests that the distribution and concentration of fast food restaurants selling foods of low nutritional value, and the absence of supermarkets selling fresh fruits and vegetables, can affect the quality of diets among residents in the local area, creating risks for weight gain and metabolic disease.[149] New York City created zoning and tax incentives to encourage grocery stores to carry an appropriate selection of fresh produce (see **Box 16.5**). Economic incentives for large supermarket and grocery chains to open stores in underserved and disadvantaged neighbourhoods may also increase access to fresh and healthy food, since the scale and supply chain management of these stores may enable them to carry healthy foods at lower prices than smaller stores.[150] New York City also created a new class of permit for "green carts" that were specifically authorized to sell (only) fresh fruit and vegetables on city streets. It provided micro-loans and technical assistance to assist new operators to become established.[151]

Box 16.5: Creating incentives for local grocery stores to carry fresh produce, dairy products and meats

In New York City, the Food Retail Expansion to Support Health project (FRESH) provides zoning and tax incentives to retailers who qualify as FRESH food stores (i.e. those devoting certain amounts of floor space to the sale of fresh produce, dairy, canned and frozen foods, and fresh and prepared meats, fish and poultry).[152] Qualifying stores are eligible for additional floor space in mixed residential and commercial buildings, a reduction in required parking for patrons, increased access to real estate in districts designated for light manufacturing, real estate tax reductions, sales tax exemptions and mortgage recording tax deferrals.[153]

Amendments to zoning laws and retail permit laws can also remove barriers to farmers' markets selling fresh produce in appropriate locations, such as near schools, close to public transport and in underserved areas.[154] The City of Detroit in the United States requires a minimum distance of 500 feet (approximately 150 metres) separating schools and specified kinds of fast food and take-away restaurants.[155] As noted in Section 16.5, legislation in the Republic of Korea has created "green food

zones" around schools, and provides certification for "exemplary" businesses selling children's preferred foods within the zone that meet minimum nutritional criteria.[156] Scholars and public health institutions have pointed to the clustering of fast food restaurants around schools and advocated using zoning controls to reduce their density, or to prevent their location close to schools.[157]

16.8 Addressing hunger and food insecurity

Despite rising rates of overweight and obesity, undernutrition remains a problem in many parts of the world. The Food and Agriculture Organization of the United Nations has estimated that, in 2014–2016, 795 million people (one in nine of the global population) were undernourished.[158] The vast majority of these people – 780 million – lived in developing regions. Despite significant reductions in morality among children under five years, malnutrition remains a significant hurdle to efforts to improve the health of women and children, particularly in sub-Saharan Africa and south Asia.[159] In 2010, child and maternal undernutrition, including suboptimal breastfeeding, childhood underweight and child micronutrient deficiencies, were responsible for over 1.4 million deaths, and around 7% of the global burden of disease.[160] In 2012, WHO Member States made the commitment to achieve a range of global targets for maternal, infant and young child nutrition, to be met by 2025. These include a 30% reduction in low birth weight, a 40% reduction in the global number of children who are stunted, and a goal of reducing childhood wasting to less than 5%.[161]

An important element in the success of Brazil's efforts to reduce hunger and improve infant nutrition was the legal recognition, in the Organic Law of Food Security and Nutrition, that Brazilian citizens have a right to adequate food and nutritional security (**Box 16.6**).[162] The legislative commitment of the Government of Brazil to fulfil this right, in collaboration with civil society, provided the basis for a diverse set of policies addressing access to food, supporting income-generating activities (including smallholder agriculture), and improving primary health care. As a result of these policies, Brazil has achieved impressive reductions in underweight, wasting and stunting (see further, section 6.3(c)).[163]

Box 16.6: Legal recognition of the right to adequate food and nutritional security in Brazil

Organic Law of Food Security and Nutrition[164]

Article 1 This Law establishes the definitions, principles, guidelines, objectives and composition of the National System for Food Security and Nutrition (SISAN), through which the government, with the participation of civil society, will formulate and implement policies, plans, programmes and actions aimed at ensuring the human right to adequate food.

Article 2 Recognizing that adequate food is a fundamental right of human beings, inherent to human dignity and essential to the realization of the rights enshrined in the Constitution, the government should adopt policies and actions as necessary to promote and ensure the food safety and nutrition of the population.

Article 7 Achieving the human right to adequate food and ensuring the food and nutritional security of the population will be accomplished through SISAN, comprised of a set of entities including federal, state, federal district and municipal institutions, private or non-profit, which are interested in food security and nutrition and which show an interest in joining the system, with respect to the applicable legislation.

In some countries, the right to food is justiciable, whether through constitutional recognition of the right to food or related human rights, or through framework legislation for food security.[165] In the course of public interest litigation which began in 2001, the Supreme Court of India recognized that the right to life enshrined in Article 21 of the National Constitution includes a right to "live with human dignity", which encompasses the right to food.[166] Further support for this right appears in two Directive Principles of State Policy, which recognize the right to an adequate standard of living (Article 39(a)), as well as the primary obligation of the State to "raise the level of nutrition and the standard of living of its people" (Article 47). In a series of orders based on Article 21, the Supreme Court has ordered national and state governments to implement various programmes to ensure food access, including midday meal programmes in primary schools, converting the benefits offered under these schemes to legal entitlements, and expanding coverage. In 2003, the Supreme Court ruled that six priority groups were entitled to food assistance, including aged, infirm, disabled and destitute men and women, pregnant and lactating women and widows, single women and persons aged over 60 years with no means of support.[167] In 2002, the Supreme Court appointed two Commissioners to act on the Court's behalf, monitoring compliance with court orders, investigating violations and seeking further court interventions if required.[168]

Government programmes to improve food security for women and children are an important strategy for fulfilling the right to adequate food and nutrition. The entitlements and conditions for participation in these programmes must be carefully defined. As illustrated by **Box 16.7**, the impact of food aid programmes on nutrition at the household level may vary by gender and should be carefully monitored. Cash transfer programmes, such as Brazil's Bolsa Família (Family Grant), are an alternative to direct food aid, and have been shown to be successful in reducing undernutrition and improving maternal and child health. By giving each female head of household a monthly cash stipend based upon the number of children in the household, the programme has increased food security and provided a flexible safety net that can be spent on a variety of needs, including food, clothing, safe accommodation and health care.

Box 16.7: Food programmes for maternal and child health: food distribution and food-for-work in Ethiopia

The Government of Ethiopia implemented a comprehensive food aid programme, basing assistance on food-for-work (for able-bodied persons), or free distribution for those unable to work.[169] Analysis of this programme revealed different impacts based on gender. Food-for-work assistance resulted in an improvement in the nutritional status of boys, relative to girls, while food assistance delivered for free (no work required) improved the nutrition of girls.[170] Ethiopia's experience of linking food distribution to work demonstrates the importance of monitoring the outcomes of nutrition assistance programmes to ensure both efficacy and equity. Food-for-work programmes should also be carefully scrutinized, not only in terms of the distribution method (free assistance or food-for-work), but also who is targeted for each kind of programme. For example, the hard physical labour required for food-for-work programmes may cause deterioration in the nutritional status of workers, while also reducing the time available for household administration, and for other income-generating activities.

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Chapter 17: Maternal, reproductive and child health

SUMMARY POINTS

· **The right to health requires countries to invest in maternal, reproductive and child health. Progress in maternal and child health depends on improvements in a range of areas both within and beyond the health sector.**

· **Discrimination is a formidable barrier to improvements in maternal and child health. Discrimination encompasses not only direct, physical exclusion, but unequal access, the stigma that results in self-exclusion, lack of courtesy and mistreatment by service providers, and loss of control over fertility, including through lack of access to contraception.**

· **Parties to the International Covenant on Economic, Social and Cultural Rights have an immediate obligation to respect the right to health by preventing discrimination in access to curative, palliative and preventive services, and to ensure legal protection from discrimination on the basis of "race, colour, language, religion, political or other opinion, national or social origin, property, birth or other status".**

· **Violence against women is a serious form of discrimination that violates the right to health and is prohibited by the Convention on the Elimination of All Forms of Discrimination Against Women. Violence against women includes domestic violence within the family, rape and sexual assault, coercion and deprivation of liberty, sexual harassment, trafficking and forced prostitution, forced marriage, acid attacks, so-called "honour killings", and female genital mutilation.**

· **Legal responses to violence should address both the causes and consequences of violence, and include primary, secondary and tertiary prevention. Countries must take steps to improve their capacity to deliver justice to victims of violence, by investigating cases and enforcing remedies and penalties.**

· **Legislation can support access to prenatal and maternal health services by recognizing women's entitlement to these services, and by committing governments to developing strategies to fund them and to address barriers to care.**

· **Systemic failures may negate the right of women and children to adequate health services. These include the inequitable geographical distribution of emergency obstetric care facilities, and unacceptably high levels of unmet need for emergency obstetric care and of obstetric deaths in facilities.**

· **Countries have an obligation to monitor the performance of private health care organizations, including private insurers, to ensure that services that are essential to women's health are not excluded. These include prenatal assessment, attended birth, postnatal care and family planning.**

· **The Comprehensive Implementation Plan on Maternal, Infant, and Young Child Nutrition, adopted by the World Health Assembly in 2012, includes a range of global targets for mothers and children. Progress towards these targets requires both nutrition-specific interventions, such as support for breastfeeding, and nutrition-sensitive interventions across a range of sectors.**

- **The WHO International Code of Marketing of Breast-milk Substitutes supports infant nutrition by reducing commercial marketing practices that undermine breastfeeding. Governments should consider implementing the Code through national legislation, and by monitoring the marketing practices of companies that manufacture and sell infant formula.**

- **A legal entitlement to paid maternity leave is an important component of a comprehensive strategy for maternal and infant health. The Maternity Protection Convention of the International Labour Organization incorporates standards that may assist governments in specifying national legal entitlements to maternity leave.**

- **Legislators should ensure that family planning programmes are adequately funded and that women have full access to whatever fertility methods they choose.**

- **Universal primary and secondary education is an important strategy for improving maternal and child health. In the poorest communities, where children work to ensure the economic survival of their families, school attendance cannot be separated from family-focused poverty reduction efforts.**

Investing in the health of women and children is a vital part of the right to health, encompassing reproductive and maternal health (prenatal and postnatal), and child health care.[1] Article 12.2(a) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) requires States to take the necessary actions "for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child".[2] Improving maternal, reproductive and child health not only helps to secure the right to health, but reduces poverty and stimulates economic growth.[3] Over the period 1990–2015, the mortality rate for children under five years declined by more than 50%, yet in 2015, 5.9 million children under five years still died from preventable causes.[4] In 2015 there were an estimated 303 000 maternal deaths.[5] Around three quarters of maternal deaths have obstetric causes, including haemorrhage, hypertensive disorders and sepsis.[6]

Progress in maternal and child health depends on a country's capacity to achieve improvements in a range of areas both within and beyond the health sector. Health sector improvements include immunization, family planning, skilled birth attendance and the provision of antenatal and postnatal care. Improvements outside the health sector include reductions in the total fertility rate, economic development, good governance (control of corruption), the participation of women in politics and in the workforce, strong leadership, poverty reduction, female education and good environmental management.[7] This chapter considers a select number of mostly health sector policies that may be strengthened through law and regulation.

17.1 Preventing discrimination

Women and children are entitled to the highest attainable standard of health: this necessarily includes access to adequate health care services and to a fair and adequate allocation of resources for maternal and child health (**Box 17.1**). Women and children may face discrimination in access to

health care due to the stigma associated with particular diseases and conditions, including HIV and AIDS,[8] diabetes,[9] and prolapse of the uterus.[10] Women face mistreatment from service providers, reducing their ability to access care or their willingness to engage with the health system.[11] Women may also face discrimination or harassment that interferes with their right to breastfeed infants. Discrimination and inequality can impair women's ability to move freely, to own property and to control their fertility – each of which can threaten a woman's ability to access health care or to protect her health and the health of her children. Discrimination against indigenous persons can also have a disproportionate impact on women and children.[12]

Box 17.1: The duty to secure maternal and child health

The Millennium Development Goals called for a reduction in the mortality rate of children under five years of age by two thirds between 1990 and 2015 (Goal 4), and a reduction in the maternal mortality ratio by three quarters over the same period (Goal 5). Between 1990 and 2015, under-five mortality rates dropped by 53%,[13] and maternal mortality rates declined by 43%.[14] In 2015, the global maternal mortality ratio was 216 maternal deaths per 100 000 live births, although a woman's chance of dying in childbirth remains 20 times higher in developing regions than in developed regions.[15] Despite this, significant gains have been made in some countries. For example, Sri Lanka reduced its rate of maternal mortality by 87% over a 40-year period by ensuring that 99% of pregnant women receive four prenatal visits and thereafter give birth in a health facility.[16]

International law recognizes the vulnerability of women and children and their right to the highest attainable standard of health. The Universal Declaration of Human Rights recognizes that "motherhood and childhood are entitled to special care and assistance".[17] The Convention on the Elimination of All Forms of Discrimination against Women specifically protects the status of motherhood and the special health needs of women, and requires Parties to provide access to medical care and to other resources necessary for a safe pregnancy.[18] The Convention on the Rights of the Child recognizes that children are vulnerable in their health and that Parties must take steps to ensure that all children achieve the highest attainable standard of health. This includes taking steps to reduce infant and child mortality, to provide access to health care consistent with the needs of children, to combat disease and malnutrition, to provide maternal health care, and to ensure adequate health education for children and their families.[19]

As explained in Section 1.1(a), Parties to the ICESCR have an immediate obligation to respect the right to health by preventing discrimination in access to curative, palliative and preventive services.[20] Under the ICESCR itself, countries have an obligation to undertake to guarantee the rights recognized in the Covenant without discrimination on the grounds of "race, colour, language, religion, political or other opinion, national or social origin, property, birth or other status".[21] A legal entitlement to protection from discrimination has been included in the constitutions and domestic laws of many countries: this entitlement provides an important foundation for national efforts to improve the health of women and children (**Box 17.2**).

Box 17.2: Legal protection from stigma and discrimination in national constitutions

Basic Law for the Federal Republic of Germany[22]

Article 3. Equality before the law

(2) Men and women shall have equal rights. The State shall promote the actual implementation of equal rights for women and men and take steps to eliminate disadvantages that now exist.

(3) No person shall be favoured or disfavoured because of sex, parentage, race, language, homeland and origin, faith, or religious or political opinions.

Constitution of Uganda[23]

Article 21. Equality and freedom from discrimination.

(1) All persons are equal before and under the law in all spheres of political, economic, social and cultural life and in every other respect and shall enjoy equal protection of the law.
(2) Without prejudice to clause (1) of this article, a person shall not be discriminated against on the ground of sex, race, colour, ethnic origin, tribe, birth, creed or religion, social or economic standing, political opinion or disability.

Constitution of Portugal[24]

Article 13. Principle of equality

1. Every citizen shall possess the same social dignity and shall be equal before the law.

2. No one shall be privileged, favoured, prejudiced, deprived of any right or exempted from any duty on the basis of ancestry, sex, race, language, place of origin, religion, political or ideological beliefs, education, economic situation, social circumstances or sexual orientation.

In addition to discrimination, reproductive and maternal health is protected by the constitution in some countries, and may also be enforceable through the courts. For example, the Constitution of Uganda commits the State to "provide the facilities and opportunities necessary to enhance the welfare of women to enable them to realize their full potential and advancement". It stipulates that the State "shall protect women and their rights, taking into account their unique status and natural maternal functions in society".[25] In addition to motivating action by governments, constitutional recognition of the State's duty to address inequalities in health – and to invest the resources required to meet its health obligations – can mobilize civil society to seek greater access to health care and quality of care on behalf of women, children and vulnerable groups.

17.2 Freedom from violence

Freedom from violence is a fundamental precondition to enjoyment of the right to health. Violence against women is itself a form of discrimination and is prohibited by the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW).[26] CEDAW protects women from violence that is "directed against a woman because she is a women or that affects women disproportionately".[27] It applies to actions taken by the State, by private persons and non-State

actors.[28] It includes violence within the family, rape and sexual assault, coercion and deprivation of liberty, sexual harassment in the workplace, trafficking and forced prostitution, and other practices involving coercion and violence, such as forced marriage, dowry-related violence, acid attacks, "honour killings" and female genital mutilation.[29]

Violence against women is extremely common and may occur in both public and private life. Globally, 30% of women have experienced physical or sexual violence carried out by an intimate partner; in some regions the rate is as high as 37%.[30] The global rate of sexual violence against women by persons other than their intimate partner is 7%.[31] While as many as 38% of murdered women are killed by their intimate partners, only 6% of men who are murdered are killed by an intimate partner.[32]

Many women are victims of violence during pregnancy. In 11 of the 19 countries surveyed by WHO, over 5% of women who had carried a child had experienced violence during pregnancy (in rural areas, the prevalence was much higher).[33] In addition to the long-term consequences of violence upon the physical and mental health of women, violence directly affects the health of children and may affect the health and survival of the fetus. Women who have been physically or sexually abused by an intimate partner are 16% more likely to have a low birth weight baby, and more than twice as likely to have an induced abortion, than those who have not suffered such abuse.[34]

Women who are victims of violence experience negative health effects across the life-course.[35] A woman who has ever suffered abuse, regardless of how recent, is more likely to have suicidal thoughts and demonstrate symptoms of emotional distress than her peers.[36] In some WHO regions, women who have suffered intimate partner violence are 1.5 times more likely to acquire HIV or syphilis.[37] Women who have suffered either violence from an intimate partner or sexual violence from someone other than their partner are more likely to experience depression and to have alcohol abuse disorders.[38]

Laws that promote the safety and equality of women must be consistent with human rights standards, while responding to the specific challenges faced in each country. Although they may include criminal penalties for domestic violence, "honour killings", and other forms of gender-based abuse, these laws alone will not be sufficient. The public health approach to protecting women's health is therefore interdisciplinary in nature. It includes information campaigns, monitoring of trends in violent behaviour, training programmes for service provides, and a functioning criminal justice system with adequate resources to deliver justice to victims of violence by investigating complaints, and enforcing remedies and penalties. **Box 17.3** provides a case study of how the Government of India, legislature and Supreme Court have responded to both the causes and consequences of acid attacks upon women.

Box 17.3: India's response to acid attacks against women[39]

India's national Ministry of Home Affairs responded to the growing number of acid attacks on women by drafting model rules that classify corrosive acids such as hydrochloric acid and sulphuric acid as poisons under India's Poisons Act. Under the rules, the strength of acids available for retail sale would be reduced, retailers of acids would require a licence, acid sales would be restricted to

adults, and purchasers would need to produce a photo identity card prior to sale.[40] In order to hasten the implementation of the draft model rules by the states, the Supreme Court of India issued interim orders in 2013 that prohibit acid sales unless retailers declare all stocks of acid with a subdivisional magistrate and thereafter maintain a register which records the details of all persons to whom acid was sold. Undeclared stocks of acid may be confiscated, and penalties apply for failure to comply with the directions.[41]

India's Penal Code has also been amended to include specific offences for acid attacks, including a minimum term of 10 years (and up to life) imprisonment for voluntarily causing grievous hurt by throwing or administering acid.[42] Additional offences have been introduced for failure to record information relevant to the commission of an acid attack, or for failing to ensure full and free hospital treatment for all victims of acid attacks.[43] A fine is also payable to the victim to meet (her) medical expenses.

In India, the provision of health care is a state responsibility. Although a number of Indian states have created compensation schemes for victims of acid attacks, the Supreme Court pointed to significant variations in the amount of compensation between states and concluded that the amount of compensation payable was inadequate. In order to fund the series of surgeries that are often required by victims of acid attacks, the Supreme Court ordered that all states and territories shall pay compensation of at least 3 lakh rupees (300 000 rupees) to each victim, with one third payable within 15 days and the balance within two months.[44] India's Criminal Procedure Code was subsequently amended to require each state government, in coordination with the central government, to prepare a scheme providing compensation to those who have suffered injury as a result of acid attacks. This compensation is in addition to the fine payable by the perpetrator to the victim.[45]

WHO has released a comprehensive strategy that takes a life-course approach to preventing domestic violence. This strategy encompasses primary, secondary and tertiary prevention strategies.[46] Primary prevention strategies seek to prevent violence from occurring. They include programmes to promote equality between men and women, and legislation granting men and women equal rights in access to health care, property ownership, education, political participation, employment, and entering and leaving marriages (**Box 17.4**).

Box 17.4: Responding to violence against women in Kyrgyzstan

Following the dissolution of the Soviet Union, women and children in Kyrgyzstan lost many of the formal legal rights they had previously enjoyed. Enrolment of girls in school decreased, and polygamy and bride theft, among other discriminatory practices, increased.[47] Although men and women are equal under the Constitution, in practice men were usually registered as the sole owners of house plots held by the owners of the residence, since "custom and tradition assume [men] are the heads of household and usually control the household's productive assets".[48] Similarly, although formal succession law does not discriminate, customary law favours men; for example, divorced women have great difficulty in obtaining their share of household land or its value.[49] In response, the United Nations Entity for Gender Equality and the Empowerment of Women (UN Women) has focused on providing training to government staff (especially local government officials) and civil

society groups to improve understanding of CEDAW, and of women's rights, including their land rights.[50] Over the period 2004–2009, nearly 3000 women attended legal training workshops, and 1200 gained access to land previously denied to them.[51]

Secondary prevention strategies seek to respond swiftly and appropriately to cases of violence. They include training programmes to enable police to investigate and respond effectively to allegations of rape and family violence, criminal justice reforms to enable courts to investigate complaints and to make restraining orders, and resources to provide safe havens for victims. South Africa's Domestic Violence Act has been praised for its extensive protections against intimate partner violence, which include a duty upon police to assist victims to find shelter and medical treatment.[52] While critically important, these provisions are not self-executing, and their implementation must be matched by adequate resourcing of courts and the police to enable women to overcome the obstacles to seeking relief from violence.[53]

As the Constitutional Court of South Africa has stated, a common feature of domestic violence is that it is hidden, repetitive and frequently goes unpunished.[54] Civil protection orders authorize courts to remove a person who is the subject of a complaint of domestic violence from a joint place of residence, and to require the accused not to further threaten or approach the applicant. For example, in Costa Rica, when a woman or members of her family file a complaint, the judge will investigate the evidence, and in order to protect the woman from retaliation or further abuse, will require the accused to leave the joint matrimonial home.[55] In addition, the judge will require the accused to make available an adequate sum of money to ensure that those who are economically dependent on the accused are not deprived of support. Central American countries have introduced a range of additional protections for victims of sexual abuse, including legal protection for relatives, orders to protect the confidentiality of the victim's identity, the assignment of bodyguards, relocation, change of identity, provision of living expenses, and the use of video links to enable victims and witnesses to testify.[56]

The Government of Pakistan has enacted ground-breaking legislation to protect the health and welfare of women by introducing a criminal offence of sexual harassment into the Penal Code. This offence applies to conduct at home, in workplaces, and in streets, markets and other public places. A separate Act requires government bodies, corporations and civil society organizations to implement a Code of Conduct for Protection against Harassment of Women in the Workplace into their management policies (**Box 17.5**).[57] The Act requires organizations to establish a three-person enquiry committee within each organization to hear complaints of harassment. Where a complaint is upheld, the enquiry committee is authorized to recommend penalties to a supervising government authority: these penalties range from censure and delays in promotion or pay increments to demotions, dismissals and fines. Alternatively, women can complain to a federal or provincial ombudsman, who can impose the same penalties. By reducing sexual harassment and intimidation, these initiatives seek to remove the obstacles that prevent women from pursuing an education, accessing health care services, entering the job market and working their way out of poverty.

..

Box 17.5: Protecting women from sexual harassment in Pakistan

Amendments to the Penal Code

Section 509A. **Sexual harassment.** Whoever makes sexual advances, or demands sexual favours or uses written or verbal or physical conduct of a sexual nature which intends to annoy, insult, intimidate or threaten the other person or commits such acts at the premises of [a] workplace, or makes submission to such conduct either explicitly or implicitly a term or condition of an individual's employment, or makes submission to or rejection of such conduct by an individual a basis for [an] employment decision affecting such individual, or retaliates because of rejection of such behaviour, or conducts such behaviour with the intention of unreasonably interfering with an individual's work performance or creating an intimidating, hostile, or offensive working environment, shall be punished with imprisonment which may extend to three years or [a] fine up to five hundred thousand rupees or with both.

Protection Against Harassment of Women at the Workplace Act 2010

Section 2(h) "Harassment" means any unwelcome sexual advance, request for sexual favours or other verbal or written communication or physical conduct of a sexual nature or sexually demeaning attitudes, causing interference with work performance or creating an intimidating, hostile or offensive work environment, or the attempt to punish the complainant for refusal to comply to such a request or is made a condition for employment.

Tertiary prevention is critical to preventing women from falling back into abusive relationships and environments, although unfortunately it is less commonly included in public health laws and policies. Tertiary prevention strategies include options for women to access long-term care, and rehabilitation to assist women to return to normal life after suffering abuse.[58] Legislation can commit governments to a comprehensive strategy for violence prevention; for example, by recognizing a duty on government to ensure the provision of adequate services (not necessarily provided directly by government agencies themselves) to victims of violence and sexual abuse.

17.3 Prenatal and maternal health care services

The provision of reproductive, prenatal and postnatal health care services is a critical part of the right to health, comparable with the core obligations that are subject to immediate effect, rather than progressive realization under Article 12 of the ICESCR (see Section 1.1). Universal access to prenatal care, including folic acid supplements, HIV testing, malaria prevention, assessment for diabetes, and other prenatal assessments, is a cost-effective way to reduce mortality and morbidity, both during pregnancy and birth, for both the mother and the child.[59] Legislation can support access to prenatal and maternal health services by recognizing women's entitlement to these services and by committing governments to developing strategies to fund them. Since many clinics rely on user fees to pay salaries and purchase supplies, government policies to provide free health care services must be accompanied by financial arrangements to ensure that they can be delivered sustainably, whether from government or other sources.[60] Vital statistics legislation should require all births to be registered, with reporting and investigation of perinatal and neonatal deaths.[61]

In 1994, the government of Ecuador introduced and subsequently updated a law for the provision of free maternity and child care in order to improve the reproductive health of low-income women (**Box 17.6**).[62] This law included a number of unique features. It was administered by local management committees, which comprised not only the mayor and director of each health district, but representatives of community, women's and indigenous organizations. Funds to pay for the provision of services were received both from the central government (partly generated by consumption taxes), as well as from local governments. In addition to administering the local health solidarity fund derived from these sources, the role of the local committees included carrying out local health needs assessments, identifying local health priorities, and identifying additional funding sources. Community participation was also strengthened by local users' committees, which promoted participation, evaluated the quality of the health services provided, and coordinated with health facilities in order to improve quality.

Box 17.6: Eliminating user fees for prenatal and obstetric care: an example from Ecuador

Free Maternity and Child Care Law[63]

1. Every woman has the right to free quality health care during pregnancy, including childbirth and postpartum, and access to sexual and reproductive health programmes. Likewise, free health care is to be given to newborn infants and children under five years of age as a public health responsibility of the State.

2. This Act has as one of its purposes the financing of the costs of medicines, materials, micronutrients, supplies, basic laboratory tests and complementary tests for the care of pregnant women, newborn infants, and children under five years of age in the following areas:

(a) Maternity: ensure that women have access to necessary and timely antenatal care services regardless of the level of complexity; basic treatment for sexually transmitted diseases... care for childbirth, both normal and high-risk, including caesarean delivery and vaginal delivery; emergency obstetric care, including treatment for domestic violence, toxaemia, and haemorrhage; and pregnancy-related sepsis, both at delivery and postpartum, including the provision of blood or blood products.

(b) Infants and children under 5 years of age: ensure necessary and appropriate care regardless of complexity to newborn infants, including healthy infants, premature infants, infants with low birth weight and/or disorders (perinatal asphyxia, jaundice, fetal distress and sepsis), and to children under 5 years of age who have diseases included in the Comprehensive Care Strategy for the Management of Childhood Illness, and all complications according to current regulations of the Ministry of Public Health.

The physical accessibility of maternal health care services is a determinant of use and of maternal mortality.[64] The case of Alyne da Silva Pimentel v Brazil[65] illustrates this important issue. The Committee on the Elimination of Discrimination Against Women, which oversees the implementation of CEDAW[66] by States Parties, found that the failure to provide a Brazilian national of African descent with timely access to emergency obstetric care violated her right to life and her right to health under the Convention. The Committee found that these rights are "obligations of

immediate effect" which are immediately enforceable under CEDAW, and which require urgent government action.[67] In this case the deceased died as a result of preventable delays in conveying her to hospital, in carrying out diagnostic tests, and in performing surgery to remove the placenta after she gave birth to a stillborn fetus at six months. The underlying problem that the Committee identified was the inequitable geographical distribution of emergency obstetric care facilities, unacceptably high levels of unmet need for emergency obstetric care, and of obstetric deaths in facilities.[68] The Committee emphasized that the State's obligations under CEDAW extend to monitoring the performance of private health care institutions, and that the State cannot outsource its obligation to ensure compliance with human rights obligations to private health services.[69]

One practical strategy for improving maternal outcomes for women living in isolated locations is through the construction of maternal waiting homes. This allows women living in remote and rural areas to plan for the birth of their children and to travel to a clinic before labour commences. Obstetric care has repeatedly been demonstrated to increase health outcomes related to birth.[70] Maternal waiting homes enable women to benefit from government strategies to ensure that all births are monitored by a skilled birth attendant, without the need to pay for lodging days before she expects to deliver (**Box 17.7**).

Box 17.7: Improving maternal and child health: maternal waiting homes in rural Zambia

Maternal death is unacceptably high among women in developing countries, particularly in rural areas. In sub-Saharan Africa in 2015, there were approximately 546 maternal deaths per 100 000 live births, and women face a lifetime risk of maternal death of 1 in 36, more than four times higher than the global average, and 100 times higher than the risk of maternal death in developed countries.[71] To improve maternal outcomes, women with high-risk pregnancies in Zambia are encouraged to travel to maternal waiting homes during their 36th week of pregnancy. This enables the health of the woman to be monitored, and their delivery to be attended by a skilled professional, with access to the necessary surgical procedures if complications arise. A review of the maternal waiting homes in Zambia found that the provision of free lodging and free meals were important components of the strategy. A review of maternal waiting homes in other countries found that those that did not provide meals were less well attended then those in Zambia.[72] Maternal waiting homes are part of a continuum of services supporting maternal and child health that will vary according to country circumstances. The law should support women's access to these services on a non-discriminatory basis, with priority based on economic need.

Women's ability to control their fertility through family planning substantially reduces the number of maternal deaths and improves the health of infants.[73] WHO has estimated that 225 million women globally have an unmet need for contraception; in Africa, this extends to more than 23% of women of reproductive age. The WHO publication, *Family planning: a global handbook for providers*,[74] gives evidence-based guidance on 20 family planning methods, and discusses other components of effective family planning programmes, including treatment for sexually transmitted infections, counselling and strategies for dealing with violence against women. Legislators should ensure that family planning programmes are adequately funded and that women have full access to whatever fertility methods they choose.

For countries without national health care schemes, ensuring that pregnant women and mothers can access health care services is crucial. In private markets, health insurance providers may reduce costs by excluding coverage for services that are critical to women's health, including prenatal assessment, attended birth, postnatal care, family planning, and preventive health services such as mammograms. Women may be unaware that these services are excluded, or may be unable to purchase higher levels of insurance cover due to cost. One legislative option, where appropriate, is to mandate that relevant insurance products offered in the private market must include an essential package of maternal and child health services (**Box 17.8**). Minimum entitlements expand access and demand by reducing barriers to the health care services women need to improve their own health and the health of infants. They also provide economic stability, protecting women and families from catastrophic expenses in times of emergency.

Box 17.8: Mandatory insurance coverage of women's health in the United States (State of Colorado)

> All individual health care or indemnity contracts issued ... shall insure against the expense of normal pregnancy and childbirth or provide coverage for maternity care and provide coverage for contraception in the same manner as any other sickness, injury, disease or condition is otherwise covered under the policy or contract.[75]

17.4 Maternal and child nutrition

Improving nutrition during pregnancy is critical not only to reduce the incidence of low birth weight, but to improve long-term childhood development.[76] Even temporary interruptions to a family's food supply can have lasting effects on a child's growth and development.[77] The Comprehensive Implementation Plan on Maternal, Infant, and Young Child Nutrition, adopted by the World Health Assembly in 2012, includes a range of global targets for mothers and children (**Box 17.9**).[78] Legislation and governance arrangements play an important role in progress towards these targets. As recognized by the Scaling Up Nutrition (SUN) movement,[79] progress in child and maternal nutrition requires both nutrition-specific interventions, such as support for exclusive breastfeeding and micronutrient supplementation, and a range of multisectoral, nutrition-sensitive interventions. These include education, access to health care, clean water and sanitation and support for resilience. Multisectoral collaboration is an important strategy for countries involved in scaling up nutrition, helping to ensure that important interventions outside the health sector that have an impact on maternal and child nutrition are included in national plans and strategies.[80]

Box 17.9: Global targets for maternal, infant and young child nutrition

In 2012, the World Health Assembly adopted the following voluntary targets:

- Global target 1: by 2025, a 40% reduction in the global number of children under five years who are stunted;
- Global target 2: by 2025, a 50% reduction in anaemia in women of reproductive age;
- Global target 3: by 2025, a 30% reduction of low birth weight;
- Global target 4: by 2025, no increase in child overweight;
- Global target 5: by 2025, increase the rate of exclusive breastfeeding in the first six months up to at least 50%;
- Global target 6: by 2025, reduce and maintain childhood wasting to less than 5%.

WHO has estimated that optimal breastfeeding of infants aged 0–23 months could avoid up to 800 000 deaths each year in children under five years.[81] The International Code of Marketing of Breast-milk Substitutes,[82] adopted by the World Health Assembly in 1981, supports infant nutrition by reducing commercial marketing practices that undermine breastfeeding. The Code prohibits the advertising of infant formula and other breast-milk substitutes to the general public, to pregnant women and mothers, and to health workers who are concerned with infant and maternal nutrition. It also prohibits the giving of samples and other incentives for purchase.[83] Governments are urged to implement the Code through national legislation, regulations or other suitable measures.[84] In 2016, WHO reported that 136 countries had included some aspects of the Code in national legislation; 39 countries had comprehensive legislation.[85] Although important, legislation is not likely to be sufficient by itself: governments should monitor the marketing practices of companies promoting infant formula, and civil society may also have an important role in exposing companies that ignore the Code or engage in inappropriate marketing practices.[86]

17.5 Maternity leave

Laws and policies requiring employers to provide women with paid maternity leave are another important component of a comprehensive strategy for maternal and infant health.[87] An extended period of maternity leave significantly reduces infant mortality, low birth weight and post-neonatal mortality, even after accounting for other government infant health programmes.[88] The Maternity Protection Convention (2000) of the International Labour Organization (ILO) includes a number of provisions that may assist governments in meeting minimum requirements for the protection of maternity leave (**Box 17.10**).[89] ILO Conventions are adopted by a two thirds majority of the ILO Conference – which provides representation for governments, labour and employment organizations – and are legally binding on countries that have ratified them.[90]

Box 17.10: Maternity protection standards under the International Labour Organization Maternity Protection Convention (2000)

Article 3: Health protection: national laws must protect pregnant or breastfeeding women from performing work that harms or creates a serious risk to the health of the mother or child.

Article 4: Maternity leave: national laws must provide for not less than 14 weeks' maternity leave; in order to protect maternal and child health, 6 weeks of this period must be postnatal leave. Countries ratifying the Convention are to specify the minimum period of maternity leave to which women are entitled.

Article 5: Illness or complications: in addition to maternity leave, national laws must also provide for leave in the case of documented illness, complications, or risk of complications arising out of pregnancy or childbirth.

Article 6: Benefits: the financial support provided to women under articles 4 and 5 "shall be at a level which ensures that the woman can maintain herself and her child in proper conditions of health and with a suitable standard of living". In general, these benefits must not be less than two thirds of the woman's previous earnings.

Article 8: Employment protection: national laws must ensure that it is unlawful for an employer to terminate the employment of a women during pregnancy, or during a period of leave under articles 4 or 5, or following her return to work, except on grounds that are unrelated to her pregnancy, childbirth, or nursing. Following maternity leave, a woman is guaranteed the right to return to her previous position or an equivalent position.

Article 9: Non-discrimination: countries shall adopt measures to ensure that maternity does not constitute a source of discrimination in employment. Employers may not require a woman to be tested for pregnancy as a condition of employment, except where national laws prohibit pregnant or breastfeeding women from performing specified work, or where such work would create a significant risk to the health of the mother and child.

Article 10: Breastfeeding: national laws must specify permitted nursing breaks, which shall be counted as working time and remunerated accordingly.

17.6 Education

Achieving universal primary and secondary education is a critical step towards improving maternal and child health. The education of women not only benefits women themselves, but the survival and development of children: child mortality rates are highest in households where the mother's level of education is lowest.[91] National laws can mandate primary and, where possible, secondary education and should commit governments to spending the resources that are needed to ensure that all children can attend school, without discriminatory barriers, and regardless of the economic position of their family (**Box 17.11**).

National governments may also create economic incentives or impose conditions on the payment of grants to city and local governments, and regional authorities, as a strategy for encouraging higher

rates of school attendance. In the poorest communities, where children work in order to ensure the economic survival of the family, school attendance cannot be separated from family-focused poverty reduction efforts, including safety nets and new economic opportunities. Similarly, mandatory education for all children will require governments to address human workforce issues, including teacher shortages, and to implement plans for building or opening new schools in underserved areas.

Box 17.11: Mandatory childhood education: an example from India

The Right of Children to Free and Compulsory Education Act[92]

3. **Right of child to free and compulsory education:** (1) Every child of the age six to fourteen years… shall have a right to free and compulsory education in a neighbourhood school till the completion of his or her elementary education.

(2) For the purpose of sub-section (1), no child shall be liable to pay any kind of fee or charge or expenses which may prevent him or her from pursuing and completing elementary education.

8. **Duties of appropriate Government:** The appropriate Government shall –

(a) provide free and compulsory education to every child …

(b) ensure availability of a neighbourhood school …

(c) ensure that the child belonging to the weaker section and the child belonging to disadvantaged group are not discriminated against and prevented from pursuing and completing elementary education on any grounds;

…

(g) ensure good quality elementary education conforming to the standards and norms specified in the Schedule.

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