Setting Norms and Standards in Global Health: Challenges and Opportunities

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Abstract

The establishment of global norms and standards is one of the cornerstones of global health. Standards raise the quality of health care and improve health outcomes by guaranteeing a minimum quality of health products and services that is acceptable, thereby ensuring compatibility and interoperability of services, and enhancing measurements in global health. This study explores the relevance of standards in global health, as well as the historical, ethical, economic, and political dimensions of setting and adopting standards in this area. It also explores the experiences of low- and middle-income countries in standard-setting, as well as the influence of international professional associations, multinational companies, and multilateral institutions such as the World Health Organization, the World Bank, and United Nations agencies.

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Contents

Abbreviations

Africa CDC	Africa Centres for Disease Control and Prevention
AHFS	American Hospital Formulary Service
AI	artificial intelligence
AQG	air quality guidelines
ARV	antiretroviral medicine
ASHP	American Society of Health-System Pharmacists
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
COVAX	COVID-19 Vaccines Global Access
DALY	disability-adjusted life year
DCP3	Disease Control Priorities, 3rd Edition
EMA	European Medicines Agency
EML	Essential Medicines List (the WHO Model List of Essential Medicines)
FAO	Food and Agriculture Organization
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration (United States)
FOP	front-of-the-package
Gavi	Gavi, the Vaccine Alliance
GBD	global burden of disease
GDWQ	Guidelines for Drinking Water Quality
GMP	good manufacturing practice
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HALE	Health-adjusted life expectancy
HSR	Health Star Rating
IAQ	indoor air quality
ICD	International Classification of Diseases

IHR	International Health Regulations
ISO	International Organization for Standardization
NAAQS	National Ambient Air Quality Standards
NSS	non-sugar sweetener
NTD	neglected tropical disease
ODA	official development assistance
OECD	Organisation for Economic Co-operation and Development
PHEIC	public health emergency of international concern
$PM_{2.5}$	fine particulate matter (diameters that are 2.5 micrometers and smaller)
QALY	quality-adjusted life year
QUM	quality use of medicines
SDG	Sustainable Development Goal
TPP	target product profile
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WFME	World Federation for Medical Education
WTO	World Trade Organization

Introduction

The establishment of global norms and standards is one of the cornerstones of global health—and a key reason why they are so foundational relates to the very definition of "global health." A widely recognized definition from the U.S. National Academy of Medicine (formerly the Institute of Medicine) frames global health as a goal–specifically, "the goal of improving health for all people in all nations by promoting wellness and eliminating avoidable disease, disability, and death" (Institute of Medicine 2009). This goal can be achieved by combining population-based interventions—which can be internal to the health sector (such as vaccination campaigns) or external to the health sector (such as reducing air pollution)—with individual-level interventions in clinical care, including those targeting disease prevention, treatment, rehabilitation, and palliation. Ensuring that these two interventions meet established norms and standards based on the best available scientific evidence and that they can be implemented in varying contexts are critical drivers in achieving this goal.

A strong base of empirical research demonstrates that the adoption of standardized evidence-based interventions that are effective, safe, and high quality is a major driver of progress in global health (Yamey and Volmink 2014). For example, national health policy makers, public health workers, and clinicians in a country facing a high burden of endemic malaria can adopt the recently updated World Health Organization (WHO) malaria guidelines, which serve as evidence-based practices in the control of malaria (WHO 2024a). The guidelines set out recommended standards for: (1) controlling the mosquito vector that transmits malaria; (2) using malaria medicines to prevent the disease (preventive chemotherapies); (3) how to use the world's first two licensed malaria vaccines (both licensed since 2021); (4) diagnosing and treating malaria; (5) eliminating malaria to achieve malaria-free status; and (6) surveillance of malaria. The guidelines also summarize the level of strength of each recommendation (such as "strong recommendation," "conditional recommendation") and the level of certainty of the evidence supporting these recommendations (such as "high," "moderate," "low"), as well as provide "good practice statements."[1]

The global health community looks to the World Health Organization (WHO) as the key global norm-setting body, an agency with an "unrivalled reputation in setting global standards" in global health (Yamey 2002). Member states of WHO highly value its normative products, which include guidelines, standards, classifications, policy options, implementation guidance, learning materials, evaluation methods, and research agendas (Askie et al. 2024). WHO's credibility in setting norms and standards derives both from its inclusive governance mechanism (it is governed by its 194 member states through the World Health Assembly) and its convening power (its ability to bring together experts into committees to help determine best practice) (Yamey 2002). Some experts have argued that WHO is the only agency with the authority to develop and implement international health norms and standards and facilitate ongoing dialogue among member states on priorities (Prah Ruger and Yach 2009).

Nevertheless, such standard-setting is not a straightforward scientific, technocratic exercise conducted seamlessly by a single agency without regard for political economy considerations and ethical challenges. For example, the processes for setting standards at WHO have been criticized for their lack of rigor and transparency, such as failing to be based on systematically reviewed evidence, lacking the use of appropriate methodological expertise, and lacking focus on the challenges of implementing the standards. Another criticism relates to the inadequate consultations with end users such as public health workers, clinicians, and health researchers based in low- and middle-income countries. The process is often too "top-down," with technical working groups dominated by experts from advanced economies neglecting the realities of the health systems in low- and middle-income countries, as well as the cultural contexts in these countries (Askie et al. 2024; Gopinathan and Hoffman 2018; Oxman, Lavis, and Fretheim 2007).

WHO has worked to address these criticisms through a process of reform (see discussion in the third section of this paper). In 2007, it launched a Guidelines Review Committee to help ensure that its guidelines are based on the best available evidence. Its 13th General Programme of Work, which set out its strategy for the five-year period between 2019 and 2023, emphasized evidence-based practice and normative guidance. In 2019, WHO launched a Science Division and appointed its first Chief Scientist to oversee it and lead the reform process. And in April 2021, WHO's Director General launched a Science Council to provide guidance on scientific issues.

Other multilateral and regional agencies, such as the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Bank, and the Africa Centres for Disease Control and Prevention (Africa CDC), also generate normative products related to health. The extent to which countries adopt these recommended standards from different agencies depends on the country's capacity for evidence-based policymaking and policy implementation, on whether the legislative environment is conducive, and on the availability of adequate financing to purchase the recommended interventions such as medicines and other health technologies. In addition, ethical considerations play a role at all stages in the diffusion of global standards to local contexts. For example, if the best available evidence suggests that the optimal treatment for a specific disease is an expensive medicine that only high-income countries can afford, it raises the question: what are the ethical ramifications of a global norm-setting body like WHO recommending it as a global standard?

This study examines the opportunities that standards provide in rapidly reducing mortality and morbidity rates worldwide, as well as the many challenges in setting global health standards. It identifies options to strengthen the setting, diffusion, and implementation of global health standards in ways that can help improve global health outcomes. In doing so, the study adopts a broad view of what constitutes global health norm and standard-setting, given the wide range of normative products applicable in global health, from regulations to guidelines to effectiveness standards and other products. The first section provides a framework for thinking about standard-setting in global health. The second section discusses the enforcement and implementation of health standards, including the roles of global mandatory and voluntary standards and the conditions under which mandatory standards are more likely to apply. The second section also discusses the tools available to governments, such as national legislation. The third section discusses the political economy of standard-setting in global health. The fourth section highlights the challenges faced by both the standard "makers" and the standard "takers" in global health. The last section presents a set of recommendations.

A framework for standard-setting in global health

A proposed framework for thinking about standard-setting in global health considers questions of who, what, and why: *who* are health standards set for, *what* dimensions of health are being standardized, and *why* are health standards used?

Who are global health standards set for?

Norms, guidelines, or standards guide those who work in any domain of global health.[2] For example, pharmaceutical manufacturers follow WHO Good Manufacturing Practice (GMP) to ensure their products are of high quality (WHO 2014a); clinicians use clinical practice guidelines; and health researchers adopt the EQUATOR network's international standards for reporting different types of studies.[3] The end users of global health standards can be categorized by the level of the global health system in which they operate (refer to figure 1). Such categorization is also helpful when examining what issues standards are addressing and for seeing how common standards, such as WHO prequalification of medicines, can apply across multiple levels of the system.

Figure 1. End users of global health standards based on the level of the global health system in which they operate

Source: Original work for the *World Development Report 2025*.
Note: The figure is not representative of all end users.

Global health organizations and aid donors

Many health standards apply to global health organizations and multilateral and bilateral aid agencies, such as standards that aim to coordinate, align, and harmonize the work of these organizations in order to improve the effectiveness of health aid in recipient countries. Over the last two decades, donor and recipient countries signed multiple coordination and aid effectiveness standards, most of which applied to official development assistance more broadly rather than being specific to health aid. But nonetheless, they were relevant to health aid.

Wickremasinghe et al. (2018) summarized the six key principles of aid effectiveness that such standards aim to drive: (1) country ownership over programs; (2) alignment between donor funding and country priorities; (3) harmonization of donor activities (to avoid duplication and fragmentation of efforts); (4) transparency and accountability; (5) providing predictable, long-term funding; and (6) engaging civil society. Examples of such standards include the Paris Declaration on Aid Effectiveness (OECD 2005) and the Accra Agenda for Action (OECD 2008). The Lusaka Agenda—a culmination of a 14-month consultative process called "The Future of Global Health Initiatives"—is a more recent set of standards aimed specifically at (1) improving strategic and operational coordination and coherence among global health initiatives in how they support primary health care, (2) strengthening health systems, and (3) ensuring sufficient domestic financing of health services, health equity, and the development and manufacturing of health products in underserved regions (Future of Global Health Initiatives 2023).

The pooled procurement (that is, the large-scale purchase) of health products such as medicines and vaccines is another example of global health organizations as end users of global standards. Multilateral health agencies such as Gavi, the Vaccine Alliance; UNICEF (United Nations Children's Fund); and the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), are bound by their rules to only purchase products that have undergone an approved, standardized pre-qualification program that ensures their safety and effectiveness.

Regional health organizations

Standards set at the global level, such as those set by WHO, typically diffuse through multiple levels of the system, including to regional health organizations such as WHO's six regional offices.[4] A wide range of characteristics such as the types and burden of diseases, demographics, and the presence of conflicts, can vary across regions and hence the need to adapt global standards to regional contexts. Reinap et al. (2024) describe the process of how WHO guidelines are adapted to a region's context, using Europe as a case study.

In addition to regional health organizations adopting global health standards, one of the most important recent shifts in the global health architecture has been the rising influence of regional bodies that are now setting their own norms and standards. For example, for the first time since its creation in 2017, the Africa CDC declared a Public Health Emergency of Continental Concern related to its mpox outbreak in August 2024 through a standard-setting process based on its statutes that mandate it to mobilize and coordinate a regional outbreak response (Africa CDC 2024). However, if there are multiple regional bodies with similar mandates in standard-setting such as the WHO African Region office and the Africa CDC, this overlap can lead to challenges in coordination and inefficiencies (Lancet 2023).

National level policy makers

Global health norms and standards are used by a wide range of policy makers at the national level, especially ministries of health and finance in their planning and financing of health services and strengthening of health systems. This study provides the example of global standards guiding national planners in their choice of health interventions to be included in universal health coverage packages.

National policy makers use global norms and standards to develop packages of interventions to achieve universal health coverage (that is, achieving the goal of ensuring access to quality, affordable services to all people when they need them, along with financial risk protection). A key global norm-setting database is the Universal Health Coverage Compendium, a database of health services and intersectoral interventions designed to assist countries in making progress toward universal health coverage.[5] The compendium is accompanied by the WHO's Universal Health Coverage Service Planning, Delivery, and Implementation Platform that guides governments in creating packages of universal health coverage interventions that can be implemented and tailored to country contexts,[6] taking into account countries' financial transition away from development aid toward domestic health finance and aspects of countries' changes in demographics and epidemiology. For example, the third edition of Disease Control Priorities (DCP3), another global compendium of cost-effective interventions, defines a "high priority package" for countries with limited fiscal resources versus a broader package, "essential universal health coverage," for countries that have greater fiscal resources.[7]

Public health programs and providers

National disease control programs, such as those for HIV, tuberculosis, malaria, vaccine-preventable diseases, and noncommunicable diseases, are key end users of global standards in population health approaches to reducing the burden of disease. For example, several dimensions of the WHO malaria guidelines target public health programs and providers, such as malaria vaccination campaigns and large-scale vector control (including through the mass distribution of bednets treated with long-lasting insecticides).

Given the adage that "an outbreak anywhere can become an outbreak everywhere" (that is, it can become an epidemic or pandemic), standardized public health approaches have been developed that target public health providers, including epidemiologists and field investigators. These standards include the legally binding International Health Regulations (IHR) that require countries to detect, assess, and respond to public health threats that can cross national borders; minimal requirements for disease surveillance; and standardized toolkits for the investigation of outbreaks.[8]

Clinical providers

Clinical practice guidelines generated by WHO and other international bodies, such as guidelines on managing heart disease developed by the World Heart Federation, are established primarily for providers of care at the individual level, with the goal of improving patient outcomes through standardization of best practice. For example, the WHO malaria guidelines include guidance for clinicians on treating a patient with malaria. Examples of other recent WHO guidelines include those for treating pneumonia and diarrhea in children and managing serious bacterial illness in infants.[9] But the process for developing WHO guidelines has come under scrutiny in recent years (Askie et al. 2024), leading to reforms such as the introduction of a Guidelines Review Committee (refer to the fourth section for more information). A range of other standard setters also produce clinical guidelines, including international societies such as the International Society of Hypertension,[10] the International Diabetes Federation,[11] and the International Federation of Gynecology and Obstetrics.[12]

Health researchers

Standards set primarily for health researchers include best practice guidelines for conducting particular types of studies (such as household surveys, clinical trials); standards for the ethical conduct of medical research involving human participants (such as the Declaration of Helsinki) (WMA 2024); ethical standards for conducting research during public health emergencies (WHO 2020a); and standards for improving the quality of research reporting.[13]

Medical product developers

One standard-setting process aimed at developers of medical products is WHO's target product profiles (TPPs), which can help guide these developers toward developing products that are necessary but currently absent. These TPPs describe the desired characteristics of a product aimed at tackling a specific disease or diseases such as the ideal efficacy, safety characteristics, and the target population (Moorthy and Yamey 2022). Examples of published TPPs include a TPP for a common pneumonia caused by the bacterium *Streptococcus pneumoniae* and a TPP for Ebola vaccines. In both cases, the needed vaccines have been developed, licensed, and provided to those most at risk following the preferences articulated by the WHO TPP documents (Moorthy and Yamey 2022).

What dimensions of global health are being standardized?

This study categorizes standards into three types: minimum quality standards; compatibility standards; and measurement standards, and discusses some of the major dimensions of global health where standards are being applied.

Minimum quality standards

A key example of a minimum quality standard is the *regulation of medicines, vaccines, and diagnostics*—one of WHO's core functions. Such regulation is aimed at ensuring that medical products are safe and effective, and that they meet quality standards for pooled procurement by global health funding agencies. This process of regulation has many components, including prequalification, quality assurance, guidelines on inspecting pharmaceutical manufacturing plants, monitoring for fake or substandard medicines, and standards on the choice and use of diagnostics. WHO launched its Prequalification of Vaccines Programme in 1987, its Prequalification of Diagnostics and Medical Devices Programme in 1988, and its Prequalification of Medicines Programme in 2001 (starting with prequalifying the safety, efficacy, and quality of antiretroviral medicines [ARVs]). Most ARVs administered worldwide have been prequalified by WHO, as have nearly two-thirds of vaccines procured globally as of 2023 (WHO 2024b).

Health facilities and equipment standards specify the minimum acceptable characteristics of health care spaces and equipment that would guarantee the provision of good quality health care. In a joint report issued in 2018, WHO, World Bank Group, and the Organisation for Economic Co-operation and Development (OECD) discuss the quality of health care and list health facilities and devices as two of the five foundational elements of a good quality health system. In addition, WHO hosts a robust quality of health care program that collates evidence-based recommendations for global dissemination. Through this program, they collaborate with important partners such as PATH, the Institute for Healthcare Improvement, the International Society for Quality in Healthcare, and ministries of health across various countries to both adopt and adapt these recommendations (PATH 2020; WHO 2024c).[14] In response to more recent challenges like climate change, WHO has partnered with other relevant organizations to issue guidance on how to build climate resilient and environmentally sustainable health care facilities (WHO 2020b). Furthermore, WHO, in collaboration with USAID (the United States Agency for International Development), developed a service availability and readiness assessment tool to help countries assess and track the readiness of their health facilities to provide good quality care (O'Neill et al. 2013).

Guidelines aimed at improving public health or clinical practices are another type of minimum quality standard. They guide end users in implementing specific evidence-based actions that satisfy standards for safe, effective, and high-quality practices, such as in managing outbreaks, choosing diagnostics, or treating specific illnesses.

Ethical standards are widely applied across global health research to ensure the safety and protection of humans who participate in medical research. Important considerations include protecting the health, rights, privacy, autonomy, confidentiality, and dignity of participants, as well as taking measures to reduce risks and burdens (WMA 2024).

Applying minimum quality standards can also benefit the field of medical education and training. Different cadres of health workers (physicians, nurses, community health workers, and so on) must fulfil specific training requirements before they can be licensed to provide patient care (WHO 1974). These requirements specify the duration of training and a list of subject matter areas, skills, and experience that must be mastered. Global institutions such as WHO, the World Federation for Medical Education (WFME), and the International Council of Nurses collaborate with national governments to ensure these standards are met (Weisz and Nannestad 2021; WFME 2020; WHO, Regional Office for the Western Pacific, 2001).

Compatibility standards

Global compatibility and interoperability standards in health informatics have been widely adopted and applied across a diverse range of areas related to health. For example, the International Organization for Standardization (ISO) Technical Committee 215, which sets standards on health informatics, aims to facilitate the capture, interchange and use of health-related data, information and knowledge.[15] Examples of published ISO standards applicable to global health include those for genomics informatics, telehealth, and personalized digital health.

Regulatory harmonization is another type of compatibility standard in which regulatory agencies of health products worldwide align their activities to ensure there are common technical requirements for product development and marketing. A related concept is *regulatory reliance,* in which the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision (WHO 2023a). Schäferhoff et al. (2024) note that regulatory harmonization enables work sharing between agencies, including joint reviews of marketing authorization applications, joint inspections of manufacturing sites, and the increased use of reliance in health product regulation.

Some minimum quality standards, such as standards for medical education and health facility standards, can also be classified as compatibility standards. Specifying minimum standards for health care facilities enables manufacturers to produce medical equipment that can be used in similar facilities across different countries. Similarly, by ensuring that the minimum standards for medical education are met before licensing health workers, workers trained in one country can more easily migrate to and work in another country with minimal restrictions. However, some countries intentionally create special categories of health workers that are recognized only in their countries; thus, these workers cannot migrate with any transferable skills (for example, physician assistants in the United States and clinical officers in Tanzania).

Measurement standards

Standardized health research tools generated by normative bodies set out standardized guidance for studying the health of populations, such as through health surveys, cohort studies, and other tools for health assessment. A key example are the Demographic and Health Surveys, a program of standardized household surveys administered in more than 90 countries that use standardized model questionnaires and are based on nationally representative samples.[16]

The International Classification of Diseases (ICD), which has now undergone its 11th revision (ICD-11), standardizes the diagnosis of diseases and causes of death globally. The ICD is a critically important measurement standard that is also a compatibility standard, as it allows a comparison of data on disease morbidity and mortality across different regions and countries, and across time. Such comparisons are possible because the diseases are classified in the same way universally. The disease statistics generated by the ICD are fundamental to global health, including health services research, health payment systems, and health planning (Harrison et al. 2021). The ICD also functions as an important global measurement standard for health conditions and diseases. Adding a new code to the ICD formally recognizes the new condition and clarifies the difference between that condition and others. This in turn can spur additional research and health care payments for that condition.

Additionally, the Anatomical Therapeutic Chemical (ATC) classification system was developed by WHO to classify drugs and other medical products. It describes what a drug is, how it works, what it is used for, and how it is used for drug utilization research, pharmacovigilance, and regulatory purposes.[17] There are also country-specific classifications such as the American Health Formulary Service (AHFS) Pharmacologic-Therapeutic classification system maintained by the American Society of Health-System Pharmacists (ASHP) in the United States. The AFHS organizes drugs by therapeutic use and pharmacologic properties and is used to facilitate the review of drugs and medical safety efforts (ASHP 2016).

Global health estimates, including summary measures of health (such as disability-adjusted life years [DALYs], quality-adjusted life years [QALYs], and health-adjusted life expectancy [HALE]), provide standardized data on the causes of disability and death worldwide based on a variety of sources, such as WHO technical programs and the Global Burden of Disease study.[18]

Why use standards in global health?

The previous sections that discussed who standards are *for* and *what* dimensions of global health are being standardized have pointed to the primary reasons *why* global health standards are used, Five of the most important of these reasons are discussed next: (1) improving health outcomes; (2) promoting equity; (3) driving efficiency/value for money; (4) comparing health data across places and over time; and (5) stimulating innovation.

Improving health outcomes. Several decades of research provide strong evidence that the adoption of standards can improve many aspects of health care and public health. For example, rigorous evaluations of clinical practice guidelines have shown that such guidelines can improve the process and quality of care (Grimshaw and Russell 1993). Adherence to such guidelines has been associated with improved patient outcomes across a wide range of diseases, including heart failure, breast cancer, and pneumonia (Murad 2017). Standardized surgical checklists outlining a list of steps to be adhered to by the surgical team, such as verifying the patient's identity and marking the surgical site, have been shown to reduce the rate of surgical complications, including mortality (Haynes et al. 2009; Qaiser et al. 2024). Standardizing treatment of childhood illnesses in communities and health facilities through the approach, Integrated Management of Childhood Illness, which includes clinical algorithms, is associated with reduced childhood mortality when used at scale (Gera et al. 2016). For the prevention and management of global health crises such as pandemics, adopting common approaches to key elements such as the surveillance and reporting of outbreaks aims to minimize global morbidity and mortality. Environmental standards, such as those related to air or water quality, play an important role in protecting and promoting public health.

Promoting equity. By setting out principles for universality in the delivery of essential health services through universal health coverage, standard-setting processes in global health also play an important role in promoting equity. The UN Political Declaration on Universal Health Coverage played a pivotal role in establishing political commitments at the global level and setting standards for achieving universal health coverage (United Nations 2019). The declaration outlined principles and benchmarks that countries should follow to ensure progress toward universal health coverage, such as equity, financial risk protection, and access to essential medicines, vaccines, and health facilities. Some 89 percent of countries have made universal health coverage a central goal in their national health policy plans and strategies and 41 percent have enacted legislation to support universal health coverage, according to a 2023 study by UHC 2030, a global partnership that works to accelerate progress toward achieving universal health coverage.[19]

To assist countries in fulfilling these commitments, WHO offers several tools and frameworks for countries to develop universal health coverage benefits packages that are tailored to their local needs, availability of resources, and priorities. These tools include the Universal Health Coverage Compendium of Health Interventions, a digital tool that lists over 3,000 evidence-based intervention;[20] the Services Package Delivery and Implementation Tool, which assists countries in translating selected interventions into service packages that can be implemented within the local context;[21] and Disease Control Priorities, a compendium of the most cost-effective essential health interventions and highest priority packages endorsed by WHO. The compendium can be adopted by resource-constrained countries (Watkins, Qi, and Horton 2017). Such tools and processes establish norms and provide guidance on a standard to ensure that *all people* have the right to access quality health services when needed regardless of their income level, while accounting for the local context.

Driving efficiency/value for money. Several global health standards previously described have an important component of efficiency, such as governments adopting national essential medicines lists guided by the WHO Model List or the use of standards in the design and implementation of health benefits packages. National essential medicines lists can be used to rationalize the use of medicines, such as by matching the choice of medicines to the burden of disease, to ensure that the use is evidence-based and that costs are controlled by using low-cost generics of equal efficacy to expensive branded formulations. As for benefits packages, the Disease Control Priorities project has developed an "essential universal health coverage package" of interventions that represent high value for money and is supporting several countries in the implementation of the package (Watkins et al. 2020).

Comparing health data across places and over time. Compatibility and measurement standards, including the ICD-11, standardized household surveys, and global health estimates using DALYs, aim to ensure consistency in how disease is measured in order to determine trends over time and make comparisons between countries and regions. DALYs have been critical in showing that some diseases or conditions, such as neglected tropical diseases (NTDs) and mental health conditions, are highly disabling even if they are not a major cause of premature mortality. Such findings, in turn, have led to policy action.

Stimulating innovation. A standardized approach to the development of medical products helps to identify market failures in global health, such as in cases where few products (or none at all) exist for important conditions, including neglected tropical diseases. Global health standards like TPPs identify these gaps, the products that are required, and the ideal product characteristics around which product developers and research funders can align (Moorthy and Yamey 2022).

Implementing and enforcing global health standards

While WHO plays a pivotal normative role in global health by establishing standards and guidelines to promote public health and ensure consistent practices among member states, the organization (along with other global standard-setting bodies that influence global health such as WHO and ISO) lack the power to enforce these standards, because the standards they set are rarely legally binding. Most standards they set are voluntary but they encourage or expect countries to adopt them through national instruments such as national laws, regulation, or policies, as well as through technical support, monitoring, linking standards to the Sustainable Development Goals (SDGs), and through global financing mechanisms (including the Global Fund and Gavi).

While there are no clear criteria outlined for determining whether standards become mandatory versus voluntary, this study argues that four underlying principles are very important.

1 *The severity of the risk*. For example, in the face of a public health emergency of international concern (PHEIC), such as epidemics and pandemics, the International Health Regulations (IHR) were made legally binding upon member states.

2. *The degree of consultation and buy-in from key stakeholders.* The Framework Convention on Tobacco Control (FCTC) was adopted as mandatory as a result of broad consultation with member states and stakeholders.

3. T*he feasibility of adoption and availability of enforcement mechanisms.* For example, the WHO EML and the WHO Air Quality Guidelines (AQGs) are voluntary, but countries are encouraged to integrate them into their national policies.

4. *In the case of vaccines, the strength of the scientific evidence combined with the opportunity for community-wide protection*. For example, 194 member states have endorsed WHO's Global Vaccine Action Plans, which are voluntary, but during pandemics such as the COVID-19 pandemic, some countries mandated mass vaccination.[22] A 2021 study of childhood vaccination policies worldwide

found that 89 countries had a policy of mandating one or more childhood vaccines and 20 had a policy of mandating vaccination for school entry (Vanderslott and Marks 2021).

Table 1 summarizes some of the key mandatory and voluntary standards and guidelines used in global health. The discussion that follows the table examines five key standards that shed light on the discussions and debates surrounding mandatory versus voluntary standards in global health, the enforcement of mandatory standards, and the national adoption and adaptation of such standards: (1) IHR; (2) FCTC; (3) the WHO Essential Medicines List (EML); (4) mandatory versus voluntary nutrition labelling; and (5) WHO's AQGs.

Table 1. Key mandatory and voluntary standards in global health

Standard/Guideline	Standard-setting body	Voluntary vs. mandatory	Description
International Health Regulations (IHR) of 2005[a]	WHO	Mandatory (treaty-based for 196 countries)	Legally binding framework that requires countries to detect, assess, and respond to public health risks that have the potential to cross borders (such as pandemics)
Framework Convention on Tobacco Control (FCTC)[b]	WHO	Mandatory for ratifying countries	Legally binding global treaty to control the use of tobacco, including advertising bans, taxation, and packaging
Essential Medicines List (EML)[c]	WHO	Voluntary, recommended for adoption	Universal list of essential medicines that countries often voluntarily adapt to their local needs
Global Vaccine Action Plan (GVAP)/ Immunization Standards[d]	WHO	Voluntary, but mandated at the national level by some countries	Provides guidance on immunization programs, but countries can mandate vaccines (for example, for COVID-19, measles, other childhood diseases) at the national level
Codex Alimentarius: Food Safety Standards[e]	FAO/WHO	Voluntary	Voluntary guidelines for national policies on food safety, labelling, and hygiene; used by the WTO in trade law
International Classification of Diseases (ICD-11)[f]	WHO	Voluntary, recommended for adoption	Widely used global standard for diagnostic health information
Global Health Sector Strategies[g]	WHO	Voluntary framework for strategic guidance	Standard framework used to guide strategies and help set global goals and targets for disease control such as HIV, and hepatitis.
ISO 27799: 2016 Health informatics – Information security management in health using ISO/IEC 27002[h]	ISO	Voluntary	Data security standards for health information systems that hospitals can adopt for compliance and that countries can adopt into national law
Air Quality Guidelines (AQGs)[i]	WHO	Voluntary	Evidence-based recommendations for limits to air quality that minimize health risks
Guidelines for Drinking Water Quality (GDWQ)[j]	WHO	Voluntary	Evidence-based recommendations for the management and supply of safe drinking water with health-based limits of contaminants

Sources: FAO; ISO; UN; WHO.
Note: FAO = Food and Agriculture Organization; ISO = International Organization of Standardization; UN = United Nations; WHO = World Health Organization.
a. IHR: https://www.who.int/publications/i/item/9789241580496.
b. FCTC: https://fctc.who.int/.
c. EML: https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists.
d. GVAP: https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/global-vaccine-action-plan.
e. Codex Alimentarius: https://www.fao.org/fao-who-codexalimentarius/en/.
f. ICD-11: https://icd.who.int/en/.
g. Global Health Sector Strategies: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/strategies/global-health-sector-strategies.
h. ISO 27799:2016: https://www.iso.org/standard/62777.html.
i. AQGs: https://www.who.int/publications/i/item/9789240034228.
j. GDWQ: https://www.who.int/publications/i/item/9789240045064.

Implementation and enforcement of five key global health norms and standards

International Health Regulations

The International Health Regulations (IHR) are the primary legally binding instrument under the purview of WHO and apply to 196 member states. Adopted in 1969 and revised in 2005 and 2024, the IHR aim to minimize the risks of threats to cross-border health by mandating countries to build their capacity to detect, assess, and respond to public health risks and emergencies. The IHR require member states to appoint an IHR focal point, to conduct public health surveillance, and to follow legally binding reporting requirements for a public health emergency of international concern (PHEIC).

The mandatory nature of the IHR does not necessarily ensure compliance. Although the IHR are legally binding for 196 member states, WHO lacks the legal mandate to enforce them. Moreover, gaps in compliance such as poor data sharing are common, as seen during the COVID-19 pandemic. Kavanagh et al. (2023) find that the key reasons for noncompliance include insufficient resources in low- and middle-income countries for the preparedness of outbreaks and response activities (such as surveillance); poor awareness by countries of their obligations; a range of administrative, legal or political obstacles; and countries prioritizing trade, finance, and intellectual property treaty obligations over the IHR. Without an enforcement mechanism and WHO's inability to impose penalties for noncompliance, other approaches are likely to be needed to improve compliance (refer to the fifth section for a further discussion).

There is also scope to improve the consistency, transparency, and timeliness of PHEIC declarations to enhance global health security. PHEIC declarations have significant implications for mobilizing resources, guiding international responses, and influencing travel and trade policies. Mullen et al. (2020) examined the processes and outcomes associated with WHO's declarations of a PHEIC under the IHR. Since the IHR's revision in 2005, WHO has declared PHEICs for several events, including the H1N1 influenza pandemic (2009), Ebola outbreaks (2014 and 2018), polio resurgence (2014), Zika virus outbreak (2016), the COVID-19 pandemic (2020), and mpox (2022 and 2024). The establishment of emergency committees has been pivotal in assessing potential PHEICs. However, there has been variability in the transparency and documentation of the deliberations of these committees, which can affect global understanding and response strategies (Mullen et al. 2020). Furthermore, there have also been delays in the timing of PHEIC declarations and a lack of uniform application of the IHR criteria, as their application is heavily influenced by political, economic, and social considerations (such considerations are discussed more fully in the third section of this paper).

Framework Convention on Tobacco Control

The WHO Framework Convention on Tobacco Control (FCTC), adopted in 2003 and entered into force in 2005, is the first global health treaty. It was ratified and implemented by more than 180 countries to combat the global tobacco epidemic through evidence-based strategies (WHO 2025a).

Under the FCTC, signatories are required to: (1) implement measures to reduce tobacco demand through taxation and pricing strategies; (2) mandate clearly visible health warnings on tobacco packaging to inform consumers about the risks associated with the use of tobacco; (3) enforce comprehensive bans on the advertising, promotion, and sponsorship of tobacco to reduce the appeal of tobacco products; (4) protect individuals from exposure to tobacco smoke by establishing smoke-free public and work environments; and (5) offer assistance to individuals seeking to quit tobacco use through accessible cessation programs.

The main mechanism for promoting compliance is the requirement for countries to report on their implementation activities to the Conference of the Parties (the FCTC's governance mechanism) every two years. WHO also initiated an Implementation Review Mechanism in 2019, although its rollout was delayed by the COVID-19 pandemic (WHO 2019).

However, implementation and enforcement of FCTC provisions has been fraught with challenges, despite their widespread adoption. First, tobacco companies have actively lobbied against strict regulations, delaying or weakening enforcement in some countries. Second, some economies, particularly low- and middle-income countries, rely heavily on tobacco production and trade and therefore, these governments are reluctant to fully implement the treaty. Furthermore, some governments resist implementation due to concerns over job losses in the tobacco industry and reduced tax revenues (Flintoff et al. 2024). For example, in China the tobacco industry contributes to about 7 percent of the central government's revenue, leading to lax enforcement of smoking regulations (WHO, Western Pacific Region; UNDP 2017). Third, many countries lack the legal mechanisms and infrastructure to enforce tobacco control policies effectively (WHO 2025b). In addition, the illegal sale of tobacco products undermines taxation policies and efforts to promote public health (WHO 2024b).

Despite these challenges, the adoption of the FCTC has led to significant advancements globally in the control of tobacco. WHO bolstered country and regional efforts to introduce and enforce tobacco control laws, such as Kenya's 2014 Tobacco Control Regulations, the Islamic Republic of Iran's National Tobacco Control Act, and the European Union's 2014 EU Tobacco Products Directive. The FCTC has enabled the enforcement of existing legislative frameworks and garnered political support for tobacco control initiatives in several countries (Craig et al. 2019). For example, by 2021, 134 countries had mandated that warnings on tobacco packages cover at least 50 percent of the package's surface area, in line with FCTC guidelines to ensure that health warnings are more prominently displayed. In that same year, 122 countries required that health warnings be in the form of a graphic, enhancing the impact and visibility of health messages on tobacco packages. Countries such as Australia, Canada, and Thailand have implemented laws requiring plain packaging, which makes tobacco products less appealing and discourages tobacco use, and strong graphic warnings. Both requirements have played a role in reducing the rates of smoking (Cohen et al. 2020).

Table 2, based on Paraje et al. (2024), compares trends in the number of smokers and the prevalence of tobacco use and cessation before and after the FCTC was ratified. Ten years after ratification the projected number of smokers under 25 years had fallen by 15.5 percent and the prevalence of smoking within this age group had dropped by 7.5 percent. Additionally, the quit ratio (former smokers divided by people who had ever smoked) among individuals aged 45–59 years increased by 1.8 percent. Countries that increased their taxes on tobacco by at least 10 percentage points experienced more significant declines across all metrics: a 28.4 percent reduction in the number of young smokers, a 21.8 percent decrease in prevalence, and a 5.5 percent increase in the quit ratio. Low-income countries experienced the most substantial reductions, with a 54.9 percent reduction in the number of young smokers and a 36.8 percent reduction in prevalence. However, the quit ratio declined by only 1.7 percent. High-income countries saw modest reductions in the number of young smokers (1.9 percent) but a more substantial reduction in prevalence (an 11.5 percent decrease) and the quit ratio (a 1.5 percent increase) (Paraje et al. 2024).

Table 2. Projected impact of FCTC one decade after its adoption, by income levels and by adoption of type of tax policy

Category	Percent reduction in the number of young smokers (under the age of 25)	Reduction in share of smokers under the age of 25 (as share of total smokers)	Quit ratio (ages 45–59) (former smokers as share of total number of people who had ever smoked)
Global (excluding China)	-15.5%	-7.5%	+1.8%
High-income countries	-1.9%	-11.5%	+1.5%
Upper-middle-income countries	-32.3%	-11.0%	-1.1%
Lower-middle- income countries	-8.4%	-6.8%	+0.7%
Low-income countries	-54.9%	-36.8%	-1.7%
Countries that increased their tobacco tax by 10% or greater	-28.4%	-21.8%	+5.5%
Countries that did not increase their tobacco tax, or increased it by less than 10%	-11.5%	-7.1%	-1.4%

Source: Adapted from Paraje et al. 2024.

WHO Essential Medicines List

Unlike the IHR and FCTC, many of WHO's standards are advisory, such as those related to medical products, air quality, nutrition, and clinical practice. Some of these voluntary standards and guidance have been widely adopted and adapted and have led to positive health outcomes. For example, WHO has encouraged many low-income and middle-income countries to develop their own national essential medicines lists (NEMLs), guided by the WHO EML, thereby improving access to essential medicines.

The WHO EML, first developed in 1977, is defined as a list of medicines "of utmost importance, basic, indispensable and necessary for the health and needs of the population" (WHO 1977). The 1977 list included 186 medicines, but it had expanded to 502 medicines by 2023, as more treatments entered the market. The EML is updated every two years through a rigorous, evidence-based, and consultative process led by the WHO Expert Committee on the Selection and Use of Essential Medicines. WHO invites government stakeholders, experts, health professionals, and non-governmental organizations to submit additions, removals, or amendments of medicines on the list (Piggott et al. 2024). All submissions must be backed by strong scientific evidence on the efficacy, safety, cost-effectiveness, and public health relevance of the medicines. The WHO Secretariat conducts a preliminary review of the list, followed by a review by the Expert Committee, accompanied by additional independent evaluations (where necessary) and further deliberations and discussions, before publishing the list (WHO 2023b). Key aspects of the process are summarized in table 3.

Table 3. Overview of the World Health Organization Essential Medicines List (EML)

Feature	Description
What is the EML?	A curated list of medicines that satisfy the priority health care needs of populations, based on evidence of efficacy, safety, and cost-effectiveness assembled and overseen by the World Health Organization (WHO)
What is the purpose?	To guide countries in developing national essential medicines lists (NEMLs) and ensure access to critical, life-saving medications
Is the EML updated?	Yes, the WHO Expert Committee on Selection and Use of Essential Medicines updates it every two years
What are the selection criteria?	○ Relevance to public health ○ Proven efficacy and safety ○ Cost-effectiveness in different settings
What categories are included?	Two key categories are included: • Core list: Specifies the minimum medicine needs for a basic health system • Complementary list: Requires specialized care or higher cost infrastructure
How is the EML used by countries?	Countries are encouraged to develop their own NEMLS by adapting the EML to: • The local burden of disease • Account for the available resources and infrastructure • Guide procurement and reimbursement • Shape standard treatment guidelines
Does the EML set manufacturing or import quality standards?	While the EML itself does not set pharmaceutical quality standards, WHO encourages procurement from manufacturers that comply with WHO prequalification, good manufacturing practices (GMP), or other stringent regulatory authorities
How is the EML related to the WHO Quality Norms?	The EML is linked to WHO's efforts in regulating medicine through: • The Prequalification Programme • The WHO Pharmacopoeia and GMP guidelines

Source: https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists.

According to Laing et al. (2003), the WHO EML has become a global concept used by governments and healthcare providers worldwide. National governments decide whether to adopt the list, and whether and how to adapt it to the local context within their country, with the WHO EML seen as a reference guide. More than 150 countries have developed their own national medicines lists (Piggott et al. 2024). NEMLs are tailored to address a country's specific health priorities and take into account the degree of availability of resources. They can also vary significantly depending on factors such as political commitment and health infrastructure. But overall, NEMLs have played a key role in developing standard treatment guidelines, promoting the rational use of medicine and improving the overall quality of health care. The updated EMLs have evolved to reflect changing disease burdens such as the growing burden of noncommunicable diseases and aging populations. NEMLs have enhanced the availability of essential treatments, particularly in public health facilities, by focusing on priority medicines. Studies have shown that the implementation of the WHO EML, along with the essential medicines policies promoted by WHO (such as free provision of medicines at the point of care, EML trainings for nurses and doctors, and promotion of rational use of medicines), is associated with improved quality use of medicines (QUM), particularly in low-income countries. For example, Holloway and Henry (2014) analyzed data from 2002 to 2008 and found that countries implementing NEMLs and WHO's essential medicine policies reported better QUM indicators, which are standardized measures used to evaluate how appropriately, safely, and effectively medicines are prescribed, dispensed, and used in health care settings. Notably, countries that adopted multiple policies—such as providing essential medicines free of charge at the point of care, integrating standard treatment guidelines into medical education, and establishing dedicated units to promote the rational use of medicine—demonstrated significant improvements in QUM indicators. This positive correlation was especially pronounced in countries with lower gross national income per capita (Holloway and Henry 2014). Such studies demonstrate that prioritizing essential medicines can in turn lead to an efficient allocation of limited resources and the most impactful treatments.

Nevertheless, while many countries have established NEMLs, the extent of their alignment with the WHO EML varies, reflecting differing national health policies and disease burdens (Peacocke et al. 2024). Piggott et al. (2022) compared 137 NEMLs with the 2017 WHO EML and found significant variation in alignment. Compared with the 406 medicines listed in the WHO EML, NEMLs listed anywhere between 43 to 983 medicines, with the median being 315. The NEMLs in Southeast Asian countries were most aligned with the WHO EML, while NEMLs among European countries were the least aligned. The NEMLs also included core medicines more often than complementary ones. While the study did not explicitly analyze the differences by income level, low-income countries such as The Gambia and Somalia had the shortest NEMLs. Ethiopia is the only low-income country with a long NEML that aligns highly with the WHO EML.

While the WHO EML can serve as a key tool for improving access to essential medicines in low- and middle-income countries, its successful implementation depends on various factors, including a government's commitment to implementing national policy, health care infrastructure, availability of resources, and international support mechanisms. Moreover, given the wide variations between the WHO EML and NEMLs, more efforts are needed to improve alignment and consistency, as well as to understand the decision-making processes that occur at the country level when adapting the list to the country context. Lastly, having an NEML and adopting WHO's recommendations does not necessarily translate to improved availability and access to essential medicines at health facilities. Bazargani et al. (2014) assess the availability of essential and non-essential medicines globally and find a median availability of 61.5 percent for essential medicines, compared with 27.3 percent for non-essential medicines, with lower rates in low- and middle-income countries. Furthermore, the availability of essential medicines was lower at public health facilities (40 percent) than at private facilities (78.1 percent).

Nutrition labelling

Unhealthy diets are a major risk factor for non-communicable diseases, such as heart disease, diabetes, and cancer. Poor diets contribute to 12 million deaths annually worldwide, the 2021 *Global Nutrition Report* estimates (Development Initiatives 2021). Nutrition standards can play an important role in promoting healthy and balanced diets, preventing nutrient deficiencies, and reducing the risk of non-communicable diseases.

Nutrition labelling is one key aspect of maintaining nutrition standards worldwide. These labels provide consumers with information about the nutritional content and health benefits of foods, aiding people in making healthier dietary choices. They also encourage manufacturers to improve product formulations. The Codex Alimentarius, established by the Food and Agriculture Organization (FAO) and WHO, offers international guidelines on nutrition labelling and health claims, aiming to harmonize standards and protect consumer health. Table 4 outlines the general process involved in Codex leading the development of nutrition guidelines. However, the actual process by which countries implement nutrition labelling and health claim regulations varies significantly, influenced by local public health priorities, consumer understanding, and trade considerations.

Table 4. The development of global nutrition labelling guidelines

Feature	Description
Organization leading the development of guidelines	Codex Alimentarius Commission, jointly run by the Food and Agriculture Organization (FAO) and World Health Organization (WHO)
Key document for guidelines	CAC/GL 2-1985 (Guidelines on Nutrition Labelling)
Process of developing the guidelines	Five-step process: 1. Submission of proposal based on need 2. Drafting of guidelines by the Codex Committee on Food Labelling 3. Review of guidelines by stakeholders, holding consultations, and receiving feedback from global experts, governments, scientists, and organizations 4. Obtaining approval by Codex Commission 5. Voluntary adoption or adaptation of guidelines by countries into national laws legislation
Use of the guidelines	• Used to develop national legislation on nutrition labelling • Referenced by the World Trade Organization (WTO) in trade disputes

Source: https://www.fao.org/fao-who-codexalimentarius.

Research shows that while many consumers read nutrition labels, their comprehension of the labels varies. Using simplified formats and clear information can enhance understanding and positively influence food choices (WHO 2004). Countries use different types of nutrition labelling systems. Studies have found that in countries with policies that mandate food labelling, particularly when the mandated label is a nutrient warning (that is, it flags products that contain high levels of ingredients of concern, such as sugars, total fats, saturated fats, trans fats, and sodium), manufacturers improve the nutritional content of the food supply, and consumers reduce their purchase and intake of products that contain high levels of ingredients of concern.

Some countries with mandatory labelling policies, such as Chile and Mexico, use nutrient profile models to classify or rank foods based on their nutritional value to prevent disease and promote health. Taillie and Duran (2024) found that mandatory nutrient profile models are more effective at identifying ultra-processed foods by targeting products high in sugar, sodium, saturated fat, and, more recently, non-sugar sweeteners (NSS). Based on emerging scientific evidence, NSS have been found to have no nutritional value and are associated with an increased risk of type 2 diabetes, cardiovascular disease, and mortality. As a result, WHO has issued guidelines to reduce the use of NSS for weight control; many countries are adopting this guidance in their nutrition labelling practices (WHO 2023c). For example, Mexico introduced an innovative policy that includes NSS in the list of ingredients that must be labelled, aiming to prevent companies from replacing added sugars with these sweeteners, a practice previously observed in Chile. On the other hand, voluntary traffic-light labelling systems[23] (used in Ireland and the United Kingdom) had no impact on improving the food choices of consumers.

To date, no country has implemented a voluntary nutrient warning label system, indicating that government regulation may be the only viable approach for adopting this labelling scheme (Taillie and Duran 2024). Australia provides an example of this observation. In 2014, the government of Australia instituted a voluntary front-of-the-package (FOP) nutrition labelling scheme, the Health Star Rating (HSR), in which the quality of foods was assigned a rating from 0.5 stars (least healthy) to 5.0 stars (most healthy). Two years later, the government implemented a scheme mandating that food companies label the country of origin of the food. Jones et al. (2024) assessed the uptake of these two labelling systems between 2015 and 2023 across four major Australian retailers and found that only 39 percent of eligible products displayed the HSR in 2023, a drop from 42 percent in 2021. On the other hand, the compliance rate for the mandatory country of origin labelling was 93 percent. The voluntary nature of the HSR allows manufacturers to selectively label products, often omitting the HSR on less healthy items, which can mislead consumers and diminish the overall effectiveness of the HSR in promoting healthier choices. Even at the national level in Australia, mandatory labelling systems ensured consistent and comprehensive nutritional information across all products compared with the voluntary labelling system, thereby enhancing the understanding of consumers and facilitating healthier dietary decisions.

Table 5. Status of mandatory and voluntary nutrition labelling

Countries with mandatory nutrition labelling policies	
Countries and year since mandatory adoption	**Type of nutrition labelling**
Thailand (2007); Chile (2016); Peru (2019); Israel (2020); Mexico (2020); Uruguay (2021); Argentina (2023); Brazil (2023); Colombia (2023); Venezuela, RB (introduced 2021, not yet implemented); Canada (introduced 2022; mandated from 2026)	Front-of-the-package labels showing calories, sugar, sodium, saturated fat, and trans fat contents. Chile and Mexico additionally require cautionary labels showing sweetener and caffeine contents not recommended for children.
Ecuador (2014); Sri Lanka (2015); Iran, Islamic Rep. (2016); Singapore (2022); Bolivia (proposed in 2016, not yet implemented)	Traffic light labelling system showing sugar, saturated fat and salt contents. The Islamic Republic of Iran additionally requires calorie content and traffic light labelling of protein and trans fat. Sri Lanka implements the traffic light labelling system for sugar in beverages as well. Singapore uses Nutri-Grade traffic light labelling on all beverages showing sugar and saturated fat contents.
Countries with voluntary government -supported nutrition labelling policies	
Countries	**Type of nutrition labelling**
Korea, Rep. (only for children's snacks); Saudi Arabia; United Arab Emirates; United Kingdom	Traffic light label highlighting calories, sugar, sodium, saturated fat, trans fat contents.
Austria, Australia, Belgium, France, Germany, Luxembourg, Netherlands, New Zealand, Portugal, Spain, Switzerland	NUTRI-SCORE, a five-color ABCDE nutrition label and rating system. Scoring/rating summarizes the product's nutritional value based on the composition of negative contents (energy density, sugar, saturated fats, salt) and positive contents (fruits and vegetables, fiber, and protein) Australia and New Zealand use a similar rating system, known as Health Star Rating.
Brunei Darussalam, China, Czechia, Croatia, Denmark, Finland, Iceland, Indonesia, Israel, Lithuania, Malaysia, Nigeria, North Macedonia, Norway, Philippines, Singapore, Slovenia, South Africa, Sweden, Thailand, Zambia, Zimbabwe	Healthy choice, smart choice food labelling to help consumers identify healthier food options. Endorsement logos showing foods approved by health organizations such as the Nigeria Heart Association and the Heart and Stroke Foundation of South Africa.

Source: Based on Taillie and Duran 2024.

Mandatory FOP labels provide uniform nutritional information, enabling consumers to make healthier food choices and encouraging manufacturers to reformulate products to improve their nutritional profiles. Taillie and Duran (2024) emphasized that mandatory FOP labelling is a crucial public health strategy to combat diet-related diseases globally. However, only 15 countries have mandatory FOP food labelling policies and 36 other countries have voluntary FOP nutrition label policies that recommend but do not mandate companies to label their products (refer to table 5).

Air quality guidelines

In 2021, 8.1 million global deaths were associated with air pollution, particularly related to ambient fine particulate matter ($PM_{2.5}$) and ozone (O_3). $PM_{2.5}$ accounted for 58 percent of these global deaths, household air pollution contributed to 38 percent, and ozone exposure was linked to 6 percent (Health Effects Institute 2024). To address rising health threats posed by air pollution, WHO introduced air quality guidelines (AQGs), nonbinding guidelines to limit major pollutants, such as $PM_{2.5}$, coarse particulate matter (PM_{10}), nitrogen dioxide, sulfur dioxide, and ozone. While all countries are encouraged to adopt these guidelines, the majority of those that adopted them are high-income countries that have strong regulations and enforcement agencies in place, such as the EU's European Environment Agency. By contrast, low-income countries typically lack the required infrastructure to monitor and enforce air quality (Health Effects Institute 2024).

South Asia and Africa have the highest burden of disease from air pollution among regions. However, low- and middle-income countries in these regions struggle to implement and enforce the AQGs. Countries such as India, China, and South Africa have implemented the AQGs, but lack strong enforcement mechanisms, with challenges such as industrial pollution and urbanization contributing to very high levels of air pollution. These countries have tried to involve governments at the local level to improve the monitoring and implementation of air quality standards.

India has adopted several air quality regulation policies such as the Air (Prevention and Control of Pollution) Act of 1981, the Environment (Protection) Act of 1986, and the National Ambient Air Quality Standards (NAAQS). The NAAQS set permissible limits for various air pollutants to safeguard public health, but challenges of enforcement and monitoring persist due to weak capacity, resource constraints, and lack of political will. For instance, the background $PM_{2.5}$ level in Mumbai in 2022 was measured at 33 ± 7 µg/m^3, exceeding the 2021 AQGs by 6.6 times (Ouyang et al. 2022).

Similarly, China introduced the Environmental Protection Law, amended in 2014, the Air Pollution Prevention and Control Action Plan of 2013, and the Ambient Air Quality Standards. But rapid industrialization and urbanization, along with issues of coordination and capacity among the local governments, have affected their implementation. These challenges are also reflected in the high levels of pollutants compared to the AQG recommended levels. The background $PM_{2.5}$ level in Beijing was 30.6 µg/m^3—6 times higher than the 2021 AQGs (Ouyang et al. 2022).

South Africa adopted the National Framework for Air Quality and the Air Quality Act in 2005, which provide guidance on maintaining air quality by involving the national, provincial, and local authorities. However, lack of political will, inadequate consultations and communication, competing priorities, and limited use of planning tools have hindered the implementation of the policies under this act. South Africa also needs integrated planning and alignment of air quality monitoring with broader municipality development objectives (Naiker et al. 2012).

Standards for the workforce in the health care sector and delivery of health care services

Standards for the workforce in the health care sector, including health care educators, health care infrastructure, and health care–related equipment are key to ensuring good quality, safe, and equitable access to health care. WHO plays a central role in setting global standards for the workforce in the health care sector. Its Global Strategy on Human Resources for Health: Workforce 2030 urges all countries to implement accreditation systems for health training programs and institutions by 2020 to ensure the quality of education (WHO 2020c). WHO also collaborates with partners to modernize regulatory frameworks and harmonize education requirements across countries. For example, it works with the World Federation for Medical Education (WFME) to develop global standards for medical education across three phases: basic (undergraduate); postgraduate; and continuing professional development. It also manages the WFME Recognition Programme, which accredits national accrediting agencies to ensure they meet international benchmarks—a recognition that is crucial for medical schools, especially for graduates seeking international certification (WFME 2020). The International Association of Medical Colleges (IAOMC), which is recognized by the United Nations Department of Economic and Social Affairs, works to ensure that qualifications for physicians are consistent at the global level and that they meet international standards.[24] The structure and operations of accreditation agencies vary considerably across regions. For example, agencies in high-income countries often have more established frameworks and resources compared to those in lower-income countries. Some regions have their own medical education accreditation bodies, such as the European Union of Medical Specialists, which defines European training requirements for various medical specialties and oversees the accreditation of continuing medical education which are recognized across Europe and in other countries like Canada and the United States.[25]

While countries are at different stages of establishing their accreditation systems for the health care workforce due to varying resource and capacity constraints, progress has been made at the global level in standardizing education in the healthcare sector. The number of accreditation agencies for medical education worldwide has increased from 8 in 1981 to 71 in 2020. Between 2008 and 2020 the number of countries with accreditation agencies increased from 7 to 20 in Sub-Saharan Africa, from 9 to 21 in East Asia and the Pacific, and from 24 to 34 in Latin America and the Caribbean (Bedoll, van Zanten, and McKinley 2021).

Global and regional standards for health facilities and medical equipment have also been developed to ensure safe and efficient delivery of health care services that are of good quality. WHO provides frameworks and tools to ensure that the quality of care covers various aspects of delivery such as in health infrastructure, staffing, equipment, and clinical protocols. It has published several guides that lay out the standards for health care provision, such as the Global Standards for Quality Healthcare for Adolescents (2015) and the Standards for Improving Quality of Maternal and Newborn Care in Health Facilities (2016). WHO also provides guidance on regulations for medical devices, and assists countries in developing and implementing regulatory frameworks to ensure the safety and efficacy of medical devices.[26] Additionally, the ISO 15189 international standard specifies requirements for quality and competence in medical laboratories,[27] while the ISO 13485 standard specifies requirements for a quality management system for medical devices, ensuring consistent design, development, production, and delivery.[28] Compliance with ISO 13485 is often a prerequisite for regulatory approval in many countries. At the country level, regulatory agencies help to enforce these standards. For example, in the United States, the Food and Drug Administration (FDA) approves and regulates medical devices.[29]

Political economy of standard-setting in health care and global health

Aspects of political economy apply both at the global level for institutions that set health care standards and at the national level. Although the primary motivation for setting standards in health care is to promote quality, safety, and interoperability, the process of setting standards is fraught with several political and economic challenges. For example, standards serve as a gate-keeping function that determines which stakeholders are allowed to participate in the healthcare sector. They also determine how resources are allocated among the stakeholders in the sector.

Furthermore, the key actors in the process for setting global health standards—international organizations, national regulatory agencies, private sector actors, and philanthropic organizations—have varying levels of influence and enforcement capacity, which sometimes leads to subtle or overt competition in this process. This competition, in turn, often results in the overrepresentation of groups with access and power at the decision-making table (such as high-income countries and health professional associations) and the underrepresentation of groups with less political and economic influence (such as low-income countries, patient groups, and marginalized groups).

This section discusses the political and geopolitical dimensions of standard-setting, the economic drivers of standard-setting, and equity and ethical challenges in global health standards.

Political dimensions of standard-setting in health care and global health

Political dimensions significantly influence the standard-setting process due to power asymmetries among global health actors and competing national and global interests. When poorly managed, these political influences lead to a system of “standard makers” with oversized influence on the process of standard-setting and “standard takers” with little to no influence on the process.

Power asymmetry and dominance of high-income countries

Power asymmetry is best illustrated by the dominance of high-income countries in the process of standard-setting, the marginalization of low- and middle-income countries, and geopolitical conflicts over regulatory frameworks. High-income countries typically exert significant influence over the process in several ways. For example, they may try to control which issues rise to the top of the agenda in forums where standards are negotiated, such as WHO and ISO (Smith and Shiffman 2018). Powerful countries also actively “export” their regulatory models as “gold standards” to other regions, demonstrated, for example, by the influence of the FDA and the European Medicines Agency (EMA) on the processes for drug approvals in Africa, Asia, and Latin America and the Caribbean. Sometimes, less powerful stakeholders may not be invited to forums where standards are negotiated. But even if invited, they still face significant barriers to participating effectively, such as technical and financial constraints.

Conditionalities in aid and trade agreements are another example of power asymmetries. For example, grants and loans to low- and middle-income countries typically include clauses limiting the types of health products and technologies that can be procured and where they can be procured (Kim and Kim 2016). While these clauses are seemingly aimed at improving standards, they compel the “standard takers” to accept the norms stipulated by the “standard makers”—a practice that is reinforced by the dependency of low- and middle-income countries on foreign aid for crucial health programs. This type of aid can indirectly impose health standards that may not account for the local context or local needs. Gavi and the Global Fund play active roles in shaping the market for vaccines and health products through mechanisms such as advance market commitments.[30] While these efforts strengthen the global supply and access to vaccines and health products, they also create barriers to entry for some low- and middle-income countries seeking to strengthen their domestic manufacturing sectors. Gavi's African Vaccine Manufacturing Accelerator, launched in June 2024, and supported by a $1.2 billion investment from Gavi, aims to address this barrier (Adepoju 2025).

Power asymmetries also lead to geopolitical competition over regulatory frameworks, as seen during the COVID-19 pandemic when the FDA and the EMA hesitated to recognize vaccines produced by China and the Russian Federation, even though WHO had approved the vaccines. More broadly, the United States favors a market-driven approach to regulation, while the EU supports an approach based on the precautionary principle. These differing approaches sometimes result in varying recommendations for food and drug components, making it challenging for less powerful countries, bound by aid clauses, to reconcile the conflicting information and choose one over the other.

Measurement standards are also significantly influenced by power asymmetries, as demonstrated by the global dominance in the use of DALYs, despite several criticisms of its approach and applicability (Parks 2014). For example, critics have noted the lack of representativeness of the disability weights used—a concern also acknowledged by the creators of the DALY (Salomon et al. 2012). Face-to-face household surveys were conducted in only 5 of the 167 countries included in the 2010 edition, and in only 9 of the 204 countries included in the 2019 edition.[31] Surveys for all other countries were conducted online. Despite this lack of representativeness, DALYs continue to enjoy global dominance as a summary measure of health due to strong support from key global health actors, including WHO, the *Lancet* family of journals, and the Gates Foundation, which has publicly stated that it makes funding decisions based on DALYs (Mundel 2018).

Tensions between national regulatory autonomy and global harmonization

Countries must delicately balance maintaining their regulatory autonomy with their responsibilities as contributors to the global health system, which often creates tensions. For example, although WHO issued emergency use listings for vaccines during the COVID-19 pandemic, some national and regional regulators such as the FDA and the EMA imposed their own, often stricter criteria, delaying global rollout. Some countries, such as India, initially refused to recognize vaccines developed outside of their jurisdiction. This fragmentation in the recognition of global vaccines led to economic and social disruptions in low- and middle-income countries that relied on WHO-approved vaccines. Multilateral procurement mechanisms such as COVID-19 Vaccines Global Access (COVAX) relied on WHO prequalifications to decide on the quality of COVID-19 vaccines and have been credited with fast-tracking vaccine access (Mao et al. 2023). However, the limited availability of vaccines through COVAX, the dominance of bilateral deals between countries and vaccine manufacturers, and the preference of high-income countries for bilateral country-to-country vaccine donations created barriers to vaccine access.

Even when countries agree on global standards, the adoption and implementation varies widely leading to different outcomes. For example, although the IHRs require member states to report public health emergencies, countries may be reluctant to do so due to concerns about economic repercussions, such as loss of tourism and trade.

Economic drivers of standard-setting in health care and global health

In order to protect their financial and economic interests, stakeholders compete vigorously to influence the process of setting standards in health care and global health. This competition often plays out through corporate influence and regulatory capture. By contrast, countries with limited resources that are required to comply with global health and health care standards may find it financially and economically burdensome to deal with these competing interests.

Corporate influence and regulatory capture

Although health care is often viewed through the humanitarian lens, it comprises a significant part of the global economy, with large businesses and corporate entities striving to protect their financial interests, sometimes to the detriment of public health. For example, large pharmaceutical companies play a crucial role in shaping standards by investing heavily in lobbying to influence the decisions of regulatory bodies in ways that safeguard their bottom lines. Since many of these companies are based in high-income countries, the risk is that these decisions may not reflect the critical concerns of stakeholders in less influential countries. For example, the pharmaceutical industry in the United States influenced regulatory bodies to downplay the risks of opioids, leading to a public health crisis. This downplay of risks also affected other countries that depended on these regulators in high-income countries for market-entry decisions. Ongoing international disputes about the regulation and cross-border flow of fentanyl (a potent opioid) further demonstrate how effects in one jurisdiction can have negative consequences in other jurisdictions (Bowra et al. 2024).

A revolving door between “big business” and regulators perpetuates overt regulatory capture (Tansey 2018). While this capture is especially dominant in pharmaceuticals, it also occurs between the fossil-fuel industry and environmental (air and water) regulators (Biesecker, Linderman, and Lardner 2018; Friedman and O’Neill 2020; Vital Strategies 2019). Regulatory capture could also manifest in a more insidious form as lobbyist-driven modifications to already agreed frameworks. For example, although all countries have signed on to the FCTC, the implementation varies across countries—largely driven by the influences of lobbyists of the tobacco industry at the national level, using a range of tactics from questioning the scientific evidence to questioning the legitimacy of evidence-based policies (Liberman 2006; Saltelli et al. 2022). The role played by the tobacco industry professionals in defining categories of cigarettes such as “light” and “ultra-light” cannot be overlooked. These efforts, cloaked with the veneer of science and executed through the ISO, succeeded in convincing the public of the existence of “safe” forms of tobacco products (Halabi 2019).

Global trade arrangements also influence health care standards within countries by influencing the availability and use of essential medicines. For example, major pharmaceutical companies initially blocked the generic production of antiretroviral medications, or importing generic versions, thereby pricing out many people living with HIV in low- and middle-income countries. Another example is the debate on a patent waiver for tools to control COVID-19 that occurred between high-income countries and low- and middle-income countries during the COVID-19 pandemic. These issues often relate to the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of 1994, which required low- and middle-income countries to offer patents on medicines, thereby increasing prices and limiting access (Hoen et al. 2011). Subsequent opposition to this system by civil society and health system activists led to the signing of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which included some flexibility on patents for public health and led to improved access to generic essential medications in many low- and middle-income countries. However, several hurdles remain. The increasing use of voluntary mechanisms, such as negotiated discounts for global procurement mechanisms like Gavi, improves access to low-income countries eligible for Gavi assistance, but it prices out middle-income countries that are not eligible (Frontline Aids and ITPC 2019).

The burden of compliance costs and financial barriers

Many institutions face financial challenges when adopting standards for medicines, medical devices, and hospital safety. The expenses required to comply with health care standards mean that limited health care funds are often diverted from patient care to regulatory documentation. On average, countries are required to report on at least 600 indicators across health programs (WHO 2014b). Hospitals in high-income countries are particularly affected. For example, in the United States, the average hospital allocates 59 full-time staff annually for compliance with regulatory requirements, more than one-quarter of whom are doctors and nurses. These resources translate to annual expenditures at the national level of more than US$39 billion on such compliance (AHA 2017).

Trade agreements also influence health care standards. The WTO's Agreement on Technical Barriers to Trade mandates the harmonization of health regulations, which frequently favor high-income countries and multinational companies. For example, the EU's stringent pharmaceutical regulations pose significant obstacles for producers of generic medicine from Africa and Asia trying to access the European market. These producers may not even qualify to supply donor-funded medicines in their own countries if they are not included on an international prequalified list. Such countries need greater support to be able to meet these stringent requirements.

In some cases, a country may not have the capacity to regulate important medicines—making the medicines unavailable to its population. For example, biosimilars, which are generic versions of biologic drugs, continue to be unavailable in many low- and middle-income countries due in part to a lack of capacity to conduct the intricate regulatory process that is required (Access to Medicine Foundation 2023).

The introduction of government-wide regulations mandated by donors have sometimes had a negative impact on health. International financial institutions such as the World Bank and International Monetary Fund have tied health care funding to specific regulatory reforms, which may not align with local health priorities. For example, the structural adjustment programs in the 1980s and 1990s imposed austerity measures in low- and middle-income countries, such as labor market reforms and the introduction of health care user fees. These reforms weakened the ability of low- and middle-income countries to implement robust health care regulations (Kentikelenis 2017; Thomson, Kentikelenis, and Stubbs 2017).

The costs to comply with externally driven environmental regulations are burdensome for some countries (Monks and Williams 2020). Many low- and middle-income countries are unable to meet the net-zero targets set in the COP26 (the 26th UN Climate Change Conference held in 2021), while dealing with crushing debt burdens, high rates of household poverty, and high rates of maternal and child mortality. In response to these challenges, standard-setting institutions around the world are adopting more flexible approaches, including specifying ranges rather than specific thresholds, and providing room for adaptation of standards based on the local context.

Ethics and equity challenges in standard-setting in health care and global health

Ethical and equity-related issues arise from the influence of political and economic stakeholders in setting health care standards. These concerns encompass bias in global health standards, how standardization affects drug pricing and access to essential medicines, availability of clinical trials and their advantages, algorithmic bias in artificial intelligence (AI)–driven systems, and the tension between public and private sector interests in health care.

Bias in global standard-setting results from numerous health care standards initially developed with high-income countries in mind, rendering them less suitable in environments that are limited in resources. For example, cancer screening guidelines tailored for "Western" health care systems often overlook the weak (or lack of) infrastructure in low- and middle-income countries. While WHO guidelines for cervical cancer screening recommend the use of human papillomavirus DNA testing as the gold standard (based on sound evidence), this technology is not readily available to many women in poor households in low- and middle-income countries. During the COVID-19 pandemic, while many low- and middle-income countries were struggling to expand access to the first dose of the COVID-19 vaccine to essential workers and vulnerable populations, many high-income countries were already recommending booster vaccines to provide additional protection.

Ethical considerations also play a role in clinical trials for health products. Access to such trials is limited in low- and middle-income countries, effectively limiting their access to new products. The 2024 Access to Medicine Index found that only 43 percent of clinical trials were conducted in low- and middle-income countries, although these countries account for more than 80 percent of the global population (Access to Medicine Foundation 2024). Furthermore, when clinical trials for novel pharmaceuticals are carried out in low- and middle-income countries, market access for the resultant treatments is prioritized in high-income countries with greater market potential. This disparity also occurs during emergencies, prompting health care leaders from low- and middle-income countries to demand changes. Negotiations on a pandemic agreement stalled due to disagreements on access to pathogens for research & development and sharing of related treatments (so-called pathogen access and benefit sharing).[32] Many activists and thought leaders in low- and middle-income countries were opposed to pathogen access without a solid arrangement for benefit sharing.

Algorithmic bias is a growing concern in global digital health and is largely caused by AI-driven standards in high-income countries. Health care diagnostics powered by AI often rely on data sets that are significantly biased toward populations from Caucasian backgrounds, thereby diminishing their effectiveness for non-Caucasian or non-European populations. AI-driven algorithms have been shown to be less accurate in predicting cardiovascular risk in African-Americans than Caucasian Americans, and less accurate in interpreting chest radiographs of women because they were trained on data mostly from men, and less accurate in detecting skin cancer in darker-skinned people than in lighter-skinned people (Larrazabal et al. 2020; Lashbrook 2018; Norori et al. 2021; Obermeyer et al. 2019). These biases consequently result in misdiagnoses and poor health outcomes among minority populations.

Finally, balancing public versus private interests in standard-setting also presents some ethical challenges. Private health organizations, such as Google Health and Microsoft, are increasingly assuming a more prominent role in the regulation of digital health. This development raises significant concerns regarding data privacy and the potential for commercial exploitation of individual- and population-level health data. Google's collaboration with Ascension Health sparked ethical concerns related to patient data privacy and the implications of AI-driven medical decisions (O'Reilly 2019). The genetic testing company 23andMe's recent filing for bankruptcy triggered an important debate on what happens to highly sensitive and impactful patient data housed in commercial entities.

The challenges of setting standards

The processes for standard-setting, including the generation, diffusion, and local adoption of standards, face several challenges that can reduce the value of standards in supporting progress in global health. These challenges apply both to the "standard makers" (those who generate standards) and "standard takers" (the end users of standards). An important ongoing challenge relates to the interplay between standard makers and takers–specifically, how much are the context-specific needs of local end users, especially those in low- and middle-income countries, taken into account in the global standard-setting process (Strambach and Surmeier 2018)?

Challenges in generating standards

Global health and development agencies, including WHO and the World Bank, have faced scrutiny for a number of weaknesses in their processes for standard-setting, which the agencies have worked to address. These criticisms include the lack of adequate use of systematically reviewed evidence in generating their normative guidance; the reliance on the views of experts only in particular areas of health specialty; the exclusion of consultations with experts that have the relevant and adequate methodological expertise such as expertise in systematic reviews, clinical trials, and economic evaluations; and the lack of adequate consultation with end users (Hoffman, Lavis, and Bennett 2009; Oxman, Lavis, and Fretheim 2007). There have been calls for greater rigor and transparency in the generation of global guidance, including greater transparency around potential conflicts of interest among those who develop health guidance (Welch 2014) and around the methods and types of research evidence used. WHO implemented a series of reforms in response to this scrutiny, including introducing a Guidelines Review Committee and establishing a Science Division (Askie et al. 2024).

Challenges in using standards

A major challenge–and tension–at the very heart of the global health standards enterprise is around the “localization” of global guidance. How can a “global” standard be truly applicable to the very diverse contexts, needs, and resource levels of different settings worldwide? One criticism of the global norms and standards generated by development agencies headquartered in high-income countries is that they have not sufficiently included end users from low- and middle-income countries when setting standards (Strambach and Surmeier 2018). There have been calls for greater integration of the insights of these end users into the standard -setting process.

A related challenge relates to the diffusion of global guidance to local settings and its adaptation to the local context. While some countries have a conducive environment—high-quality institutions and structures, sufficient financial and technical resources, and supportive legislative and policy frameworks—to carry out such adaptation, others do not. The lack of such an environment is one important reason for the divergence between NEMLs and the WHO Model List, such as national lists not reflecting the latest recommendations or including medicines of low effectiveness. This lack of a conducive environment is also a barrier to low- and middle-income countries using evidence-based global guidance in the design and implementation of health benefits packages (Alwan, Yamey, and Soucat 2023) and in national health technology assessments.

Significant time and human capital resources are required to adapt globally produced WHO guidance for local use. Kredo et al. (2024) examined the national capacity to adopt, adapt, and develop child health guidelines in Malawi, Nigeria, and South Africa and found that despite significant efforts, Nigeria and Malawi lack independent standards agencies or clearinghouses dedicated to evaluating guidelines. As a result, guidelines may not be tailored for end users and often lack credibility regarding the foundation of their recommendations. By contrast, South Africa's National Department of Health has a well-established guideline infrastructure that manages health technology assessments, medicine selection, and national standard treatment guidelines. Nevertheless, while global standards like the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method are routinely used in South Africa’s essential medicines list program, their adoption remains limited within the child health program and related professional associations. The study also highlights the significant efforts required to adapt globally produced guidance for local use, emphasizing the necessity for context-specific modifications to fit unique health systems. And it identifies a need for enhanced local capacity to develop relevant evidence, including health economic analyses, to ensure the applicability of the guidelines and their effectiveness in local contexts (Kredo et al. 2024).

Inconsistent regulations and practices across countries pose another challenge, as they can lead to disparities in the quality of products and the safety of patients. For example, WHO provides global standards for medical products of human origin, which encompass all biological materials derived wholly or in part from the human body, including, but not limited to, blood, organs, tissues such as corneas and reproductive tissues, cells, human milk, and fecal microbiota. Only high-income countries such as Australia and the United States have successfully implemented robust national governance and quality and safety standards for blood, organs, tissues, and cells, but most low- and middle-income countries lag. As of 2018, only 73 percent of WHO member countries had a national blood policy, only 66 percent of reporting countries had specific legislation covering the safety and quality of blood transfusion, including 79 percent of high-income countries versus 39 percent of low-income countries. As of 2023, only 12 WHO member states in three of the six WHO regions had developed a robust biovigilance system (McGrath et al. 2024).

There are also several challenges in the implementation and enforcement of global health standards at the country level, including lack of political will, resource constraints, and varying national capacities. Even with legally binding standards such as the FCTC and IHR), countries may lack the capacity for implementation and enforcement. For example, they may lack the strong surveillance systems required by IHR. Differences in legal systems, economic priorities, and health care infrastructure also hinder the uniform adoption of global standards. Sovereignty concerns often limit binding agreements, while monitoring and accountability mechanisms are often weak or absent. In addition, fragmented international coordination and inequitable access to technologies or medicines exacerbate disparities. Ensuring compliance often requires incentives or technical support, especially in low- and middle-income countries (Taylor 2016).

Moreover, the success of the implementation of these standards in low- and middle-income countries depends on addressing systemic challenges through strengthened health care systems, sustainable financing, and robust policy frameworks. For example, while the WHO EML provides a critical framework for improving access to essential medicines, there are various challenges in policy, governance, infrastructure, and availability of resources. Financial constraints due to costly treatments included in the list often impede the procurement and distribution of all medicines, leading to stock-outs and inconsistent availability. Inadequate health care infrastructure and weak supply chain management limits the effective delivery and monitoring of essential medicines, affecting treatment outcomes (Wirtz et al. 2024). With respect to nutrition labelling, differences in regulatory standards can lead to inconsistencies and potential confusion among consumers. Nutrition labelling and health claim regulations can also affect international trade, as there is a need to align national regulations with international standards to minimize trade barriers while protecting the health of consumers (WHO 2004).

Global measurement standards have been critical for comparing the burden of disease between different places and over different time periods, but in some cases their application at the global level to different populations and contexts is not straightforward. For example, the body mass index (BMI)– a measure of weight relative to height, calculated as weight (kg)/height $(m)^2$–has been widely used in many health care systems to categorize people into different weight types. A BMI between 25–30 indicates that a person is overweight and a BMI over 30 indicates obesity. These ranges are also used to identify increased risk of cardiovascular disease and metabolic disorders such as type 2 diabetes. However, the metric has its origins in measurements primarily of Caucasian men, and its universal application to different racial and ethnic groups—particularly the use of cut-off points for defining weight types—is highly problematic. For example, populations of Asian descent have a higher risk of metabolic disease at lower BMI values (Stanford, Lee, and Hur 2019). An ongoing movement is trying to replace the universal application of BMI with more versions adapted for different sexes and racial and ethnic groups (Stanford, Lee, and Hur 2019; Stern 2021).

Challenges in measuring and evaluating the impact of standards

While this study has summarized key evidence on the benefits of standards in global health, measuring the impact of these standards can be challenging. Regis et al. (2024) argue that a clearer picture of the impact of WHO normative work including guidelines, codes, and regulations is needed. But evaluating the impact of this normative work is far from straightforward.

First, there are limitations in data collection. WHO relies on three primary data sources for evaluation: self-assessments, internal evaluations, and external evaluations. While Article 62 of the WHO

Constitution mandates annual reporting on compliance through self-assessments, these reports often lack standardization and consistency, providing limited insights into the actual effects of implemented norms. The internal evaluations conducted by the WHO Evaluation Office or commissioned experts provide more detailed insights than self-assessments, but the evaluations are constrained by limited resources, leading to narrowly focused studies on specific countries or norms and hampering a comprehensive assessment. External evaluations through independent assessments by academic or nonacademic experts can offer broader perspectives but face challenges accessing internal data within WHO and collaborating with key stakeholders, limiting their effectiveness. Second, evaluating the normative impact is complex and often more costly than other types of evaluations, leading to targeted assessments that may not capture the full picture (Regis et al. 2024). In summary, too little data, incomplete data, and resource constraints to conduct complex and costly evaluations all hinder the assessment of global health standards.

In other cases, the evidence on whether standards have a positive impact is mixed, making it difficult to understand the true value of the standard. In these situations, the types of reforms needed to improve impact may be unclear. One example is standards guiding the effectiveness of health aid. Research on the impact of these standards presents a mixed picture. Implementation of the Paris Declaration on Aid Effectiveness among different donors has been highly variable (Wood et al. 2011). A study of donor alignment and harmonization for reproductive, maternal, newborn, and child health between 2008 and 2013 found that harmonization remained low throughout that period (Martinez-Alvarez et al. 2017). By contrast, in Ethiopia, India, and Nigeria, when donors, governments, implementers, and civil society adopt aid effectiveness standards, this is likely to improve the scale-up of maternal and newborn health interventions, Wickremasinghe et al. (2018) found. Overall, Ogbuoji and Yamey (2019) argued that it was unclear from the available evidence at that time whether aid effectiveness principles had improved the efficiency and impact of aid.

Recommendations

Minimum quality standards, compatibility standards, and measurement standards have become an important tool in the governance of global health, with a wide range of end users at all levels of the global health system. This study has demonstrated the role of global standards in improving several dimensions of global health, including health outcomes, equity, efficiency, comparative health data analysis, and innovation. The study has also examined the implementation and enforcement of standards, as well as the political and economic issues that influence the process of standard-setting, such as power asymmetry favoring high-income countries, fragmented regulatory systems, corporate capture, and the burdens on low- and middle-income countries of complying with these standards. These factors combine to create ethical and equity-related concerns, such as algorithmic bias and disparities in access to health care.

The study has outlined some of the key challenges facing standard makers and standard takers in global health, including the inherent challenge of creating a “global” standard that can be applied in varying contexts and the variation between different countries in their capacity to adapt such standards to local contexts. How can such challenges be addressed in order to strengthen the establishment, diffusion, and implementation of global health standards in ways that will help improve global health outcomes? A set of eight broad, interlinked recommendations follows.

1. *Make the process of standard-setting in global health, including the development of global guidelines, more robust and transparent.* A critical foundation is to ensure greater rigor in the use and appraisal of evidence that has been systematically reviewed. There are many sources of such evidence, produced by many different actors. Capturing the evidence in a coordinated way is important (Piggott et al. 2024). Another way to increase rigor is to increase transparency in how expert committees make

their decisions, including whether they used GRADE or other multidimensional decision models, and in the declaration and appraisal of the conflicts of interest of committee members.

2. *Strengthen the value of standards by improving the interlinkages between them, rather than using different standards in isolation.* For example, improving links between the WHO Model List, global standards in the design, costing, and implementation of health benefits packages, and public health and clinical guidelines, and integrating these standards could maximize their impact on the practice of global health (Peacocke et al. 2024).

3. *Develop new approaches to measuring the impact of global health norms and standards. In particular, develop new approaches to impact evaluation, elevate the importance of normative evaluation by global health agencies, and build stronger normative evaluation capacities.* Regis et al. (2024) have proposed a set of internal and external measures to improve the evaluation of WHO's normative products, including strengthening the gathering, usage, and openness of data for normative evaluation and working with other partners to develop joint evaluation strategies.

4. *Support new approaches and innovation to diffuse global health standards.* The value of normative guidance ultimately depends on whether it is used in daily public health and clinical practice, and new approaches are needed to support this type of uptake. For example, WHO has recognized the need for this type of innovation and has argued that it could develop new ways of producing, disseminating, updating and embedding the Organization's normative guidance into point-of-care systems, thereby putting evidence at the center of everyday life (Askie et al. 2024). There is also a growing body of evidence showing the value of "knowledge brokers"—individuals and organizations who can help to "broker" the diffusion of knowledge standards into policy uptake (Ward, House, and Hamer 2009).

5. *Strengthen the capacity of countries through dedicated domestic financing and by improving the governance and regulatory environment*. Strengthened capacity is needed for countries to implement and adapt guidelines, develop national essential medicines lists guided by the WHO Model List, improve health technology assessment, and strengthen surveillance systems to comply with the IHR. Indoor air quality (IAQ), a major cause of premature death, is another example of where bolstering resources and capacity would improve adherence to a global health standard. Adherence to global IAQ standards in low- and middle-income countries is hindered by factors such as limited resources, skilled personnel, and insufficient institutional capacity and infrastructure (Siddique et al. 2023).

The *Lancet* Commission on Investing in Health has argued that there is an increasingly important role for official development assistance (ODA) in supporting global public goods for health. Many of the national capacities for implementing global standards constitute global public goods such as pandemic preparedness, and global knowledge generation, diffusion, and uptake. As countries transition out of what the Commission calls "country-specific aid" (that is, funding the strengthening of country-specific health-systems and disease-control activities such as reductions in maternal mortality, which benefit the specific country only), ODA for global public goods and other activities with transnational benefits will become increasingly important (Jamison et al. 2024). In the current environment of reductions in aid, directing ODA toward supporting the capacity of countries in adopting global standards should remain a high priority for ODA allocation, given the regional and global benefits.

6*. Increase the inclusion of local end users in the generation of global standards, particularly from low- and middle-income countries.* Although actors from low- and middle-income countries are expected to comply with global standards, their voice and demands are still mainly excluded from standard-setting processes (Strambach and Surmeier 2018). Actively involving end users in the processes of standard-setting, such as establishing clinical practice guidelines, increases the likelihood of their adoption into clinical practice (Harrison et al. 2010). One mechanism to help engage end users is to support "knowledge-intensive intermediaries." Intermediary organizations such as nongovernmental organizations and civil society organizations can have an important influence in bringing the perspectives of end users in low- and middle-income countries into the global processes for standard-setting, including the dissemination and uptake of these perspectives (Strambach and Surmeier 2018).

The WHO EML provides an example of how implementing many of the preceding recommendations would improve a specific global health standard. WHO implemented reforms aimed at strengthening the WHO EML, including improving transparency, enhancing the engagement of end users (health care providers, national health policy makers) in decision-making, adopting stronger evidence-based processes (including health technology assessment), and strengthening evaluation of impact (Peacocke et al.2024; Piggott et al. 2024).

7. *Improve compliance with the IHR*. As noted, the existence of large gaps in compliance is partly due to the lack of enforcement mechanisms. But even in the absence of such mechanisms, other approaches can encourage countries to follow the legally binding requirements of the IHR. Kavanagh et al. (2023) draw on approaches from areas outside the health sector—including from trade, human rights, and environmental protection—to identify a range of monitoring and review mechanisms that could be applied to the IHR. These include standing bodies to monitor compliance; delegation to states, civil society organizations, or individuals to identify violations; and states flagging their own compliance gaps and linking these with requests for support to close these gaps.

8. *Promote a global agenda on diagnosis, measurement, and management of disease in diverse populations*. This approach would acknowledge the important differences in populations that may affect the accuracy and impact of health care tools. For example, WHO has acknowledged the different associations between BMI and health risks in populations in Asia and the Pacific and issued separate BMI guidelines for these populations with lower thresholds for obesity (Choo 2002). Similar initiatives are needed as the use of AI-related and digital health care continue to expand (Panch, Mattie, and Atun 2019). For example, guidelines should promote health care that properly accounts for important differences between darker-skinned and lighter-skinned people, between men and women, and between different racial and ethnic groups.

Notes

[1] WHO (World Health Organization) Good Practice Statements are concise, actionable statements that provide guidance on specific interventions or actions in health care or public health.

[2] Several definitions exist for norms, standards, and guidelines. Organizations define them differently, and sometimes an organization may have multiple definitions for each term. This study adopts WHO's description of guidelines as recommendations for clinical practice or public health policy, designed to help end users make informed decisions. For more information, refer to https://www.who.int/publications/who-guidelines. This study also aligns with WHO's descriptions of standards and norms as evidence-based technical specifications, defined levels of quality, and performance expectations *required* to meet the needs of intended beneficiaries, and form the basis for comparison. For more information, refer to https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards, WHO (n.d.), and WHO and UNAIDS (2015). These definitions imply that guidelines encourage voluntary participation, while standards and norms establish minimum requirements. Despite these differences, these terms are frequently used interchangeably in the global health literature.

[3] "EQUATOR" refers to Enhancing the QUAlity and Transparency Of health Research. For more information, refer to https://www.equator-network.org/reporting-guidelines/.

[4] The six regional offices are: African Region, Pan-American Health Organization, Eastern Mediterranean Region, Europe, South-East Asia, and the Western Pacific.

[5] For more information, refer to https://www.who.int/universal-health-coverage/compendium.

[6] For more information, refer to https://uhcc.who.int/uhcpackages/.
[7] For more information, refer to https://www.dcp-3.org/dcp3.
[8] For more information, refer to https://www.who.int/emergencies/outbreak-toolkit.
[9] For more information, refer to https://www.who.int/publications/who-guidelines.
[10] For more information, refer to https://ish-world.com/.
[11] For more information, refer to https://idf.org/about-diabetes/resources/.
[12] For more information, refer to https://www.figo.org/.
[13] For more information, refer to https://www.equator-network.org/reporting-guidelines/.
[14] For more information on WHO's definition of "quality of care," refer to https://www.who.int/health-topics/quality-of-care#tab=tab_1.
[15] For more information, refer to https://www.iso.org/committee/54960.html.
[16] For more information, refer to https://dhsprogram.com/methodology/survey-types/dhs-questionnaires.cfm.
[17] For more information, refer to https://www.who.int/tools/atc-ddd-toolkit/atc-classification.
[18] For more information, refer to https://www.who.int/data/global-health-estimates.
[19] For more information, refer to https://www.uhc2030.org/who-we-are/.
[20] For more information, refer to https://www.who.int/universal-health-coverage/compendium.
[21] For more information, refer to https://uhcc.who.int/uhcpackages/.
[22] For more information, refer to https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/global-vaccine-action-plan.
[23] Voluntary traffic-light labelling systems use a color-coded system (red, amber, green) on food packaging to indicate the nutritional content of saturated fat, sugars and salt in a product, with red indicating high levels of certain nutrients, amber indicating medium levels, and green indicating low levels.
[24] For more information, refer to https://www.imperialwhocc.org/IAOMC/?page_id=155.
[25] For more information, refer to https://www.uems.eu/.
[26] For more information, refer to https://www.who.int/health-topics/medical-devices#tab=tab_1.
[27] For more information, refer to https://www.iso.org/standard/76677.html.
[28] For more information, refer to https://www.iso.org/standard/59752.html.
[29] For more information, refer to https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation.
[30] Advance market commitments are negotiated contracts which provide multi-year guarantees for the purchase of prespecified volumes of vaccines and medical products from preselected producers.
[31] The five countries where face-to-face household surveys were conducted in the 2010 edition were Bangladesh, Indonesia, Peru, Tanzania, and the United States. In the 2019 edition, face-to-face household surveys were conducted in these same five countries, in addition to four others: Hungary, Italy, the Netherlands, and Sweden.
[32] Pathogen access and benefit sharing is a proposed system that aims to ensure the rapid sharing of biological materials with epidemic/pandemic potential, and that guarantees that the benefits derived from their use are shared fairly and equitably.

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