International Infectious Disease Law

Revision of the World Health Organization's International Health Regulations

Lawrence O. Gostin, JD

The International Health Regulations (IHR), the only global regulations for infectious disease control, have not been significantly changed since they were first issued in 1951. The World Health Organization (WHO) is currently engaged in a process to modernize the IHR. This article reviews WHO's draft revised IHR and recommends new reforms to improve global health, which include (1) a robust mission, emphasizing the WHO's core public health purposes, functions, and essential services; (2) broad scope, flexibly covering diverse health threats; (3) global surveillance, developing informational networks of official and unofficial data sources; (4) national public health systems, setting performance criteria, measuring outcomes, and holding states accountable; (5) human rights protection, setting science-based standards and fair procedures; and (6) good governance, adopting the principles of fairness, objectivity, and transparency. The WHO should ensure state compliance with health norms and generous economic and technical assistance to poorer countries. An important issue for the international community is how sovereign countries can join together to make global health work for everyone, the poor and the wealthy alike.

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GLOBAL PUBLIC HEALTH GOVERNANCE IS ANTIquated and structurally weak.[1] The International Health Regulations (IHR), the only global regulations for the control of infectious diseases, have not been significantly changed since they were first issued in 1951. The IHR are nonresponsive to the major challenges of emerging infectious diseases and bioterrorism that face the international community.[2] Accordingly, the World Health Organization (WHO) is currently engaged in a process to modernize the IHR.[3] This article places international infectious disease control in historical context, explains the IHR reform process, and makes recommendations to improve the IHR.

GLOBAL GOVERNANCE OF INFECTIOUS DISEASE: A BRIEF CONTEXTUAL HISTORY

The origins of the IHR date back to the First International Sanitary Conference in Paris, France, in 1851. The cholera epidemics in Europe between 1830 and 1847 spurred international diplomacy. During the latter half of the 19th century, 10 sanitary conferences were held and 8 conventions negotiated (most did not come into force) about the transboundary effects of infectious diseases. The International Sanitary Convention that dealt with cholera was adopted in Venice, Italy, in 1892, followed by another convention that dealt with plague in 1897.[4]

At the turn of the 20th century, the international community established multilateral institutions to enforce these conventions. American states set up the International Sanitary Bureau (ISB) in 1902, which became the Pan American Sanitary Bureau, a precursor to the Pan American Health Organization (PAHO). The PAHO agreed to serve as WHO's Regional Office for the Western Hemisphere in 1949.[5] The International Sanitary Convention adopted in 1903 replaced the conventions of 1892 and 1897. European states developed their own multilateral institution in 1907, L'Office International d'Hygiène Publique (OIHP). The Health Organization of the League of Nations (HOLN) was formed in 1923 between the two world wars. Article XXIII of the League of Nations Covenant meekly stated that members would "endeavor to take steps in matters of international concern for the prevention and control of disease."

The ISB, OIHP, and HOLN were separate institutions, without harmonization of goals or practices. Each was based on the enduring political understanding that nations are sovereign. The existence of multinational bodies, then and now, did not signal the existence of meaningful global norms about the control of infectious diseases. Rather, these institu-

Author Affiliations: The Center for Law and the Public's Health, Georgetown University, Washington, DC, and the Johns Hopkins University, Baltimore, Md.
Corresponding Author: Lawrence O. Gostin, JD, Georgetown University Law Center, 600 New Jersey Ave NW, Washington, DC 20001 (gostin@law.georgetown.edu).
Health Law and Ethics Section Editors: Lawrence O. Gostin, JD, Center for Law and the Public's Health at Georgetown University, Washington, DC, and the Johns Hopkins University, Baltimore, Md; Helene M. Cole, MD, Contributing Editor, *JAMA*.

tions oversaw a system based on the supremacy of nations (particularly the great powers), which entered into narrow multilateral agreements governing the movement of people, goods, and services across borders.[6]

Global governance was transformed with the establishment of the United Nations (UN) after the horrors of World War II. Article 55 of the UN Charter states that a primary objective of the UN is to promote "higher standards of living" and "solutions of international . . . health." The WHO was the first international agency established by the UN. On July 22, 1946, at the International Health Conference in New York, NY, representatives of 61 countries signed the WHO Constitution. The WHO Constitution came into force on April 7, 1948.[7] The preamble states that its "principles are basic to the happiness, harmonious relations and security of all peoples," thus expressing a universal aspiration.[8] The WHO Constitution grants to the agency power to seek member state adoption of conventions (article 19), promulgate regulations (article 21), and make recommendations (article 23).[9] Although the WHO combined the functions of regional multilateral institutions, the horizontal governance structure effectively did not change. Member states would retain sovereignty, without burdensome requirements to upgrade their domestic surveillance and sanitary systems.

CURRENT IHR: CONTENT AND REFORM PROCESS

The WHO member states adopted the International Sanitary Regulations (ISR) on July 25, 1951. The ISR were renamed the IHR in 1969. The IHR were slightly modified in 1973 (particularly for cholera) and in 1981 (to exclude smallpox, in view of its global eradication). The IHR, which currently apply only to cholera, plague, and yellow fever, contain several broad requirements for member states. First, countries must *notify* the WHO of any case of these diseases that occur in humans within their territories, and give further notification when an area is free of infection. Second, countries must adopt *hygiene measures* at ports, airports, and frontier posts, and with respect to international cargo, goods, baggage, containers, and other articles. Hygiene measures include providing potable water and wholesome food; conducting inspections of equipment, installations, and premises; and maintaining facilities for isolation and care of infected persons, and for disinfecting, disinsecting, and deratting. Third, countries may require *health and vaccination certificates* for travelers from infected to noninfected areas. Fourth, the health measures permitted by the IHR are "the *maximum measures* applicable to international traffic, which a state may require for the protection of its territory."

The WHO has experienced difficulties in enforcing the IHR in each content area. Some member states have (1) not promptly reported notifiable diseases; (2) not met hygienic standards at borders; (3) required health certificates for nonlisted diseases such as human immunodeficiency virus (HIV) and AIDS; and/or (4) exceeded the allowable maximum measures by imposing bans on entry of travelers or goods without sufficient scientific justification. Member states do not comply for diverse reasons such as popular sovereignty or self-governance, political or economic interests, and incapacity due to lack of expertise or resources.

The 1995 World Health Assembly (WHA), in response to outbreaks of cholera in Peru, plague in India, and Ebola hemorrhagic fever in Zaire, resolved to revise the IHR.[10] Since that time, the WHA[11,12] and other WHO governance structures[13,14] have affirmed the importance of the reform process. The WHO published the draft revised IHR on January 12, 2004.[15] The draft is being reviewed by member states at regional consultations, with a view to adoption by the WHA in May 2005.[16]

TOWARD NEW IHR: RECOMMENDATIONS FOR GLOBAL HEALTH IMPROVEMENT

This section reviews major deficiencies in the current IHR, assesses reform measures in the draft revised IHR, and makes recommendations. The WHO's vision for global health should include a robust mission, broad scope, global surveillance, national public health systems, human rights protection, and good governance (TABLE).

Robust Mission

The avowed purpose of the IHR is "to ensure the maximum security against the international spread of diseases with a minimum interference with world traffic."[17] The draft revised IHR, appropriately, are less emphatic, asking states to "provide security against the international spread of disease while avoiding *unnecessary* interference with international traffic." The IHR guiding principle signals something important about global public health priorities. Certainly, international commerce is a social good, and overreaction without scientific evidence can cause economic harm by diminishing trade, travel, and tourism. However, the international community cannot have it both ways—unimpeded travel and trade, with full public health protection. The IHR do not recognize the hard tradeoffs between the intercourse of people and goods and the spread of infectious diseases. The severe acute respiratory syndrome (SARS) outbreaks demonstrated the need for decisive public health action in the face of scientific uncertainty, sometimes at the expense of commerce and trade.[18] The WHO's mission should unequivocally be expressed as global health protection and promotion. The draft revised IHR should cogently state the agency's salient public health purpose, core functions, and essential services. A new preamble, for example, could specify, "It is the policy of the WHO to protect and promote the health of the world's population to the greatest extent possible, while respecting individual human rights and international commerce." That is the vision of the WHO Constitution. Neither the preamble nor article 21 mentions commerce protection, let alone minimization of barriers to commercial intercourse.

Table. International Health Regulations (IHR): Comparisons and Recommendations

Subject Area	Current IHR	Draft Revised IHR	Recommendations
Mission of IHR	Maximum security against international spread of diseases, with minimum interference with world traffic	Security against international spread of diseases, avoiding unnecessary interference with international traffic	Emphasize the World Health Organization's public health mission, core functions, and essential services
Scope of health conditions covered	Designated diseases are yellow fever, plague, and cholera	Covers any "public health emergency of international concern," including biological, chemical, and radionuclear	Non–disease-specific standard offers flexibility for new health threats, but requires detailed guidance on national surveillance
Surveillance	Limited to country reports on covered diseases	Surveillance through country notifications, unofficial sources, and real-time event management	Create surveillance capacity, monitor performance, and develop "small-world" networks
National public health systems	Limited hygiene measures on international carriers and at frontiers	Recommended health measures and national core capacities for surveillance and response	Set performance criteria, measure outcomes, hold states accountable, facilitate economic development
Human rights protections	None	No discrimination; international law rights; and informed consent for medical examination, prophylaxis, and vaccination	Elaborate on human rights; set standards and fair procedures; incorporate Siracusa Principles to balance health and human rights
Governance	Not transparent	Verification of data, communication with countries, and public availability of reported data	Implement good governance based on the principles of fairness, objectivity, and transparency

Broad Scope

The IHR are limited to the same 3 diseases originally discussed at the First International Sanitary Conference in 1851: cholera, plague, and yellow fever. This narrow scope means that the IHR are irrelevant for confronting most international threats, ranging from the HIV/AIDS pandemic to SARS.[19] The WHO needs a broader, flexible approach that legitimizes dynamic public health action. The draft revised IHR require reporting of "all events potentially constituting a public health emergency of international concern," as determined through an algorithm with the following criteria: seriousness of the event's public health impact, its unexpectedness, the potential for international spread, and the risk that international travel or trade restrictions may be applied by states. By focusing on conditions of global public health importance, the draft revised IHR break from the disease-specific approach. The new definition will allow the monitoring of global health threats, irrespective of the cause, including those associated with the accidental, natural, or intentional release of pathogens, chemicals, or radionuclear materials. This generic definition offers a more flexible and inclusive approach for addressing novel health threats. However, abandoning specific disease reporting could actually allow poor or noncompliant countries to lower their national surveillance standards. The WHO, therefore, will have to provide detailed guidance and technical assistance for national surveillance, including recommendations about specific diseases, conditions, and events that are notifiable.

Global Surveillance

Rapid and comprehensive data collection is critical to containing global health threats (eg, monitoring animal and human populations, the environment, and the blood supply).[20] The draft revised IHR encourage country notifications by standardizing data sets, creating national focal points for communication, and encouraging confidential provisional reporting. (The existing IHR require automatic publication of reported cases in the *Weekly Epidemiological Record*.) The draft revised IHR go beyond official country notifications by seeking data from multiple sources through, for example, the Global Public Health Intelligence Network, a computer application that continuously scans the Internet for reports of suspicious disease events. Similarly, the Global Outbreak Alert and Response Network is an operational system for keeping evolving infectious disease threats under close surveillance and facilitates rapid containment of outbreaks.[21] Finally, the draft revised IHR develop a system of real-time event management where collaborating scientists monitor an outbreak and give expert advice. The WHO could further enhance surveillance by creating greater capacity for underperforming countries; setting surveillance standards and monitoring compliance; and facilitating small-world networks, where diverse groups of scientists, health professionals, membership associations, and nongovernmental organizations monitor health threats. Small-world networks can become a rich source of information through advanced communications.[22]

National Public Health Systems

True health protection comes only through uniformly strong national public health systems that are able to rapidly detect and respond to health threats at their source. The current IHR do not set standards for national public health systems except for narrow requirements for international carriers and at borders. The draft revised IHR, however, (1) empower the WHO to make temporary and standing recommendations for national health measures and (2) require

member states to maintain the capacity for surveillance and response. These new powers will lead to global health improvement only if the WHO takes bold steps. To make recommendations and core capacities meaningful, the WHO should set performance criteria, measure outcomes, and hold states accountable. It is unclear, moreover, how poor countries would develop and maintain the necessary public health infrastructure. The WHO, together with developed countries, should have duties to provide significant technical and financial assistance for effective public health action. Reform of the IHR, without capacity building and norm enforcement, will not result in a better prepared global health system.

Human Rights Protection

The stated purpose of the current IHR ("maximum protection, minimum restriction") refers to trade, not human rights.[23] Indeed, the international agencies with which the WHO worked most closely in the revision process—the World Trade Organization and the Codex Alimentarius Commission—promote commerce, not human rights.[24] Yet, infectious disease powers curtail individual freedoms, including privacy (eg, surveillance), bodily integrity (eg, compulsory treatment), and liberty (eg, travel restrictions and quarantine). At the same time, public health activities can stigmatize, stereotype, or discriminate against individuals or groups.[25] The draft revised IHR improve human rights protection but do so in a generalized, oversimplified fashion, stating that health measures should be applied "without discrimination" and persons have "rights in international law." The draft revised IHR should elaborate the specific rights that people possess, set science-based standards and fair procedures for public health measures, and require states to actively prevent stigma and discrimination. Notably, the draft revised IHR lack guidance as to the appropriate use of compulsory powers. The draft states that no invasive medical examination, vaccination, or prophylaxis can be imposed without prior express informed consent. This is an oversimplified statement of international law and ethics. States should have the power to sanction individuals with dangerous contagious diseases who refuse medical interventions.[26] At the same time, the draft revised IHR are silent regarding the legal standards and fair processes necessary for isolation, quarantine, and other compulsory measures. To ensure balanced substantive and procedural safeguards for the exercise of public health powers, the IHR should incorporate by reference the Siracusa Principles. These principles, which are well accepted by the international community, offer detailed guidance on the use of public health powers in ways that are consistent with human rights.[27]

Good Governance

The WHO should become a model of good governance that all nations could emulate. The draft revised IHR encourage a deliberative and open process by verification of data accuracy, communication with the affected countries, and public availability of reported data. Good governance should be based on the principles of fairness, objectivity, and transparency. Fairness requires that decision making does not favor particular regions, countries, or power structures. International relations often favor the privileged and powerful, leaving poor nations disproportionately burdened by infectious diseases.[28] Objectivity requires evidence-based decision making. The WHO gains its moral authority through science; the WHO's judgments must be (and seen to be) influenced by the best available scientific evidence. Transparency requires open and accountable decision making. The process for arriving at recommendations or regulatory actions should be visible and the reasons publicly explained. By incorporating the principles of fairness, objectivity, and transparency in the draft revised IHR, the WHO would gain global respect and serve as a model of good governance for nations.

GAINING COMPLIANCE WITH THE IHR

The WHO's difficulty with member state compliance poses a major problem for world health. National acceptance of standards for prevention and control of infectious diseases lies at the heart of a successful strategy. Global surveillance is only as strong as its weakest link, making it vital to maintain uniformly high levels of public health preparedness in all regions of the world. A central challenge for the international community will be to reduce global disparities in health resources.

Nations fail to observe international law for a variety of reasons: sovereignty, self-interest, and lack of capacity.[29] The hallmarks of sovereignty all militate against state conformance with global health norms: national autonomy over domestic health policy, noninterference, and weak centralized governance by the WHO. Binding standards are limited to those agreed on among sovereign states, principally involving frontier barriers, such as modest restrictions on international travel and commerce. This governance structure is unlikely to provide strong public health protection. Frontiers are political, not natural, barriers that do not effectively prevent the international spread of infection.

In many ways, it is in a country's self-interest to overlook WHO recommendations and regulations. Rule compliance may risk national prestige, travel, trade, and tourism. For example, reporting a disease outbreak and offering the WHO full cooperation may incur serious economic harm by impeding the flow of people and goods. This dynamic was illustrated during the SARS outbreaks when China delayed notification to the WHO, and Ontario, Canada, resisted WHO travel advisories.

National governments may fail to comply with WHO rules not because they are protective, closed, or insular, but because they are frail and lack the capacity. Some nations are poor and cannot afford sophisticated public health systems, whereas others are failed states in the midst of civil strife, war, or natural disaster.

The WHO should move from horizontal governance to vertical process—the process by which nations incorporate international health rules into domestic policies, practices, funding, and law.[30] The greatest promise lies in a balanced use of "hard law," making health rules binding, and "soft law," creating incentives to internalize health norms. The WHO should seek to embed public health norms in governments, nongovernmental organizations, professional organizations, corporations, foundations, and other actors. At the same time, the WHO should mobilize international economic assistance for states that lack the capacity for public health preparedness. Major resources dedicated to core public health infrastructure (eg, surveillance, data systems, laboratories, and workforce) would empower countries to make public health a priority. A combination of economic development, technical assistance, incentives, recommendations, and directives could achieve a higher level of conformity.

There is, of course, no guarantee that revised IHR will lead to bold changes in compliance and economic development. Indeed, the international community has resisted strong global health governance and failed to answer the call for generous investment in poor nations' public health. Consequently, IHR reform should only begin a broader process of health norm internalization and capacity building, bridging the gap between international goals and real-world public health preparedness.

INTERNATIONAL RELATIONS AND THE REFORM PROCESS

The IHR once held great promise for reducing the worldwide burden of infectious diseases. The regulations were intended to be flexible and continually updated based on the best science.[31] However, the WHO has been unable to use the regulatory process with vigor and good effect. The IHR have become scientifically obsolete and irrelevant in the face of novel health threats and terrorism. The draft revised IHR provide an opportunity for a major advance in global health even if, for prudential reasons, they do not include all the innovations recommended here. Yet, if the reform process is to succeed, the world must relinquish important aspects of state sovereignty and insular self-interest to come together for a universal good. One of the most important issues that humankind must deal with today is how sovereign countries can join together to make global health work for everyone—not just the privileged.

Disclaimer: Mr Gostin is working with the World Health Organization on the International Health Regulations revision process. The views in this article do not necessarily represent the views of the World Health Organization. As a *JAMA* Health Law and Ethics section editor, Mr Gostin did not influence the decision to publish this article.

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