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The International Health Regulations 10 years on: the governing framework for global health security

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Fundamental revisions to the International Health Regulations in 2005 were meant to herald a new era of global health security and cooperation. Yet, 10 years later, the International Health Regulations face criticism, particularly after the west African Ebola epidemic. Several high-level panels¹ are reviewing the International Health Regulations' functions and urging reforms.² The Global Health Security Agenda, a multilateral partnership focused on preventing, detecting, and responding to natural, accidental, or intentional disease outbreaks, has similar capacity building aims, but operates largely outside the International Health Regulations.^{3,4} Here, we review the International Health Regulations' performance and future.

The International Health Regulations⁵ is a legally binding instrument, which came into force in June, 2007, and now has 196 States Parties—every WHO member state plus Lichtenstein and the Holy See.⁶ The scope of the International Health Regulations is “to prevent, protect against, control and provide a public health response to the international spread of disease” (article 2). The scope embraces an all-hazards strategy, covering health threats irrespective of their origin or source (article 1), which is distinct from the disease-specific model used in previous versions of the International Health Regulations. The intention was to incorporate biological, chemical, and radionuclear events.

The International Health Regulations requires States Parties to develop core capacities for rapid detection and response, including for surveillance, laboratories, and risk communication—buttressed by legislation, financing, and national focal points. Core capacities embrace a public health strategy of strengthening local infrastructure and systems to detect, prevent, and contain outbreaks at their source before spreading internationally. States Parties agreed to “collaborate with each other” to develop and maintain core capacities.

Furthermore, States Parties must promptly notify WHO of events that might constitute a public health emergency of international concern, with a continuing obligation to inform WHO of any updates. To guide notifications, annex 2 of the International Health Regulations contains a “decision instrument” to aid in assessing whether to notify WHO of a health event of potential international concern. Certain threats, such as smallpox, always require notification. For other threats, States Parties must use the instrument to establish whether they need to notify WHO. Departing from previous versions, the International Health Regulations authorises WHO to consider unofficial sources, such as scientists and the media. When it receives an unofficial

report, WHO seeks verification from States Parties in whose territory the event occurs.

The declaration of a public health emergency of international concern is the crucial governance activity of the International Health Regulations. The Director-General has sole power to declare and to terminate a public health emergency of international concern but must consider information provided by a State Party; the decision instrument; Emergency Committee advice; scientific principles and evidence; and a risk assessment of human health, international spread, and interference with international traffic. If the Director-General declares a public health emergency of international concern, she must issue temporary, non-binding recommendations describing health measures that States Parties should take.

Since 2007, the Director-General has declared three public health emergencies of international concern. During the 2009 H1N1 influenza pandemic, WHO declared the first ever public health emergency of international concern but was criticised for fuelling public fear. State Parties widely disregarded WHO's temporary recommendations;^{7,8} however, in 2011, the Review Committee on International Health Regulations functioning during the H1N1 influenza pandemic cautioned, “The world is ill-prepared to respond to a severe influenza pandemic.”⁹

In 2014, the Director-General declared two further public health emergencies of international concern, for polio and for Ebola. The designation of polio seemed counterintuitive because only a handful of cases had been diagnosed compared with previous years. Yet, small pockets of polio in Afghanistan, Pakistan, and Nigeria were putting global eradication at risk. In the case of Ebola, the Director-General waited 4 months after Médecins Sans Frontières announced an “unprecedented outbreak” to declare a public health emergency of international concern on Aug 8, 2014.¹⁰ WHO's Ebola Interim Assessment Panel in July, 2015, said urgent warnings “either did not reach senior leaders or senior leaders did not recognise their significance.”¹¹

Several health emergency events have not resulted in a declaration of a public health emergency of international concern. Currently, the world is watching outbreaks of Middle East Respiratory Syndrome, which has not triggered a public health emergency of international concern declaration despite reaching more than 26 countries and causing 575 deaths by November, 2015.^{12,13} The Emergency Committee advised that, without sustained community transmission, the conditions for a public health emergency of international concern have not been met.¹⁴ The Director-General did not even convene an Emergency Committee for major events such

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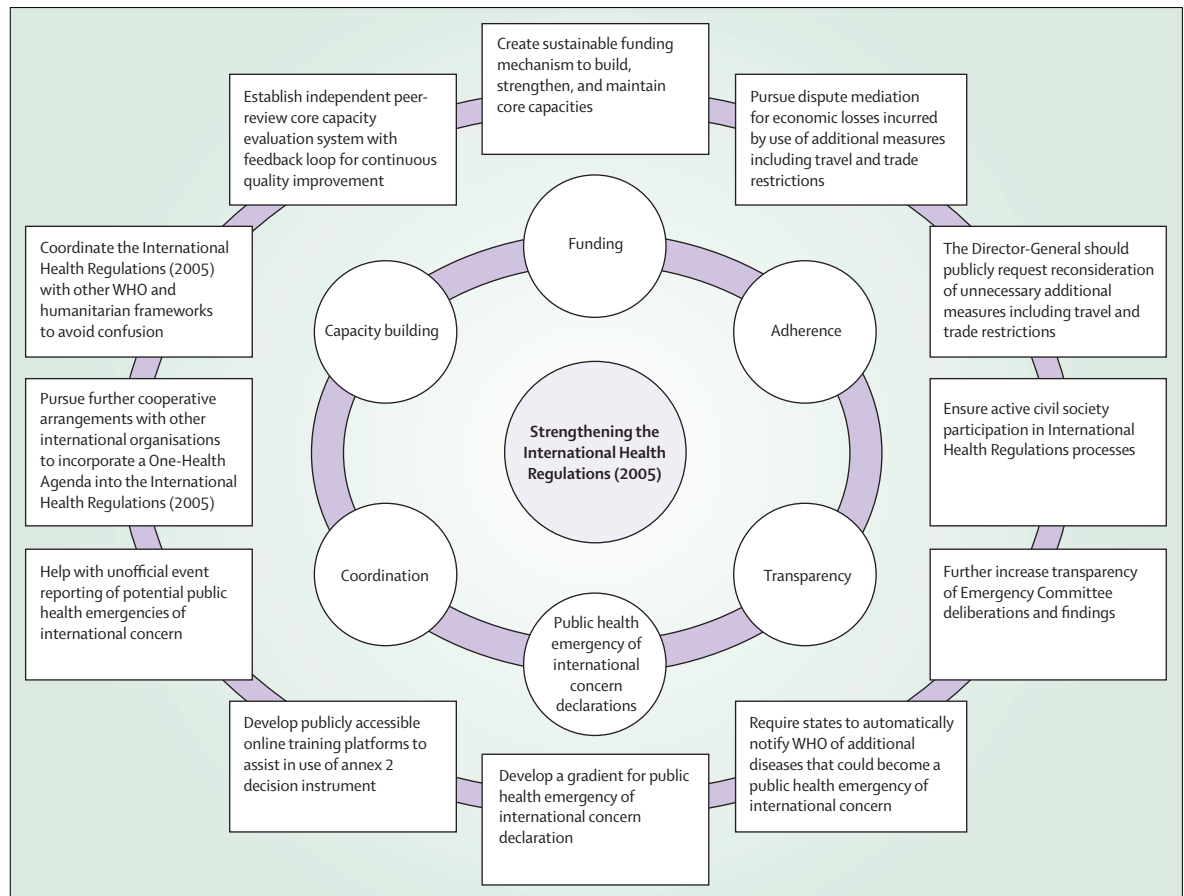


Figure: Strengthening the International Health Regulations (2005)

as cholera in Haiti, the Fukushima nuclear disaster in Japan, and the use of chemical weapons in Syria.

Reforming the International Health Regulations Towards a well functioning global detection and response system

Despite shortcomings, the International Health Regulations is an important governing framework. Yet, a crisis of confidence in the Regulations exists, with the Review Committee on International Health Regulations functioning during Ebola currently deliberating.¹⁵ We propose a series of operational and legal reforms. Operational reforms are often preferable. Amendments to the text of the International Health Regulations require World Health Assembly approval, do not enter into force immediately, and must be operationalised to be successful. Furthermore, reopening the full text could entail a multiyear negotiating process, which risks weakening the International Health Regulations' norms and protection of human rights. Even for our proposed legal reforms, we suggest ways to achieve them by textual interpretation and annex amendments in an attempt to avoid renegotiating the main text of the International Health Regulations.

As shown in the figure, although none of the following proposed reforms is a solution on its own, collectively they could help to build a well functioning global detection and response system. Some proposals will be easier to achieve than others, although all are needed reforms.

National core capacities

Achievement of core capacities by all States Parties remains an indisputable baseline for preparedness. The initial deadline to meet the International Health Regulations' core capacities was 2012, but WHO extended the deadline to 2016 for 81 States Parties. Only 64 States Parties have affirmed meeting core capacities.¹⁶ A well funded, prioritised, and comprehensive global plan is now past due. The November, 2014, International Health Regulations Review Committee offered a sound roadmap: strengthen self-assessment; test capacities through simulations; promote regional and cross-regional learning; and measure performance through peer review and external assessments.¹⁶ Such capacity building must go hand-in-hand with universal health coverage, a major target in the Sustainable Development Goals. The following three recommendations could

advance the International Health Regulations' aspiration for comprehensive preparedness in every country:

First, an "International Health Regulations Capacity Fund" should be established. The International Health Regulations (article 44) require State Parties to mobilise financial resources to build, strengthen, and maintain core capacities. The World Health Assembly should create an "International Health Regulations Capacity Fund," refreshed every 2 years through increased assessed dues—a logical funding source in view of the fact that core capacities and international cooperation are legally binding requirements of the International Health Regulations and WHO oversees the International Health Regulations. Voluntary financing is unpredictable, encourages earmarked contributions, and wanes in intercrisis periods. To ensure States Parties live up to their responsibilities, the World Health Assembly could establish domestic co-financing expectations as a baseline for accessing Capacity Fund resources.

Increasing assessed dues, although important to WHO's future, is politically fraught. Alternative financing mechanisms could include the Global Health Security Agenda, the World Bank's proposed Pandemic Emergency Financing Facility, or a donors' conference.^{17,18} Irrespective of the funding mechanism, ensuring sustainable resources would strengthen security for all.

Second, WHO should establish an independent peer-review core capacity evaluation system, with a feedback loop for continuous quality improvement. More rigorous evaluation of core capacities need to be undertaken. WHO allows States Parties to self-assess their capacities, with many not reporting whether they have met their obligation to develop core capacities. States often resist external assessment because of sovereignty concerns, but the new system would aim to foster cooperation. Domestic and external experts would work constructively with governments to identify capacity gaps, develop a jointly funded roadmap, and identify measurable benchmarks for success. If evaluations consistently led to technical and financial assistance, States Parties would be more likely to cooperate.

Third, civil society participation in reviewing core capacities should be enhanced. States Parties' reports and WHO evaluations should be open to public scrutiny to increase transparency. As with other spheres of international law, such as human rights and climate change, civil society could offer "shadow" reports to States Parties' reports and WHO evaluations and advocate for full funding of national capacities and fulfilling international obligations.

International Health Regulations Emergency Committees: transparent and independent

After facing criticism for disclosing the names of Emergency Committee members only after the H1N1 public health emergency of international concern was

terminated, WHO improved public trust by releasing member names for all subsequent Emergency and Review Committees.¹⁹ WHO also pledged transparency about conflicts of interest.²⁰ Concerns persist, however, that Emergency Committees are influenced by politics rather than strictly reviewing scientific evidence. To increase transparency, WHO could publish full meeting minutes, provide web access to documents, and offer live updates through social media platforms.

Transparent Emergency Committee deliberations showing independence would build public trust, but reforms are of little value if the Director-General does not convene an Emergency Committee. Outside WHO's governing structure and drawing on civil society, an expert independent committee could convene to review data for disease outbreaks and recommend actions to the Director-General.

Reporting and surveillance: the decision instrument (annex 2)

The World Health Assembly could amend the decision instrument to reduce States Parties' reporting discretion, avoiding delayed notification or verification. Presently, four diseases automatically require notification. Annex 2 of the International Health Regulations could be modified to require that additional listed diseases become automatically reportable. Limiting States Parties' discretion could simplify decision making and reinforce the norm of early notification. Routine notifications, moreover, would reduce the risk of under-reporting. Guinean officials, for example, initially downplayed the risk, reporting only confirmed Ebola cases.²¹ Procedurally, the World Health Assembly could update annex 2 of the International Health Regulations as it did with annex 7 regarding yellow fever vaccination.²²

The Ebola Interim Assessment Panel said there was unawareness or incomplete understanding of International Health Regulations requirements at many levels.¹⁴ WHO could assist States Parties in using the decision instrument by making International Health Regulations training publicly accessible through online platforms. The Health Security Learning Platform is a promising start, but is hard to find on WHO's website; tutorials should be accessible without needing registration.

Furthermore, WHO should publicly acknowledge information received from non-governmental sources, and help with unofficial reporting. For example, to help gather real-time intelligence, WHO could develop web, phone, and tablet applications to report to WHO's Strategic Health Operations Centre.²³ Even if a State Party does not corroborate an unofficial source, WHO should undertake its own analysis, sharing information transparently to the fullest extent possible in accordance with article 11 of the International Health Regulations. The new web portal that WHO is developing for information sharing and transparency may assist in implementing this recommendation.²⁴

Public health emergencies of international concern

A public health emergency of international concern declaration is the public face of WHO's outbreak response, but WHO has several instruments supporting earlier action. In view of the public symbolism of a public health emergency of international concern declaration, we believe that these emergency response frameworks must be integrated with International Health Regulations' processes. For example, WHO uses the Emergency Response Framework to inform the international community of an outbreak's severity in a graduated manner.²⁴ WHO's use of two distinct frameworks (the Emergency Response Framework and the International Health Regulations) resulted in confusion during the Ebola outbreak. Similar confusion arose during the H1N1 outbreak, when WHO did not coordinate the six pandemic phases of the Pandemic Influenza Preparedness and Response Framework²⁵ (since revised) with the International Health Regulations.

The WHO Ebola Interim Assessment Panel recommended an intermediate level emergency.²⁶ A gradient system would not necessarily require amending the International Health Regulations. Rather, WHO could develop informal guidelines through article 11. Alternatively, the World Health Assembly could formulate a new annex in the International Health Regulations to illustrate the risk gradient. Different grades must also trigger clear operational and financial responses. For example, an intermediate-level emergency could release resources from WHO's new emergency response contingency fund. A public health emergency of international concern declaration, however, would still be needed to raise the global alert, stiffen political resolve, and mobilise further resources.

Travel and trade restrictions: temporary recommendations and additional measures

State and private industry disregard for WHO temporary recommendations—particularly travel and trade restrictions and injudicious quarantines—undermine the International Health Regulations. Temporary recommendations for Ebola did not succeed on two fronts: the Ebola-affected countries' health systems did not have the resources to implement WHO temporary recommendations; and States Parties, because of domestic political pressure, disregarded temporary recommendations and did not discourage private disruptions of travel and trade, such as airlines cancelling flights. Governments imposed additional measures, impeding deployment of health workers and medical supplies to the affected region.

To enhance compliance, WHO should publicly request States Parties to justify additional measures and urge businesses to reconsider restrictions. WHO should publicly acknowledge States Parties and businesses that comply with temporary recommendations, while publicly naming those that impose unnecessary travel and trade restrictions.

States Parties should consider pursuing dispute mediation through the Director-General or compulsory arbitration (article 56 of the International Health Regulations). Successful cases by States Parties harmed by travel or trade restrictions or human rights violations would be a powerful precedent to enhance compliance. Lastly, the World Health Assembly could amend the International Health Regulations to increase temporary recommendations to a binding status. Even if temporary recommendations remain non-binding, trade restrictions could be challenged through the World Trade Organization, as Mexico did during the H1N1 pandemic.

Broadening the International Health Regulations: toward "One-Health"

The International Health Regulations (article 14) requires WHO to cooperate and coordinate its activities with intergovernmental bodies, including entering into formal agreements. These agreements could focus on one-health strategies, approaches based in the connections between human, animal, and environmental health. Cooperative arrangements can help one-health strategies, such as reducing antibiotic use in animals and misuse in humans; monitoring and preventing zoological infections; ensuring secure handling of hazardous materials; and facilitating vaccine research. Furthermore, equitable sharing of the benefits and burdens of scientific technology is crucial. The World Health Assembly should expand the Pandemic Influenza Preparedness Framework during its upcoming review of the Framework and integrate it with the International Health Regulations.

The way forward

10 years after its adoption, the time has come to realise the International Health Regulations' promise. The unconscionable Ebola epidemic opened a window of opportunity for fundamental reform—both for the International Health Regulations and the organisation that oversees the treaty. That political window, however, is rapidly closing. Donor fatigue, fading memories, and competing priorities are diverting political attention. Empowering WHO and realising the International Health Regulations' potential would shore up global health security—an important investment in human and animal health, while reducing the vast economic consequences of the next global health emergency.

Contributors

All authors contributed equally to the report.

Declaration of interests

LOG is a member of the WHO's International Health Regulations Expert Roster, the Harvard/London School of Hygiene & Tropical Medicine Independent Panel on the Global Response to Ebola, and of the US National Academy of Medicine Commission on a Global Health Risk Framework. MCD and EAF declare no competing interests.

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