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GLOBAL CRISES – GLOBAL SOLUTIONS

MANAGING URGENT INTERNATIONAL PUBLIC HEALTH EVENTS WITH THE REVISED INTERNATIONAL HEALTH REGULATIONS

International Health Regulations (IHR) Revision Project
World Health Organization
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(16 pages)

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A. INTERNATIONAL HEALTH REGULATIONS AND DISEASES IN A GLOBALIZING WORLD: AN OVERVIEW

In the 21st century, the phenomenon of globalization has altered the traditional distinction between national and international health. Very few, if any, urgent public health events are solely within the purview of national authorities. One of the obvious consequences of globalization is the increased risk of international spread of infectious diseases. People and goods are crossing national borders in massive numbers unparalleled in human history. While some countries may still opt for extreme protectionism, importation of diseases is always difficult to prevent. The cross-border impact of infectious diseases is better addressed through multilateral efforts by countries.

The most concrete measures to stop importation of infectious diseases are quarantine and trade embargoes, and the ultimate way to stop international spread of disease would of course be to stop all international traffic. Such drastic measures, although unlikely options in today's globalizing world, nonetheless underline the close connection between disease control, trade and traffic. The International Health Regulations (hereafter IHR) represent the earliest multilateral initiative by countries to develop an effective global surveillance for cross border transmission of diseases. The IHR strives to harmonize public health, trade and traffic, and today remains the only binding set of regulations on global surveillance for infectious diseases by WHO Member States.

B. BACKGROUND AND HISTORICAL DEVELOPMENT

The historical evolution of the International Health Regulations dates back to the mid-19th century when terrible epidemics of cholera overran Europe between 1830 and 1847. These cholera epidemics paved the way for an intensive infectious disease diplomacy and multilateral cooperation in the field of public health, which started with the first International Sanitary Conference, held in Paris in 1851.

From 1851 to the end of the nineteenth century, ten conferences were convened and eight conventions were negotiated on the spread of infectious diseases across national boundaries. Although most of these international sanitary conventions never entered into force, it became clear that the transboundary effect of infectious diseases was a problem that required multilateral efforts by countries. In 1892 the International Sanitary Conference held in Venice adopted the International Sanitary Convention, which was restricted to cholera. In 1897, another International Sanitary Convention dealing with preventive measures against plague was adopted. These two conventions were replaced in 1903 by a new International Sanitary Convention.

At the dawn of the twentieth century, the development of international regimes for cross-border surveillance of diseases coincided with the need to establish multilateral institutions to enforce these conventions. In 1902 an international conference of American States meeting in Washington DC established the International Sanitary Bureau – the precursor of the Pan-American Sanitary Bureau and the present Pan-American Health Organization. In 1907, the bulk of the European States that had negotiated the nineteenth-century international sanitary conventions met in Rome and adopted an agreement establishing "L'Office International d'Hygiène Publique", OIHP, (International Bureau of Public Health) with a permanent secretariat in Paris.

During the inter-war years, international health regimes were highly uncoordinated institutionally. Between 1919 to 1945, the health office of the League of Nations in Geneva, the Pan-American

Sanitary Bureau in Washington DC and the OIHP in Paris, existed independent of each other and enforced conventions and agreements within their respective areas of competence.

On April 7 1948, the Constitution of the World Health Organisation came into force, and in 1951 WHO member states adopted the International Sanitary Regulations – the product of intensive infectious disease diplomacy by countries in the mid-nineteenth and early twentieth centuries. WHO renamed these regulations the International Health Regulations (IHR) in 1969, and the Regulations were slightly modified in 1973 and 1981. Since then the IHR have been in force, representing the first international binding set of regulations adopted by WHO member states.

C. THE PRESENT IHR: ITS VISION AND PROBLEMS

The IHR is a regulatory mechanism for the sharing of epidemiological information on transboundary spread of infectious diseases. Its fundamental principle is to ensure *maximum security against the international spread of diseases with a minimum interference with world traffic.* The IHR also contains rules on the application of non-urgent public health measures to international travellers, conveyances and goods.

To achieve this purpose, the present IHR provides for obligations on WHO member states to notify WHO of the outbreaks of cholera, plague and yellow fever in their territories, lists the maximum measures applicable during such outbreaks, and makes rules for international traffic. These measures cover the requirements for health and vaccination certificates for travellers from infected to non-infected areas, deratting, disinfecting and disinsecting of ships and aircraft as well as detailed health measures at airports and seaports in the territories of WHO member states.

The reason to list maximum measures allowed is simple: if a template is not given for protective measures to be taken by countries in an outbreak situation, then there is great risk of overreaction, which could be very damaging to the country suffering the outbreak: tourism, traffic and trade might well suffer, with economic consequences that are far beyond the necessary and sufficient from a public health point of view.

Because of extensive globalization in travel and trade, countries are worried that diseases from even remote parts of the world could be imported. Potentially damaging traffic and trade embargoes can thus be imposed, often based only on the perception of risk for disease importation. This overreaction on the part of contiguous neighbours, trading partners and other countries can sometimes take on global proportions, as happened during the plague outbreak in India in 1994. $1.7 billion was lost by India before the event could be put into proper public health focus. These situations require a measured and evidence-based response from a credible third party. The IHR are the only legally-binding global tool for public health, and enable WHO, in direct collaboration with the Member States, to address these problems.

The present IHR, as a global regulatory tool for disease surveillance has the following major constraints:

- *Limited coverage:* It regulates only cholera, plague and yellow fever.
- *Dependence on country notification:* The IHR wholly depends on a country that has suffered an outbreak of any of the three diseases to make an official notification to the WHO.

- *Lack of mechanism for collaboration:* At present little exists in the IHR to foster collaboration between WHO and an affected country.
- *Lack of incentives:* The present IHR lack effective incentives to induce compliance by member states.
- *Lack of risk-specific measures*: At present WHO lacks the capacity to provide specific measures to prevent international spread of disease. WHO measures cannot be tailored to the event.

With these major constraints in mind, key changes have been proposed to develop an IHR that would adapt to emerging trends in twenty-first century epidemiology and global travel.

D. PROPOSED CHANGES TO THE IHR

The IHR revision is a collaborative process. Its essence is to review the gaps in the present IHR and transform it into an effective regulatory tool for WHO Member States to strengthen global disease surveillance and to act pro-actively in international outbreaks. Although some of the core concepts proposed for the revision of the IHR are new, most of them already exist in the present IHR. They are being developed and fine-tuned to adapt to contemporary global surveillance demands and control of international outbreaks. All of the items listed are proposals, and as such require extensive conusltation before presentation to the World Health Assembly and ultimate acceptance by Member States.

Definitions

- Some of the terms used below are still incompletely defined and must be finalized before inclusion in the IHR text. As in the existing IHR, part of the revised text will include all relevant definitions.
- As for the central term "risk of urgent international importance related to public health", see below under item II for a first attempt at a definition. In the text below this rather long term will be replaced by "urgent international risk", or sometimes only "risk".
- No clear position has been taken whether non-infectious events should be included in this definition or not.

The proposed core concepts in the new IHR will cover the following areas:

I. The new IHR may reference a list of important notifiable diseases, but it will also require the reporting of all risks of urgent international importance related to public health. This dual approach should ensure that all public health events that could have international impact are captured, not just the listed diseases. Both the listed diseases and risks notified to WHO will be assessed to see if they are both urgent and international.

Rationale. In the present world of new and re-emerging diseases, any disease list could become obsolete the day after it was printed. Also, a case of a disease in itself does not always pose a danger of international spread or impact. The disease must be coupled to circumstances, such as place, time, size of outbreak, closeness to an international border (or an airport), speed of spread and mode of transmission.

A key concept of the revised IHR – and one which will require a change in the way countries interact with WHO – is that *risks of urgent international importance related to public health* should be notified to WHO. The new IHR will contain an algorithm - a test, to help decide when an event would be both urgent *and* international. Obtaining agreement on such an algorithm will be one of the main tasks of the IHR Revision Team. An early draft of this algorithm, which was tested during the Syndrome Pilot Study, contained the following parameters:

- high potential for spread outside the community/country;
- unexpectedly high case fatality ratio;
- unusual or unexpected event;
- country capacity to control and contain the event;
- high international media profile;
- potential for imposition of trade/traffic barriers by other countries;
- occurring in a high density/urban area;
- significant possibility of international transport of infected persons or contaminated goods/conveyances; and
- significant possibility of vector transport.

Impact. The concept of urgent risk of international importance related to public health means that countries will need to assess unlisted disease risks to determine if the event has international consequences. If it does, the national administration will have to quickly decide if the risk fulfils the WHO criteria, and whether it should be reported to WHO. Tools like the algorithm should assist this process.

II. Each country will need a focal point for the IHR process

Rationale. Since the new IHR will cover a much wider span of public health risks, and since these risks may appear very quickly, communication with WHO needs to be available 'round the clock'. This will be required both for information going out from a country affected by a disease risk, and for information from WHO about risks in other countries. In the latter case, this information may have to be distributed nationally to hospitals, health officials, ports, and airports very quickly.

Impact. The communication will have to be electronic, and there needs to be a back-up system within each Member State, so that one single e-mail address always leads to someone who is available. In an urgent situation, a single contact point is vital to ensuring that the Member State can protect itself from the emergency.

III. Each country must have a capacity to quickly report and analyse national disease risks, to determine their potential to affect other Member States

Rationale. In order for urgent national risks that could be of international importance to be identified early, each country will require a surveillance system which feeds information on the listed diseases and unusual and unexpected risks from the periphery into the central administration in a very short time. Further, the system must have the capacity to rapidly analyse such data. The revised IHR will contain a recommended template for core requirements for a national surveillance system.

Impact. In many countries, this surveillance/analysis capacity may already be in place. Others may need a grace period to fulfil this IHR requirement, and external assistance and funding may become necessary. One advantage of having an IHR template for core requirements is that countries could use this in defining their core surveillance needs to external donors.

IV. Member States will have the option to make confidential, provisional notifications to WHO. This option is not available within the existing IHR, which automatically lists notified cases of cholera, plague or yellow fever in the Weekly Epidemiological Record (WER)

Rationale. In the early days of an outbreak, it will often not be clear if the criteria for an urgent international risk are fulfilled. With this proposed change, Member States will have the option to contact WHO on a provisional basis, with no information made public. The affected State can then work together with WHO to assess the extent and potential impact of the risk. This process could lead to a joint statement from the country and WHO, either to inform other Member States that the risk was only national in scope, or to state that there is a possibility of international spread, but that only certain control measures need to be taken. In many instances, the risk will remain national, and no further action will be required.

Provisional notification would be ended when there is an increased threat or evidence of international disease spread. In this case, and after direct consultation with the affected State, WHO would release the information necessary for the protection of other Member States.

Impact. The affected Member State(s) can have an opportunity to reduce potential economic damage by gaining credibility through collaboration with WHO, and other countries can reduce their response activity costs due to overreaction. Any country which has not involved WHO in the assessment of a problem will not have the protection of recommendations (and credibility) from the Organization if the news becomes public, and would be open to arbitrary restrictions from other countries.

V. Other information than official notifications will be used by WHO to help identify and control urgent international risks. There will be an obligation on Member States to respond to requests from the Organization to verify the reliability of such information.

Rationale. In the present era of rapid electronic communication – the global information super highway – news about many urgent international risks will become public before even the most efficient administration has had time to react and notify. Such news, even if unverified, may quickly lead to restrictions on traffic and trade from other countries feeling threatened. WHO should become an important collaborator in the assessment of the situation as early as possible. In situations where apparently reliable information about an outbreak in a Member State has been provided to WHO, the Organization will contact the State and ask for verification of the risk status within a very short time period.

Faced with non-notification of what appears to be an urgent international risk, the Organization will need to inform other Member States for their protection, and if necessary, issue recommendations on appropriate measures.

Impact. The present IHR obligation on Member States to notify for three diseases is thus extended to an obligation to notify other listed diseases and to respond to inquiries from WHO about any potential urgent risk within a limited time frame. It can be foreseen that, in most such instances, the affected country will work closely with WHO to protect itself from unnecessary traffic restrictions. In the case of non-notification, however, the decision process must be consistent and clear.

VI. The new IHR will attempt to ameliorate the economic losses associated with international disease risks, by issuing recommendations that in effect establish a template for the measures required for the protection of other Member States. These measures will be based on the actual public health threat or impact of the risk, as determined by assessing all of the evidence available during the risk period, in collaboration with the affected State.

Rationale. Any functioning global surveillance system must take into account the economic consequences of reporting of disease risks. If the WHO notification and response system cannot help to reduce tourism and trade losses to what is strictly required from a public health perspective, compliance with IHR reporting and notification obligations will likely be ignored by member states. This is in keeping with the historic purpose of the IHR. "to ensure the maximum security against the international spread of diseases with a minimum interference with world traffic".

Impact. WHO is attempting to maintain a dual-purpose regulation (health/traffic), and the new IHR must try and address both aspects. Besides working with Member States and Regional Offices, the revision consultation must include all WHO departments involved in goods, such as Food Safety, Environment, Pharmaceuticals, as well as a plethora of external stakeholders which could be impacted by international disease events.

VII. There will be an obligation on WHO to rapidly assist member States in assessing and controlling outbreaks.

Rationale: Both after a provisional notification (Item IV) and after a request from WHO for further information (Item V), many countries may need external assistance. If the extent and potential threat of the outbreak is unclear, the Organization will offer to send a response team, which will collaborate closely with the Member State government in controlling both disease spread and minimizing economic damage related to the event.

A key benefit of working with the WHO response team would be to assist affected countries to achieve international acceptance of their capacity to prevent international spread through an independent, third-party evaluation. This should reduce unnecessary economic hardship for the affected country.

Impact. The capacity of WHO to react and assist in outbreaks, even when there are multiple outbreaks occurring simultaneously, must be improved.

VIII. There will be a transparent process within WHO to issue recommendations

Rationale. When there is imminent risk of international spread of disease or disruption of international traffic, WHO will issue recommendations for Member State action. These recommendations could be directed either at the affected country regarding containment and control measures, at all other Member States, or both.

Impact. This decision process requires rapidity, while at the same time building on consensus of as wide a representation as possible. Determining the most workable format remains one of the major tasks of the IHR Revision Project, but with all probability it will have to be a virtual, electronic process. It is important that these recommendations come from one single point within WHO.

IX. The revised IHR will contain a list of all key measures that could be used in a WHO recommendation.

Rationale. Each urgent risk is unique, and there is no way to describe the measures appropriate for each risk in advance. The proposed model is a compromise: the list of measures that could be taken to prevent international spread of disease – at embarkation, during travel, and at point of entry – is really not very long, and should be contained in the new IHR.

Some of the examples of the draft measures currently under assessment for the ongoing revision process are shown below:

Measures potentially applicable at point of entry into non-affected member States from an affected member State.

1. *To Travellers*
   - *no measures required*
   - *require travel history in affected country*
   - *require proof of medical examination*
   - *require medical examination on entry*
   - *require proof of vaccination or other prophylaxis for entry*
   - *require vaccination or other prophylaxis for entry*
   - *require protective measures for suspected cases*
   - *require active or passive medical surveillance from travellers from affected area*
   - *require isolation of traveller for incubation period of disease*
   - *refuse entry of persons from affected area*

2. *To Goods and Conveyances*
   - *no measures required*
   - *require inspection of conveyance, cargo or goods*
   - *require treatment of conveyance, cargo or goods*
   - *require isolation of conveyance, cargo or goods*
   - *require destruction of cargo or goods*
   - *refuse entry of conveyance, cargo or goods*

During an actual urgent health risk, WHO would choose the appropriate measures to be taken from the complete list, and use this as a basis for a for a recommendation for Member States. This recommendation would be time-limited, and may change during the risk period. A clear protocol for ending risk measures would be included in the IHR text.

Impact. The current disease response measures listed in the IHR are the maximum permitted, and they are binding on member States. To create the flexibility required to adapt to each major international threat, both non-binding recommendations for events and fixed binding measures are required, where appropriate, for the listed diseases.

X. A permanent IHR review body needs to be established to build continuity within the IHR process

Rationale. The existing IHR became out of date due to lack of a mandatory review process. The new IHR will have broad-based provisions, and will require on-going interpretation and precedence setting.

For example, the similar network for reporting of urgent events between EU Member States is backed by a committee that meets several times per year to clarify the application and scope of this obligation.

Impact. The Organization needs to ensure that this process is fully supported.

E. SUMMARY OF VISION BEHIND THE PROPOSED CHANGES

In a globalized world of the twenty-first century, the IHR builds on the emergent inexorable link between national and global surveillance for diseases. As the regulatory framework for global surveillance of diseases, the new IHR will contain functional and effective templates for national surveillance as well as response processes for international disease threats and the harmonization of control measures.

The need for WHO to issue recommendations for international disease risks is founded on the following chain of reasoning, which underscores the cross-border impact of globalization and public health:

- First, the best way to prevent international spread of diseases is to either detect disease pathogens or other public health threats early, and stamp them out when they are still a small national problem.

- Second, early detection of unusual disease events requires good national surveillance.

- Third, international coordination is necessary since many countries may need assistance from multilateral institutions during serious disease risks, and international traffic may be quickly affected, to the detriment of many States.

- Fourth, the need for international coordination presupposes the existence of international coordinator to help harmonize and standardize notifications, responses from other countries and the global sharing of epidemiological information.

- Fifth, effective notification of disease risks to an international coordinator (WHO) will be facilitated by an assurance of how this information will affect the Member States' economic interests in trade and tourism.

Building on the five-pronged dimensions of this chain of reasoning, the IHR as a legally-binding regulatory mechanism for global surveillance of international disease events seeks to strike a critical balance between public health and interference with international traffic movement. It is not an easy task to maintain this delicate balance, and it is in this context that the difficulties of the IHR revision will be understood.

F. BENEFITS OF THE NEW IHR TO WHO MEMBER STATES

The new IHR recognizes health as a global public good. As already stated, the traditional distinction often drawn between national and international public health has been shattered by the phenomenon of globalization. Pathogenic microbes carry no national passports. National boundaries have become highly vulnerable to diseases in the twenty-first century. The only effective solution to reduce this spread is to develop an effective global surveillance system, which builds on responsive national surveillance systems. The proposals for a new IHR seek to do this within a multilateral framework, which emphasises a national-global

surveillance and response partnership and collaboration. Within this multilateral framework, the new IHR revision stands to benefit Member States by:

- improving national surveillance in many countries;
- developing system to detect and quickly respond to potential international health events developing the use of modern communication tools;
- recognizing the fact that disturbances to free international traffic movement constitute an obstacle to reporting and the need to develop mechanisms to counter this interference;
- developing a set of generic rules to resolve different kinds of urgent events; and
- developing a rapid mechanism to agree on appropriate levels of national protection within this set of rules.

No isolated national control strategy will work in the long run. The only certain way for countries to protect their populations from the impact of international disease threats is to come together and agree on global solutions. These solutions can be made available to Member States by including them in the new IHR.

G. BUILDING CONSENSUS FOR THE IHR

The IHR revision process strives to build broad consensus with WHO Member States. The current collaboration between the Secretariat and interested Member States is designed to test the proposed changes and to seek suggestions on how the Member States would want the new IHR to operate. An extension of this collaboration has led to the setting up of an electronic virtual discussion forum between the IHR team and representatives of WHO Member States. The revision team wrote to all the Member States asking them to nominate focal points from their relevant ministries to act as resource persons to make inputs to the revision process.

The next stage of consensus building involves WHO Country Representatives in various Member States, WHO Regional Offices as well as collaboration with international agencies and institutions whose work is related to the IHR. Examples of these organizations include the FAO, IATA, ICAO, WTO and IMO. The requirements of the IHR will impact on many stakeholders, and they need to be consulted during the revision process.

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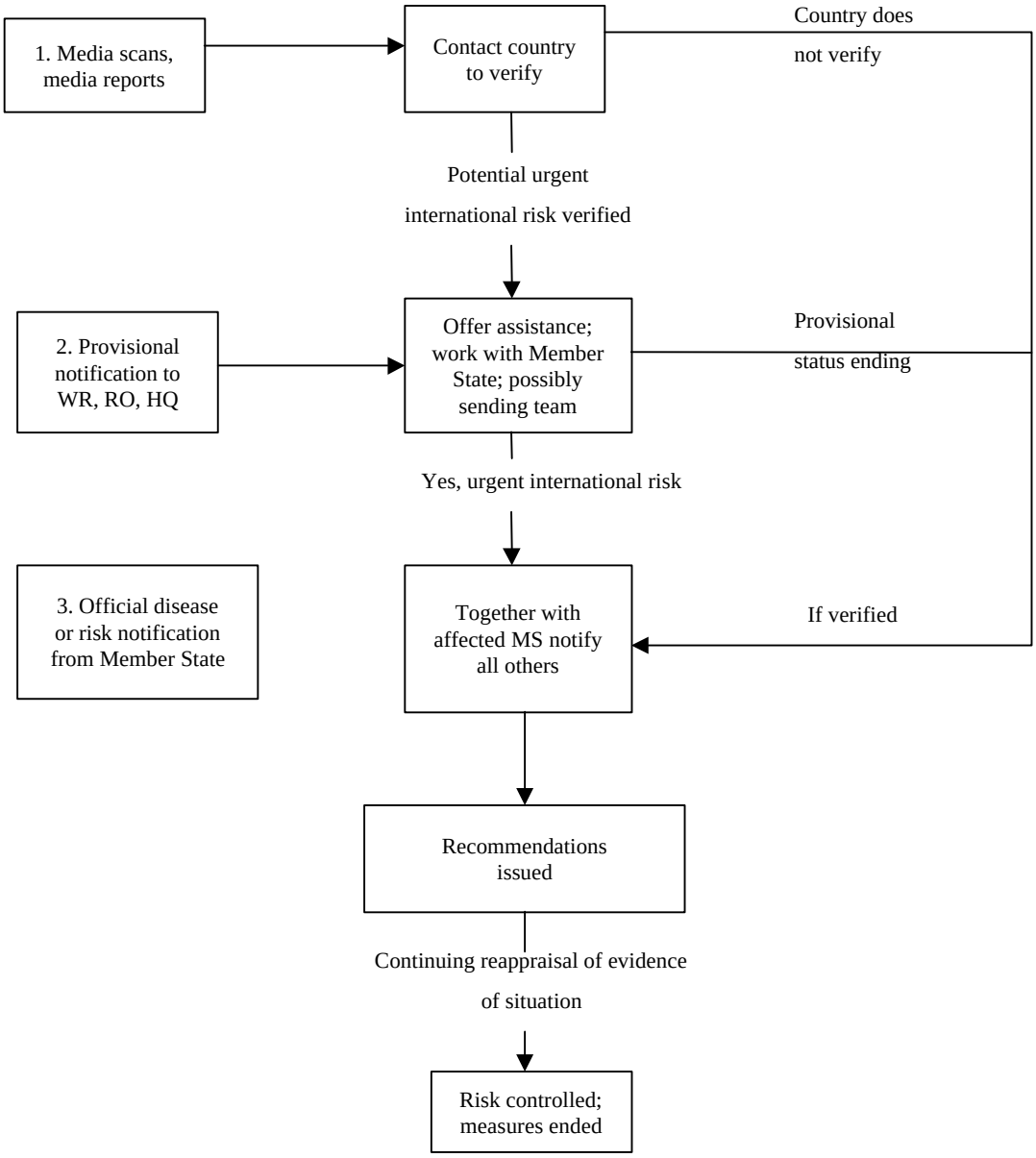
APPENDIX 1

Schematic flow chart of revised IHR notification process



Information can thus reach the Organization via three different routes. After verification and collaboration with affected country, all routes lead to the same action.

(Please note that this is a superficial representation: many more activities would be included. For example, no boxes show what happens if an event is eventually shown not to be of international importance.)

APPENDIX 2

Summary of proposed core obligations, capacities and operational requirements in the new IHR

Definitions

Core obligations. Those unchanging and essential public health needs that establish the framework for the Regulations.

Core capacities. The elemental level of activity needed to fulfil the core obligations.

Operational requirements. The detailed instructional models for carrying out activities to fulfil IHR obligations.

Core obligations for Member States

- Notify the Organisation of cases of the listed diseases and potential urgent international risks.
- Respond to requests for verification of urgent national risks.
- Control national urgent public health risks that threaten to transmit disease to other Member States.
- Provide routine and emergent port of entry/embarkation inspection and control activities to prevent international disease transmission.

Core obligations for international conveyance operators

- Maintain the conveyance in a manner which does not contribute to international disease transmission.
- Comply with the requirements of the Regulations as directed by Member States.

Core obligations for the Organization

- Respond to Member State emergent and routine needs as regards the interpretation and implementation of the Regulations.
- Update the Regulations as required to maintain scientific and regulatory validity.

Core capacities for Member States

- Provide a surveillance system to quickly identify listed diseases and urgent national public health risks, analyse the risks against the parameters provided to determine an urgent international risk, and if indicated, notify WHO.
- Provide control mechanisms that prevent the spread of national disease to other Member States.
- Provide port of entry and related inspection and control activities for international travellers, conveyances, goods and cargoes.

Core capacities for international conveyance operators

- Provide on-board inspection and control measures to ensure that diseases are not carried by passengers, crews, goods, insect vectors or rodents, or by the conveyance itself.

Core capacities for the Organization

- Provide a 24-hour service to coordinate international response to urgent international risks that threaten Member States.
- In conjunction with the affected Member State(s), provide a consistent and transparent process to assess urgent international risks.
- Based on this assessment, issue recommendations regarding the application of selected health measures.
- Provide a collaborative notification and response process involving WHO Country Representatives, WHO Regional Offices and Headquarters and Member State health administrations, to assist Member States to deal with urgent international risks.
- Provide an assisted bilateral process and a Committee of Arbitration for disputes between Member States involving the interpretation of the IHR.

Operational requirements of the new IHR

It is the practice within WHO for departments to publish operational guidelines. These guides could be adopted for reference in the new IHR after meeting an established review process. To be referenced in the IHR, a guideline would have to answer the following questions:

- Is it directly relevant to the IHR (and Member States) as a global reference?
- Is it based on core requirements only?
- Has it completed a scientific review?
- Has it completed an operational review, by: Member States, operators, and other stakeholders?
- How will it maintain scientific validity?
- Will it be regularly reviewed and updated as required?

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APPENDIX 3

IHR revision process in retrospect

May 1995:	World Health Assembly passes Resolution 48.7 calling for the revision of the IHR.
December 1995:	Meeting of international experts decides to pursue syndrome notification, to try and capture all important disease events.
1996-1997:	Informal Working Group of internal and external experts established. The group recommends the use of disease syndromes and to continue existing public health requirements in the 1969 version of IHR.
October 1997:	Initiation of Syndrome Notification Pilot Study in 21 countries selected by WHO regional offices.
January 1998:	Preliminary IHR draft distributed to Member States for review and comment.
May 1998:	Progress report to the World Health Assembly.
November 1998:	Meeting of the Committee on International Surveillance of Communicable Diseases (CISCD).
January 1999:	Small working group met to analyse CISCD meeting and propose future changes.
March 1999:	Syndrome Notification Pilot Study terminated.
August 1999:	- IHR Revision team strengthened; - new concepts elaborated and developed ; - 21 meetings held with collaborating Member States; - electronic Virtual Discussion Forum initiated with participants from some 70 Member States; - collaboration with relevant international agencies: WTO, IMO, IATA, ICAO, IAEA, EU pursued; - IHR policy paper discussed by WHO cabinet; and - synergy between IHR and WTO's SPS agreement explored

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APPENDIX 4

Contact addresses

Since the IHR revision process is still in the development stage, no new draft IHR version currently exists. Information on the IHR revision can be obtained from the Secretariat at WHO Headquarters in Geneva.

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