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INTERNATIONAL HEALTH REGULATIONS

The International Health Regulations (IHR) are being revised in accordance with a resolution adopted by the World Health Assembly in 1995 (WHA48.7). The purpose of the revision is to adapt the IHR to the present volume of international travel and trade and take into account current trends in the epidemiology of communicable diseases, including emerging diseases threats**.** The WHA resolution urged Member States and international organizations to participate directly in the revision. Expert meetings and working groups convened by WHO have recommended that the IHR contain two key sections: a main, essentially unchanging core text and a more easily modified annex of technical requirements. They also proposed that syndromes be used for notification of disease events, instead of a disease list. A provisional draft of the IHR was prepared in 1998 after wide-ranging international consultations, using syndromes of diseases, and this draft was sent to all Member States for review. The feedback obtained from the Member States and key stakeholders acknowledged that, while syndromes were a useful tool for very early notification of undiagnosed disease, they could not be the sole reference to disease in the Regulations. Because of this obstacle, a thorough review of the problems identified in the 1998 draft was initiated. New concepts were developed and proposed in 1999-2000 to create an IHR that could adapt to each serious, unexpected public health event of potential international importance.

The importance of the IHR requires that the Secretariat ensure that all the essential international public health needs of the Member States are addressed by the IHR. Since many of the routine obligations in the IHR, such as surveillance and border responsibilities, require direct funding by the Member States, the States should decide on how these obligations can be met. They must also decide whether the current deadline of May 2004 for the submission of the revised IHR to the WHA is realistic given the need to fully consult with Member States on all key decisions.

This progress report is submitted for the Executive Committee's consideration.

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REVISION OF THE INTERNATIONAL HEALTH REGULATIONS: A PROGRESS REPORT

1. Introduction

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 best 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 strive to harmonize public health, trade, and traffic, and today remain the only binding set of regulations on global surveillance for infectious diseases by WHO Member States.

The World Health Assembly (WHA) requested the revision of the IHR in 1995 (WHA48.7), to address the threat posed by substantial increases in international travel and the potential for rapid dissemination of infectious diseases, especially by air travel. The IHR had proven to be ineffective in addressing the emergence of Ebola in the Democratic Republic of the Congo in 1995—Ebola was not included in the three diseases listed in the IHR—and with the interference with regional trade caused by the reemergence of cholera in the Americas in 1991.

The key changes proposed in the revised IHR are:

(a) Extend the capacity of the IHR and Member States to deal with all urgent international disease risks, including emerging diseases. Member States would be required to notify WHO of all public health risks of potential international importance that occur in their territory.

(b) Create a list of all the key public health measures that could be applied by Member States to contain a disease event or to counter the threat of disease importation from the event.

(c) Provide event-specific recommendations and/or time-limited directions for the application of certain measures, as appropriate, during urgent events, drawing from the above-mentioned list, which will be published in the IHR text.

(d) Allow the use of information from sources, for example the other than official Member State notifications, to request verification of the status of a disease event. No further action would be taken without direct consultation with the affected Member State.

(e) Provide Member States with a "test" for assessing national public health risks to see if they meet both urgent and international parameters, and, hence, should be notified to WHO.

(f) Provide a template to help define a consistent minimum Member State capacity for surveillance and response for urgent, potentially international risks.

(g) Provide more flexibility for Member States by using a capacity-based formula for port-of-entry organizational requirements.

(h) Provide Member States with a clearer international mandate to board and inspect international conveyances, such as ships and aircraft. The range of items included in the ship requirements, for example, will be more comprehensive to reflect emerging public health issues. WHO proposes to oblige international operators to meet the new requirements, and the conveyances would be subject to compliance inspections, as appropriate, by Member States.

The current public health protection measures, which are applied unilaterally by Member States for international travelers, conveyances, goods, and cargoes will continue in the revised IHR. These measures will be subject to review and consultation to ensure that they are still scientifically valid and meet Member State operational requirements.

2. The Present International Health Regulations: Their Vision and Problems

The IHR are a regulatory mechanism for the sharing of epidemiological information on transboundary spread of infectious diseases. Their fundamental principle is to ensure maximum security against the international spread of diseases with a minimum of interference with world traffic.

To achieve this purpose, the present IHR provide for obligations on WHO Member States to notify WHO through its Country and Regional Offices of the outbreaks of cholera, plague, and yellow fever in their territories; list the maximum measures applicable during such outbreaks; and makes rules for international traffic. These measures cover the requirements for health and vaccination certificates for travelers 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. This could be very damaging to the country suffering the outbreak: tourism, traffic, and trade might well suffer, with economic consequences that are far beyond what is 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 neighbors, trading partners, and other countries can sometimes take on global proportions, as happened during the cholera epidemic in the Americas in the early 1990s. Andean countries lost more than US$ 1,000 million before the event could be put into proper public health focus. Such situations demand a measured and evidence-based response from a credible third party. The IHR are the only international legally-binding global tool for public health and enable WHO and its Regional Offices, in direct collaboration with the Member States, to address these problems**.**

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

- *Limited Coverage:* They regulate only cholera, plague, and yellow fever.

- *Dependence on Country Notification:* The IHR wholly depend on a country that has suffered an outbreak of any of the three diseases to make an official notification to the WHO.

- *Lack of Mechanisms 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 Event-Specific Measures:* At present WHO lacks the capacity to provide specific measures to prevent the international spread of disease. IHR measures cannot be tailored to the event.

With these major constraints in mind, key changes have been proposed to develop IHR that would adapt to emerging trends in 21st century epidemiology and global travel.

3. Proposed Changes to the International Health Regulations

The IHR revision is a collaborative process. Its essence is to review the gaps in the present text and transform IHR 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 consultation before presentation to the World Health Assembly and ultimate acceptance by Member States.

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 "event of urgent international importance related to public health," see below under 3.2 for a first attempt at a definition. In the text below this rather long term will be replaced by "urgent international event," or sometimes only "event." 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:

3.1 *The new IHR will not contain a list of notifiable diseases, nor will depend solely on the use of syndromes for notification. Instead they will require the reporting of all "events of urgent international importance related to public health."*

Rationale: In the present world of new and reemerging diseases, any disease list can become obsolete the day after it is 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 with specific circumstances, such as place, time, size of outbreak, closeness to an international border (or an airport), speed of spread, and mode of transmission. Routine occurrence of endemic diseases will not be notifiable under the revised IHR. Consequently, cholera

would no longer be notifiable unless an outbreak were of urgent international importance, for instance, if it occurred in an area where the disease is not endemic, or involved a new strain with antimicrobial resistance or unusual severity, or if trade and travel restrictions were applied by other Member States.

The core concept of the revised IHR—and one that will require substantial change in the way countries interact with WHO—is that events 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
- significant possibility of vector transport

Impact: The concept of "urgent event of international importance related to public health" means that countries should no longer send off reports about diagnosed cases of cholera, plague, or yellow fever in an almost automatic fashion. When there is an event with possible international consequences, several sectors of the national administration will have to quickly decide if the event fulfills the WHO criteria, and whether it should be reported to WHO. Tools like the algorithm should assist this process.

3.2 ***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 events and outbreaks, and since these events may appear very quickly, communication with WHO needs to be available around the clock. This will be required both for information going out from a country affected by an event and for information from WHO about events in other countries. In the latter case, such 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.

3.3 ***Each country must have a capacity to quickly report and analyze national disease events, to determine their potential to affect other Member States.***

Rationale: In order for urgent national events that could be of international importance to be picked up early, each country will require a surveillance system which feeds information on unusual and unexpected events from the periphery into the center in a very short time. Further, the system must have the capacity to rapidly analyze 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 fulfill 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 the national health sector and to external donors.

3.4 ***Member States will have the option to make confidential, provisional notifications to WHO.***

This option is not available within the existing IHR, which automatically list notified cases of cholera, plague, or yellow fever in the *Weekly Epidemiological Record (WER)*.

*Rationale**:*** In the early days of an event, it will often not be clear if the criteria for an urgent international event 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 event. This process could lead to a joint statement from the country and WHO, either to inform other Member States that the event was only national, or to state that there is some risk of international spread, but that only certain control measures need to be taken. In many instances, the event will remain national in scope, 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 limit to reduce potential economic damage by gaining credibility through collaboration with WHO, and

other countries can reduce unnecessary response cost due to overreaction. Any country that has not involved WHO in the assessment of a problem will not have the protection of recommendations from the Organization if the news becomes public, and would be open to arbitrary restrictions from other countries.

3.5 ***Other information than official notifications will be used by WHO to help identify and control urgent international events. There will be an obligation by 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 events 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 event status within a very short time period.

Faced with non-notification of what appears to be an urgent international event, 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 events to, or to respond to inquiries about, any potential urgent event from the WHO within a limited time. 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-ratification, however, the decision process must be consistent and clear.

3.6 ***The new International Health Regulations will attempt to ameliorate the economic losses associated with international disease events, 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 event, as determined by assessing all of the evidence available during the event, in collaboration with the affected State.***

Rationale: Any functioning global surveillance system must take into account the economic consequences of reporting of disease events. 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 most 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, and pharmaceuticals, as well as a plethora of external stakeholders who could be impacted by international disease events.

3.7 ***There will be an obligation by WHO to rapidly assist Member States in assessing and controlling outbreaks.***

Rationale: Both after a provisional notification (3.4) and after a request from WHO for further information (3.5), many countries may need external assistance. If the extent and potential threat of the outbreak are unclear, the Organization will offer to send a response team, which will collaborate closely with the Member State government in controlling both diseases spread and minimizing the 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.

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

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

Impact: This decision process requires rapidity, while at the same time consensus is being built with 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.

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

Rationale: Each urgent event is unique, and just as it is impossible to give a list of diseases (see 3.2), there is no way to describe measures appropriate for each event 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 not extensive, 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 are:

(a) For travelers:

- 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 travelers from affected area
- require isolation of traveler for incubation period of disease
- refuse entry of persons from affected area.

(b) For 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 event, WHO would choose the appropriate measures to be taken from the complete list and use this as a basis for a recommendation for Member States. This recommendation would be time-limited for the event. A clear protocol for ending event 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, non-binding recommendations will have to replace the fixed binding measures provided in the current IHR text.

3.10 ***A permanent International Health Regulations 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 European Union 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.

4. Summary of Vision Behind the Proposed Changes

In a globalized world of the 21st 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 events 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 events, and international traffic may be quickly affected, to the detriment of many States.

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

- Fifth, effective notification of disease events to an international coordinator will be facilitated by an assurance of how this information will affect WHO 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 seek 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.

5. Benefits of the New International Health Regulations for 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. National boundaries have become highly vulnerable to diseases in the 21st century. The only effective solution to reduce this spread is to develop an effective global surveillance system that builds on responsive national surveillance systems. The proposals for a new IHR seek to do this within a multilateral framework, which emphasizes a national-global surveillance partnership and collaboration. Within this multilateral framework, the new IHR stand to benefit Member States by:

- improving national surveillance in many countries
- developing a 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 traffic constitute an obstacle to reporting and that there is a need to develop mechanisms to counter this interference
- developing a set of generic rules to handle different kinds of urgent events
- 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.

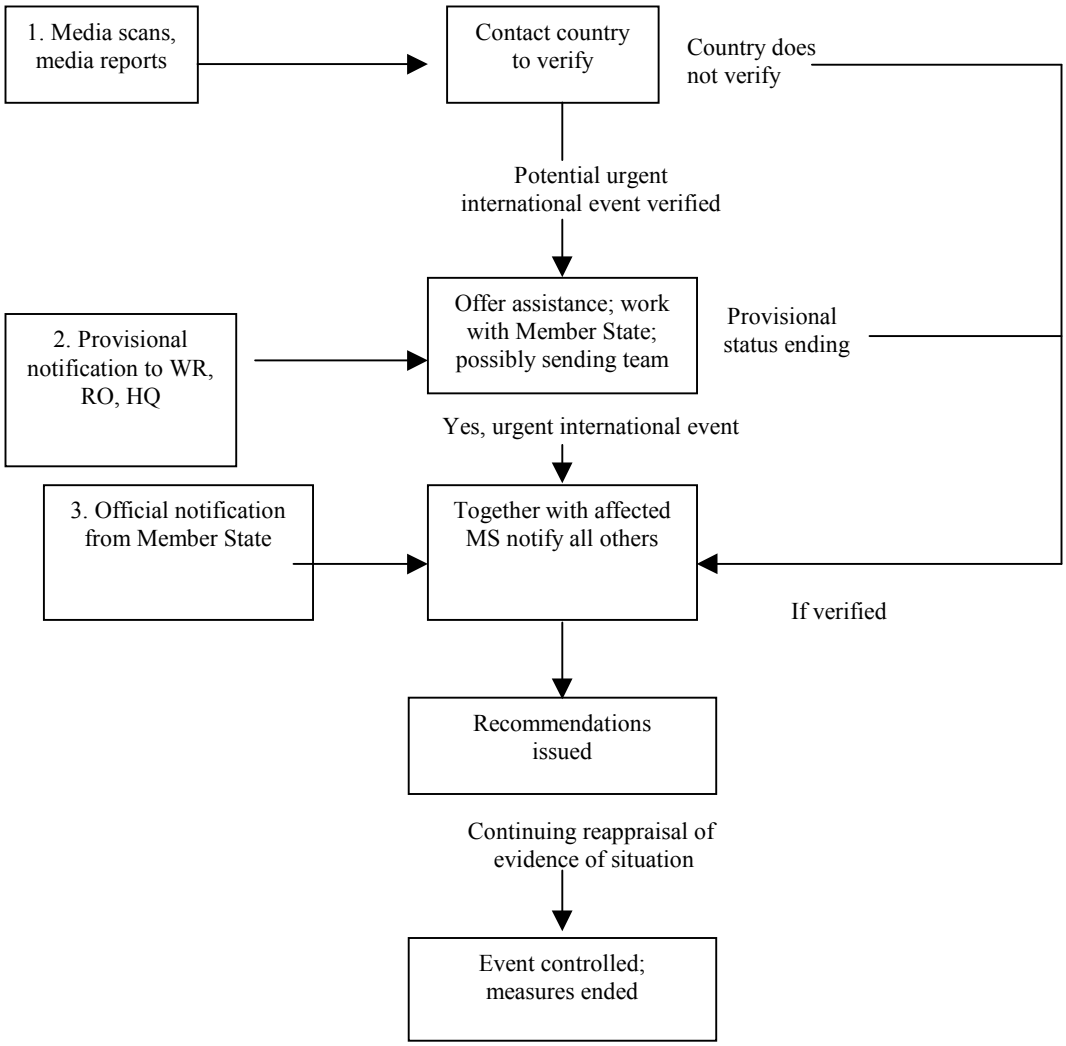
6. Building Consensus for the International Health Regulations

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. In the Region of the Americas, PAHO has been working with Brazil, Mexico, Peru, and signatory States of MERCOSUR to formally establish collaboration partnerships for the IHR revision process. In fact, MERCOSUR has included the follow-up of the IHR revision as an agenda topic of its health sector committee.

The next stage of consensus-building involves the working relations of WHO Country Representatives, Member States, and WHO Regional Offices with international agencies and institutions whose work is related to the IHR. These include the Food and Agriculture Organization (FAO), International Air Transport Association (IATA), International Civial Aviation Organization (ICAO), World Trade Organization (WTO), and International Maritime Organization (IMO).

Annexes

Schematic Flow Chart of Revised International Health Regulations 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.)

Annex B

International Health Regulations Revision Process

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 convened to analyze CISCD meeting and propose future changes.

March 1999: Syndrome Notification Pilot Study terminated.

August 1999 - Present:

- IHR revision team strengthened
- new concepts elaborated and developed
- 17 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, International Atomic Energy Agency (IAEA), European Union (EU) pursued
- IHR policy paper discussed by WHO Cabinet
- synergy between IHR and WTO's SPS agreement explored.

Contact Officers

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 and PAHO Headquarters in Washington, D.C.

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