World Health Organization

Ten things you need to know about the IHR (2005)

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1. Purpose, scope and principles

The International Health Regulations (2005) or "IHR (2005)" or "the Regulations" are a legally binding agreement among WHO Member States and other States that have agreed to be bound by them (States Parties). The IHR (2005) define their "purpose and scope" as: "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". As of 15 June 2007, the provisions of these Regulations will direct and govern particular WHO and States Parties activities aiming to protect the global community from public health risks and emergencies that cross international borders.

These activities are implemented in ways that are consistent with other international law and agreements; their implementation must "be with full respect for the dignity, human rights and fundamental freedom of persons" and "guided by the goal of their universal application for the protection of all people of the world from the international spread of disease".

2. Concepts and approaches

The IHR (2005) are purposely broad and inclusive in respect of the public health event to which they have application in order to maximize the probability that all such events that could have serious international consequences are identified early and promptly reported by States Parties to WHO for assessment. The Regulations aim to provide a legal frame work for the prevention, detection and containment of public health risks at source, before they spread across borders, through the collaborative actions of States Parties and WHO.

Notification is required under IHR (2005) for all "events that may constitute a public health emergency of international concern". In this regard, the broad new definitions of "event", "disease" and "public health risk" in the IHR (2005) are the building blocks of the surveillance obligations for States Parties and WHO. "Disease" means "an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans". The term "event" is broadly defined as "a manifestation of disease or an occurrence that creates a potential for disease". "Public health risk" refers to "a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger". A public health emergency of international concern (PHEIC) is defined as "an extraordinary event which is determined to constitute a public health risk to other States through the

international spread of disease and to potentially require a coordinated international response". Consequently, events of potential international concern, which require States Parties to notify WHO, can extend beyond communicable diseases and arise from any origin or source.
The IHR (2005) explicitly allow WHO to take into account information from sources other than official notifications and consultations, and, after assessment, to seek verification of specific events from the concerned States Parties. Notification to WHO marks the beginning of a dialogue between the notifying State Party and WHO on further event assessment, potential investigation and any appropriate local or global public health response.
The responsibility for implementing the IHR (2005) rests jointly with States Parties and WHO. In order to be able to notify events, or respond to public health risks and emergencies, States Parties must have the capacity to detect such events through a well established national surveillance and response infrastructure. States Parties are required to collaborate actively with each other, together with WHO, to mobilize the financial resources to facilitate the implementation of their obligations under the IHR (2005). Upon request, WHO will assist developing countries in mobilizing financial resources and providing technical support needed to build, strengthen and maintain the required capacities provided for in the Regulations.

3. Shared realities require a move towards collective defences

The recognition that globalisation brings with it new challenges and opportunities for preventing the international spread of disease was the starting point for the revision of the International Health Regulations (1969) or "IHR (1969)". In 2003, the outbreak and eventual control of SARS convinced the world's governments of the necessity for a collective and coordinated defence against emerging public health threats, providing the impetus needed to complete the revision process. The newly-revised IHR (2005) were adopted by the Health Assembly on 23 May 2005, and entered into force on 15 June 2007.
The IHR (2005) introduce a legal framework to support existing and innovative approaches in the global detection of events and response to public health risks and emergencies. Though the IHR (2005) were built in part on the foundations of their predecessor, the IHR (1969), they are primarily based on the recent experiences of WHO and its Member States in national surveillance systems, epidemic intelligence, verification, risk assessment, outbreak alert, and coordination of international response, all of which are part of WHO's decade-long work to enhance international public health security.
The IHR (1969) were limited to the notification of cases of cholera, plague and yellow fever and WHO's actions under the old Regulations depended on receiving official notifications of cases from an affected country. They had little in them that fostered collaboration between WHO and a State Party in which outbreaks of disease with the potential to spread internationally were occurring. They provided primarily for the implementation of specified maximum measures in response to outbreaks of the above-mentioned diseases.
In contrast, the IHR (2005) have a broad scope, provide for the use of a wide range of information and emphasize collaborative actions between States Parties and WHO in the identification and assessment of events and response to public health risks and emergencies. In WHO's coordination of the international response to public health emergencies of international concern, maximum measures are replaced by formally recommended and context-specific temporary health measures, tailored to the actual threat faced.

4. Rejections and reservations

The IHR (2005) are legally binding following their entry into force on 15 June 2007 for all WHO Member States that neither rejected them nor filed reservations thereto by the 15 December 2006 deadline. In actual fact, no Member State notified a rejection and only two Member States notified reservations to the Director-General of WHO. Article 62 of the IHR (2005) provides that reservations shall not be incompatible with the object and purpose of the Regulations and that other Member States have the opportunity to object to such reservations. Unless one third of WHO's Member States object to a reservation within six months from the date of notification of the reservation by the Director-General to all Member States, the IHR (2005) will enter into force for the reserving State with the reservation considered accepted. Should one third or more of the Member States submit objections to a

reservation, the Director-General will notify the reserving State of the non-acceptance and ask it to consider withdrawing the reservation within three months of this notification. In the case that the reserving State does not withdraw the reservation within this timeframe, the matter would come before the World Health Assembly (WHA) for decision. If the WHA objects, by a majority vote, to the reservation, the reservation is not accepted. In that case, the IHR (2005) do not enter into force for the reserving State unless and until it withdraws the whole or part of the reservation by notifying the Director-General.

5. Notification and other reporting requirements

The IHR (2005) describe key elements of the procedures to be followed by States Parties and WHO in terms of information sharing with regard to notified events. Official event-related communications under the IHR (2005) are carried out between the National IHR Focal Point and the WHO IHR Contact Point, both of whom are officially designated and required to be available on a 24 hour basis, 7 days a week. Guidance for the designation or establishment of National IHR Focal Points, including terms of reference and an explanation of principal functions, is provided in the National IHR Focal Point Guide.

The IHR (2005) specify three ways in which States Parties can initiate event-related communications with WHO:

Notification - The IHR (2005) provide new notification requirements for State Parties. These provisions move away from the automatic notification and publication by WHO of cases of specific diseases to the notification to WHO of all events that are assessed as possibly constituting a PHEIC, taking into account the context in which an event occurs. These notifications must occur within 24 hours of assessment by the country using the decision instrument provided in Annex 2 of the IHR (2005). This decision instrument identifies four criteria that States Parties must follow in their assessment of events within their territories and their decision as to whether an event is notifiable to WHO:

1. Is the public health impact of the event serious?
2. Is the event unusual or unexpected?
3. Is there a significant risk of international spread?
4. Is there a significant risk of international restriction(s) to travel and trade?

Notifications must be followed by ongoing communication of detailed public health information on the event, including, where possible, case definition, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed.

Consultation - In cases where the State Party is unable to complete a definitive assessment with the decision instrument in Annex 2, State Parties have an explicit option of initiating confidential consultations with WHO and seeking advice on evaluation, assessment and appropriate health measures to be taken.

Other Reports - State Parties must inform WHO through the National IHR Focal Point within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by imported or exported human cases, vectors which carry infection or contamination, or by contaminated goods.

In addition to these three types of communications, States Parties are required under the IHR (2005) to respond to **WHO Requests for Verification**. WHO has an express mandate to obtain verification from States Parties concerning unofficial reports or communications, received from various sources, about events arising within their territories which may constitute a PHEIC; these reports are initially reviewed by WHO prior to the issuing of a verification request. States Parties must acknowledge verification requests by WHO within 24 hours and provide public health information on the status of the event, followed, in a timely manner, by continued communication of accurate and sufficiently detailed public health information available to the notifying State Party.

6. International event detection, joint assessment and response

The IHR (2005) underpin WHO's mandate to manage the international response to acute public health events and risks, including public health emergencies of international concern. The Regulations also recognize WHO's general surveillance obligations, and set out specific procedures for concerned

States Parties and WHO to collaborate in the assessment and control of public health events and risks, even before such events have been officially notified to WHO.
At the international level, WHO's real-time analysis of public health events uses technical knowledge, an understanding of the situational and operational context, and risk communication requirements to assess public health risks in accordance with WHO's mandate under the IHR (2005). To further strengthen international alert and response capabilities, an enhanced event-management system and standard operating procedures have been developed by WHO. This web-based tool functions as the official repository of all information relevant to an event that may constitute a public health emergency of international concern. It facilitates communications within WHO, with National IHR Focal Points, with technical institutions and partners, and provides timely public health information for the management of these events and risks.
Information relating to public health risks notified or reported under the IHR (2005) to WHO is jointly assessed with the affected State Party to ascertain the nature and extent of the risk, the potential for international disease spread and interference with travel and trade, and appropriate response and containment strategies.

7. PHEIC determination and temporary recommendations

If immediate global action is needed to provide a public health response to prevent or control the international spread of disease, the IHR (2005) give the Director-General of WHO the authority to determine that the event constitutes a PHEIC. On such occasions, an IHR Emergency Committee will provide its views to the Director-General on temporary recommendations on the most appropriate and necessary public health measures to respond to the emergency.
In cases where the State Party concerned may not agree that a PHEIC is occurring, the Emergency Committee will also provide advice. The temporary recommendations issued by the Director-General are for affected and non-affected States Parties in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

8. National surveillance and response capacities

Another fundamental innovation in the IHR (2005) is the obligation for all States Parties to develop, strengthen and maintain core public health capacities for surveillance and response. In order to be able to detect, assess, notify and report events and respond to public health risks and emergencies of international concern, States Parties must meet the requirements described in Annex 1A of the IHR (2005). Annex 1A outlines these core capacities at the local (community), intermediate and national levels, including, at the national level, the assessment of all reports of urgent events within 48 hours and the immediate reporting to WHO through the National IHR Focal Point, when required.
The IHR (2005) require each State Party, with the support of WHO, to meet the core surveillance and response capacity requirements "as soon as possible", but not later than five years after the date of entry into force[1] for that country. The IHR (2005) set out a two-phase process to assist States Parties to plan for the implementation of their public health capacity obligations. In the first phase, from 15 June 2007 to 15 June 2009, States Parties must assess the ability of their existing national structures and resources to meet the core surveillance and response capacity requirements. This assessment must lead to the development and implementation of national plans of action. As specified in the IHR (2005), WHO will support these assessments and provide guidance on the national planning and implementation of these capacity strengthening plans.
In the second phase from 15 June 2009 to 15 June 2012, the national action plans are expected to be implemented by each State Party to ensure that core capacities are present and functioning throughout the country and/or its relevant territories. States Parties that experience difficulties in implementing their plans may request an additional two year period until 15 June 2014 to meet their Annex 1A obligations. On the basis of a justified need, an extension of two years may be obtained. In exceptional circumstances, and supported by a new implementation plan, the Director-General of WHO may grant an individual State Party a further extension not exceeding two years to meet its obligations.

9. Public health security in international travel and transport

International points of entry, whether by land, sea or air, provide an opportunity to apply health measures to prevent international spread of disease. For this reason, many of the provisions addressing this aspect in the IHR (1969) have been updated in the IHR (2005). A number of new provisions have

been included. When applying IHR-related health measures to international travellers, for example, it is required that they be treated with courtesy and respect, taking into consideration their gender, sociocultural, ethnic and religious concerns. They must be supplied with appropriate food, water, accommodation and medical treatment if quarantined, isolated or otherwise subject to medical or public health measures under the IHR (2005).

States Parties are required to designate the international airports and ports and any ground crossings which will develop specific capacities in the application of the public health measures required to manage a variety of public health risks. These capacities include access to appropriate medical services (with diagnostic facilities), services for the transport of ill persons, trained personnel to inspect ships, aircraft and other conveyances, maintenance of a healthy environment as well as ensuring plans and facilities to apply emergency measures such as quarantine.

10. New and updated health documents

The IHR (2005) require immediate implementation of a range of new or revised health documents at points of entry. Countries need to move quickly to introduce these new health documents into their daily operations.

Model Ship Sanitation Control Exemption Certificate/Ship Sanitation Control Certificate

The Ship Sanitation Control Exemption Certificate/Ship Sanitation Control Certificate replaces the narrower in scope Deratting/Deratting Exemption Certificate as from 15 June 2007. A Deratting/Deratting Exemption Certificate issued before 15 June 2007 is valid for six months only, and, in any case will no longer be valid after 14 December 2007.

Model Maritime Declaration of Health

The Maritime Declaration of Health has been updated to reflect the broader scope of the IHR (2005) and currently accepted technical standards and terminology.

Model International Certificate of Vaccination or Prophylaxis replaces the International Certificate of Vaccination or Revaccination against Yellow Fever

Yellow fever remains the only disease specifically designated under the IHR (2005) for which proof of vaccination or prophylaxis may be required for travellers as a condition of entry to a State. The international certificate has been revised as follows: as from 15 June 2007, the current "International certificate of vaccination or revaccination against yellow fever" is replaced by the "International certificate of vaccination or prophylaxis". Clinicians who will issue the certificate should note that the main difference from the old certificate is that they have to specify in writing in the space provided that the disease for which the certificate is issued is "yellow fever". The new certificate no longer contains references to a designated vaccination centre.

Health Part of the Aircraft General Declaration

This is a document of the International Civil Aviation Organization (ICAO), a United Nations agency. The document is periodically reviewed by ICAO Member States, and has historically, for practical purposes, been reproduced in the annexes of the IHR. Consequently, the recent amendments to this Declaration adopted by ICAO will be reproduced in future editions of the IHR (2005).

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[1] Countries that have made accepted reservations to the Regulations follow the same timeline but they may not share the same starting date.

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