I. What are the International Health Regulations (2005) and why does the world community need them to enhance global public health security?

The International Health Regulations (2005) or "IHR (2005)" are an international law which helps countries work together to save lives and livelihoods caused by the international spread of diseases and other health risks. They entered into force on 15 June 2007 and are binding on 194 countries across the globe, including all WHO Member States.

The IHR (2005) aim to prevent, protect against, control and respond to the international spread of disease while avoiding unnecessary interference with international traffic and trade. The IHR (2005) are also designed to reduce the risk of disease spread at international airports, ports and ground crossings.

Born of an extraordinary global consensus, the IHR (2005) strengthen the collective defences against the multiple and varied public health risks that today’s globalized world is facing and which have the potential to be rapidly spread through expanding travel and trade.

The IHR (2005) establish a set of rules to support the global outbreak alert and response system and to require countries to improve international surveillance and reporting mechanisms for public health events and to strengthen their national surveillance and response capacities.

This makes the IHR (2005) central to ensuring global public health security.

II. What is the history of the IHR?

The cholera epidemics that overran Europe between 1830 and 1847 were catalysts for intensive infectious disease diplomacy and multilateral cooperation in public health. This led to the first International Sanitary Conference in Paris in 1851. In 1948, the WHO Constitution entered into force and in 1951 WHO Member States adopted the International Sanitary Regulations, which were replaced by and renamed the International Health Regulations in 1969. The 1969 Regulations were subject to minor modifications in 1973 and 1981.

The 1969 IHR were primarily intended to monitor and control six serious infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever and typhus. Under the IHR (1969), only cholera, plague and yellow fever remain notifiable, meaning that States are required to notify WHO if and when these diseases occur on their territory.

In the early 1990s, the resurgence of some well known epidemic diseases, such as cholera in parts of South America, plague in India and the emergence of new infectious agents such as Ebola haemorrhagic fever, resulted in a resolution at the 48th World Health Assembly in 1995 calling for the revision of the Regulations.

In May 2001, the World Health Assembly adopted resolution WHA 54.14, Global health security: epidemic alert and response, in which WHO was called upon to support its Member States in strengthening their capacity to detect and respond rapidly to communicable disease threats and emergencies.

In May 2003, resolution WHA56.28 on Revision of the International Health Regulations, established an intergovernmental working group (IGWG) open to all Member States to review and recommend a draft revision of the International Health Regulations for consideration by the World Health Assembly. The IGWG held two sessions in November 2004 and February/May 2005 with a view to endorsing a final text for consideration by the World Health Assembly at its 58th meeting. The World Health Assembly adopted the IHR (2005) on 23 May 2005 by way of resolution WHA58.3. The IHR (2005) entered into force on 15 June 2007.

III. Why were the IHR revised?

The limitations of the IHR (1969), which led to their revision, related to their narrow scope (three diseases), their dependence on official country notification, and their lack of a formal internationally coordinated mechanism to contain international disease spread.

In recent decades, cross-border travel and trade have increased and communication technology has developed markedly. News now spreads rapidly via a multitude of formal and informal channels. New challenges have arisen in the public health control of emerging and re-emerging infectious diseases.

With its focus on just three diseases (cholera, plague and yellow fever), the IHR (1969) were not equipped to address the growing and varied public health risks that resulted from increased travel and trade in the last quarter of the 20th century.
In addition, some countries were reluctant to promptly report outbreaks of these diseases for fear of unwarranted and damaging travel and trade restrictions. A way needed to be found to increase the confidence of countries in reporting significant and/or unusual disease events, by linking early disclosure to prompt support and accurate information dissemination about the nature of the event.

The IHR (2005), which are firmly grounded in practical experience, broaden the scope of the 1969 Regulations to cover existing, new and re-emerging diseases, including emergencies caused by non-infectious disease agents. Through a new legal framework, the IHR (2005) ensure a rapid gathering of information, a common understanding of what may constitute a public health emergency of international concern and the availability of international assistance to countries.

The IHR (2005)’s reporting procedures are aimed at expediting the flow of timely and accurate information to WHO about potential public health emergencies of international concern. Under these rules, WHO, as a neutral authority, with critical technical expertise and resources, and an extensive communications network can assess information, recommend actions and facilitate or help coordinate technical assistance, when needed, that is tailored to events as they unfold.

IV. What are the main functions of the IHR (2005)?

Notification

The IHR (2005) require States to notify WHO of all events that may constitute a public health emergency of international concern and to respond to requests for verification of information regarding such events. This enables WHO to ensure appropriate technical collaboration for effective prevention of such emergencies or containment of outbreaks and, under certain defined circumstances, inform other States of the public health risks where action is necessary on their part.

These notification requirements, together with WHO’s mandate to seek verification from countries with respect to unofficial reports of events with potential international implications is intended to promote and facilitate information sharing between WHO and States Parties to the IHR (2005). Greater understanding of the event as it unfolds, plus the assurance of timely technical collaboration, leads to a climate of greater willingness on the part of countries to contact the WHO when a possible public health emergency of international concern is suspected.

National IHR Focal Points and WHO IHR Contact Points

Under the IHR (2005) countries are required to notify and report events and other information through their National IHR Focal Points to a regional WHO IHR Contact Points. Focal points and Contact points must be available on a 24 hour-a-day basis, seven days a week. There are currently 193 National IHR Focal Points and six corresponding WHO IHR Contact Points.

Requirements for national core capacities

Under the IHR (2005), each State Party is required to develop, strengthen and maintain core public health capacities for surveillance and response by using existing national resources, such as the national plans for influenza pandemic preparedness. Key sanitary and health services and facilities are also to be developed at international airports, ports and ground crossings designated for this purpose by States Parties.

Recommended measures

WHO’s response to a public health emergency of international concern will include temporary recommendations concerning appropriate public health responses, and may include recommended measures for application by the State affected by such an emergency, as well as by other States and by operators of international transport. These temporary recommendations are made by WHO on a time-limited, risk-specific basis, as a result of a public health emergency of international concern.

Standing recommendations indicate the appropriate measures for routine application for specific ongoing public health risks, and are for routine or periodic application. Recommended measures could be directed towards persons, baggage, cargo, containers, ships, aircraft, road vehicles, goods or postal parcels.

External advice regarding the IHR (2005)

The IHR (2005) include procedures for obtaining independent technical advice concerning IHR implementation. One context is the process for the establishment of an Emergency Committee to advise the Director-General of WHO in determining whether a particular event is, in fact, a public health emergency of international concern and to provide advice on any appropriate temporary recommendations. An IHR Review Committee is tasked with advising the Director-General on technical matters relating to standing recommendations, the functioning of the Regulations and amendments thereto.
V. What is meant by a "public health emergency of international concern" in the IHR (2005)?

According to the IHR (2005) a public health emergency of international concern refers to an extraordinary public health event which is determined, under specific procedures:

(a) to constitute a public health risk to other States through the international spread of disease; and
(b) to potentially require a coordinated international response.

To ensure adequate and early communications with WHO about potential international public health emergencies, the IHR (2005) include a decision instrument (Annex 2 of the Regulations) which sets the parameters for notification to WHO of all events which may constitute a public health emergency of international concern (PHEIC) based on the following criteria:

(a) seriousness of the public health impact of the event;
(b) unusual or unexpected nature of the event;
(c) potential for the event to spread internationally; and/or
(d) the risk that restrictions to travel or trade may result because of the event.

Timely and transparent notification of events combined with a collaborative assessment of the risks by the concerned State and WHO, along with effective risk communication will reduce the potential for international disease spread and the likelihood of unilateral imposition of trade or travel restrictions by other countries.

THE LEGAL FRAMEWORK ESTABLISHED BY THE IHR (2005)

VI. What is the legal status of the IHR (2005) and how did they enter into force for States?

Under the WHO Constitution, all WHO Member States were automatically bound by the new IHR because they did not affirmatively opt out within a limited time period and only a very small number made reservations. According to the procedures established in the IHR (2005), reservations are evaluated by other WHO Member States within a defined time period. Because one third of the other States did not object to the reservation(s), the Regulations entered into force for the States that filed them subject to the reservation(s).

VII. How is compliance with the IHR (2005) being achieved?

The IHR (2005) were agreed upon by consensus among WHO Member States as a balance between their sovereign rights and shared commitment to prevent the international spread of disease. Although the IHR (2005) do not include an enforcement mechanism per se for States which fail to comply with its provisions, the potential consequences of non-compliance are themselves a powerful compliance tool. Perhaps the best incentives for compliance are "peer pressure" and public knowledge. With today's electronic media, nothing can be hidden for very long. States do not want to be isolated. The consequences of non-compliance may include a tarnished international image, increased morbidity/mortality of affected populations, unilateral travel and trade restrictions, economic and social disruption and public outrage. Working together with WHO to control a public health event and to accurately communicate how the problem is being addressed has helped to protect countries from unjustified measures being adopted unilaterally by other states.

VIII. How are questions or disputes on the interpretation or application of the IHR (2005) resolved?

The IHR (2005) contain a dispute settlement mechanism to resolve conflicts arising between States in respect of the application and/or the interpretation of the Regulations. The mechanism emphasizes the amicable settlement of differences. Several options are open to States under this mechanism, including negotiation, mediation and conciliation. Disputes may also be settled by referral to the Director-General of WHO or by arbitration, if agreed to by all the parties to the dispute. Since their entry into force on 15 June 2007, the dispute settlement provisions have not been invoked.


IX. Who is responsible for implementing the IHR (2005)?

The responsibility for implementing the IHR(2005) rests upon all States that are bound by the Regulations and WHO. The State is responsible, including all of its sectors, ministries, levels, officials and personnel for implementing the Regulations at the national level. WHO collaborates with and supports States in the implementation of the Regulations.
X. How will States benefit from the IHR (2005)?

By agreeing to be bound by the IHR (2005), States:

• enjoy the benefits of a respected partner in the international effort to maintain global health security;
• receive WHO guidance in building the core capacities necessary to quickly detect, report, assess and respond to public health emergencies and public health risks, including those of national and international concern;
• are offered technical assistance and receive help in efforts to mobilize possible funding support to meet these new obligations;
• receive WHO guidance during outbreak assessment and response;
• have access to specific information gathered by WHO about public health risks world-wide which is necessary for them to protect themselves;
• receive WHO advice and logistical support, when requested, to respond to disease outbreaks and other public health events;
• have access to the Global Outbreak Alert and Response Network (GOARN), a “one-stop shop” of global resources to help manage public health risks and emergencies of international concern.

XI. According to the IHR (2005), what are the key obligations for States?

States Parties to the IHR (2005) are required:

• to designate a National IHR Focal Point (see Question 4 above);
• to assess events occurring in their territory and to notify WHO of all events that may constitute a public health emergency of international concern using the decision instrument included in Annex 2 of the Regulations (see Question 5 above);
• to respond to requests for verification of information regarding events that may constitute a public health emergency of international concern; to respond to public health risks which may spread internationally;
• to develop, strengthen and maintain the capacity to detect, report and respond to public health events; to provide routine facilities, services, inspections and control activities at designated international airports, ports and ground crossings to prevent the international spread of disease;
• to report to WHO evidence of a public health risk identified outside their territory which may cause international disease spread, manifested by exported/imported human cases, vectors carrying infection or contamination, contaminated goods;
• to respond appropriately to WHO-recommended measures;
• to collaborate with other States Parties and with WHO on IHR (2005) implementation.

XII. According to the IHR (2005), what are the key obligations for WHO?

Laying down the rules for global public health security, the IHR (2005) confer on WHO new roles and responsibilities. WHO has strengthened its ability to fulfill these fresh obligations by:

• designating WHO IHR Contact Points at the headquarters or the regional level (see Question 4 above);
• conducting global public health surveillance and assessment of significant public health events, and disseminating public health information to States, as appropriate;
• offering technical assistance to States in their response to public health risks and emergencies of international concern;
• supporting States in their efforts to assess their existing national public health structures and resources, as well as to develop and strengthen the core public health capacities for surveillance and response, and at designated points of entry;
• if required, determining whether or not a particular event notified by a State under the Regulations constitutes a public health emergency of international concern, with advice from external experts;
• if a PHEIC is declared, developing and recommending the critical health measures for implementation by States Parties during such an emergency (with advice from external experts);
• monitoring the implementation of IHR (2005) and updating guidelines so that they remain scientifically valid and consistent with changing requirements.

XIII. When and how can WHO issue recommendations concerning public health emergencies of international concern?
TRAVEL AND TRADE UNDER IHR (2005)

XV. How does the IHR (2005) affect international travel and trade and individual travellers?

International travel and trade
The extent of international travel in the modern world presents an extraordinary opportunity for international disease transmission. Global trade has implications in terms of potential foodborne disease or other contaminated goods. While health measures to control disease spread at borders remain one important element of the Regulations, evidence shows that rapid response at the source is the most effective way to secure maximum protection against international spread of diseases.

One of the objectives of the IHR (2005) is to minimize unnecessary restrictions to travel and trade by specifying, in real-time, the appropriate public health measures for the assessed risk. WHO's neutral expert guidance in assessing and controlling public health risks is key to limiting unnecessary restrictions on trade and travel. During a public health emergency of international concern, however, application of time-limited measures affecting international travel and trade may be recommended.

Individual travelers
The IHR (2005) aim at preventing the international spread of diseases while limiting unnecessary restrictions on the free movement of travellers. During public health emergencies of international concern or in connection with specific public health risks, measures affecting travel may be recommended to avoid the international spread of disease. Health information, basic examinations and vaccination documentation may be requested of a traveller by States. At the same time, under the IHR (2005), States are required to treat travellers with respect for their dignity, human rights and fundamental freedoms together with confidential treatment of their personal data.

XVI. How and why States Parties are required to designate international airports and ports and may designate certain ground crossings for capacity strengthening purposes under the IHR (2005)?

Large-scale growth of travel and trade in recent years has increased the potential and opportunities for international disease spread. Although rapid response at the source is the most effective way to prevent disease from crossing borders, routine public health measures applied to international conveyances and at airports, ports and ground crossings may further reduce the risk of spread. States Parties are, therefore, required to designate the key international airports and ports to develop and strengthen the capacities provided in Annex 1 of the IHR (2005). Additionally, where justified for public health reasons, States Parties may designate ground crossings that shall develop these capacities. These designations should be made as soon as possible because the timelines established in the Regulations started running on 15 June 2007.

COLLABORATION UNDER IHR (2005)

XVII. How are the IHR (2005) interacting with other international agreements and bodies?

Under the IHR (2005), States recognize that the Regulations and other relevant agreements should be compatible. The IHR (2005) provide for cooperation between WHO and other competent intergovernmental organizations or international bodies in the implementation of the Regulations. WHO therefore continues to foster its longstanding working relationships with a number of organizations such as the International Atomic Energy Agency, the International Air Transport Association, the International Civil Aviation Organization, the International Maritime Organization, the World Tourism Organization, the Food and Agriculture Organization of the United Nations, the Office International d’Epizooties (World Organisation for Animal Health) and the World Trade Organization. In addition to these specialized organizations, WHO works with regional economic integration organizations such as the European Union and the Mercado Común del Sur (MERCOSUR) in implementing the Regulations in the countries of their respective regions.
<table>
<thead>
<tr>
<th>XVIII. How has the IHR (2005) affected the Model Deratting and Deratting Exemption certificates, Maritime Declaration of Health, International Certificate of Vaccination or Revaccination against Yellow Fever and the Health Part of the Aircraft General Declaration?</th>
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<tr>
<td><strong>Model Ship Sanitation/Ship Sanitation Exemption Certificate replaces the Deratting/Deratting Exemption certificate</strong></td>
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<td><strong>Model Maritime Declaration of Health</strong></td>
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<tr>
<td>The Maritime Declaration of Health was updated to reflect the broader scope of the IHR (2005) and currently accepted technical standards and terminology.</td>
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<tr>
<td><strong>Model International Certificate of Vaccination or Prophylaxis replaces the International Certificate of Vaccination or Revaccination against Yellow Fever</strong></td>
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<tr>
<td>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 was revised as follows: on 15 June 2007, the “International certificate of vaccination or revaccination against yellow fever” was replaced by the “International certificate of vaccination or prophylaxis”. Clinicians issuing 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 current Certificate no longer contains references to a designated vaccination centre (See answer to Question 20) and its period of validity is limited to the date indicated on the certificate for the particular vaccine or prophylaxis.</td>
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<tr>
<td><strong>Health Part of the Aircraft General Declaration</strong></td>
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<td>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 revised version of this Declaration submitted by ICAO to WHO has been reproduced in the second edition of the IHR (2005), published in 2008.</td>
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<th>SPECIFIC DISEASES UNDER THE IHR (2005)</th>
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<td>XIX. How do the IHR (2005) help to address the risk of an influenza pandemic in humans?</td>
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<td>Under the IHR (2005), all cases of these four diseases must be automatically notified to WHO: smallpox, poliomyelitis due to wild-type poliovirus, SARS and cases of human influenza caused by a new subtype. Case definitions for each of these four diseases have been prepared by WHO and posted at on its website at <a href="http://www.who.int/ihr">www.who.int/ihr</a>.</td>
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<tr>
<td>XX. What kind of yellow fever vaccines are valid under the IHR (2005) and must they be administered at a vaccination centre designated by the State or at a listed WHO-approved vaccination centre?</td>
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<tr>
<td>Under IHR (2005), each State must designate at least one yellow fever vaccination centre, but, if it so wishes, no longer has to restrict the issuance of yellow fever vaccination certificates to such an officially-designated centre. The yellow fever vaccine used must be approved by WHO. The WHO no longer maintains a list of vaccinating centres designated for the administration of yellow fever vaccine and for the issue of International Certificates of Vaccination or Revaccination against yellow fever.</td>
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