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PRESENTATION

The process and challenges of developing and implementing the new IHR (2005)

Preben Aavitsland at Stakeholder Meeting on Global Health Preparedness, Norwegian Institute of Public Health, 12.12.2013

Summary

The IHR (2005) is a major step forward in international public health as it introduces a new international surveillance system, including obligations on Member States to build capacities to detect and handle events. The 2011 review of the IHR showed several shortcomings in the implementation. The needs are better surveillance systems, better field epidemiology capacity, improved laboratory capacity, and improved facilities for treatment and isolation. IHR asks Member States to assist and collaborate with other countries in building such capacities. Annex 1 of the IHR can be seen as a priority list for such assistance.

Introduction

I will briefly review the process of making the International Health Regulations (IHR). Then I will point to some of the major issues that proved to be challenging during the negotiations. Finally I will discuss some of the challenges in the implementation phase after 2005. All of this is, of course, my personal opinions.

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The process and challenges of developing and implementing the new IHR (2005)

Preben Aavitsland

Stakeholder Meeting on Global Health Preparedness. Oslo, 12.12.2013

Process

The IHR adopted by the World Health Assembly in 2005 is the latest in a long string of attempts at regulating measures against international disease spread, starting in Paris in 1851 with the First International Sanitary Convention. Then, the parties to the conventions were mainly the Western powers, and the purpose was to protect the West against epidemics, especially cholera, coming from the East and the South. European Muslims' pilgrimage to Mecca was considered a special threat.

For the history of the sanitary conventions and regulations, see for instance: Schepin OP, Yermakov WV. International Quarantine. Madison: International Universities Press, 1991.

After the WHO was founded, and prompted by the big 1947 cholera epidemic in Egypt, the World Health Assembly in 1951 adopted the first International Sanitary Regulations, to replace all existing conventions that were now regarded as anachronistic. Science had shown new ways of controlling infectious diseases without strong quarantine measures. Western powers wanted fewer hindrances for their trade in the South and the East, and international travels by sea and air was increasing.

The regulations were revised a few times, but not substantially so. In brief, the four main parts of the 1969 IHR, and their associated limitations, remained unchanged:

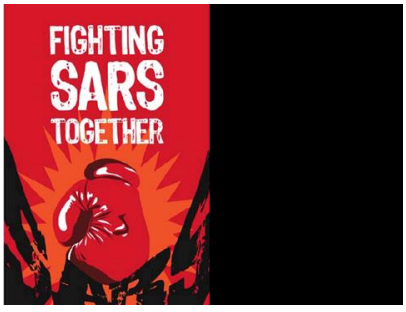
1. Mandatory notification from Member States to WHO of cases of cholera, plague and yellow fever. This was a limitation as the regulations could not be applied to any other disease, including newly merging diseases. Furthermore, WHO could only acknowledge an outbreak and act on it when the Member State's government had officially notified cases to WHO. Member States were reluctant to do this, because such events often led to closing of borders to their country and stop in export from their country. Thus, international surveillance was highly politicised and ineffective. For instance, WHO had to use the term «acute watery diarrhoea» do describe cholera outbreaks that the Member State in question had not notified as a cholera outbreak.
2. Rules for health issues in travel and trade. The rules were not dynamic and Member States were not obliged to abide by them.
3. Specifications of maximal measures at borders. Again, a limitation, both in diseases and in measures.
4. Rules on documents for travellers, ships and aircrafts. These documents were often unnecessary.

Main parts of IHR (1969)

- Mandatory notification of cases of cholera, plague and yellow fever
- Rules for health issues in travel and trade
- Specifications of maximal measures at borders
- Rules on documents for travellers, ships and aircrafts

The IHR (1969) ae here: http://whqlibdoc.who.int/publications/1983/9241580070.pdf

So, during the 1980s and 1990s there was growing unease with the IHR, and WHO started a revision process in 1995, but this moved only slowly ahead. It was only when SARS broke out in 2003 that the dismal state of affairs became clear to everyone. As IHR covered only cholera, plague and yellow fever, there was no functioning international legal framework for the SARS response. WHO could only hope that Member States would comply with notification requirements and control measures. The



then Director General, Gro Harlem Brundtland, finally understood that more rapid actions were needed and decided to speed up the revision and formed an open-ended Intergovernmental Working Group. The negotiations ended in May 2005.

I see the following three main components of the IHR (2005):

1. A new international surveillance system, including obligations on Member States to build capacities to detect and handle events.
2. A procedure for WHO's recommendations to guide the response to public health emergencies of international concern.
3. A set of international rules on routine measures against international disease spread, including border measures and documents. This component is to large extent remnants of the older conventions and regulations.

Key contents of the IHR (2005)

- A new **international surveillance system**, including national capacity building
- A procedure for WHO's **recommendations** to guide the response to public health emergencies of international concern (*PHEIC*)
- A set of international rules on **routine measures** against international disease spread

The IHR (2005) are here: http://www.who.int/ihr/publications/9789241596664/en/index.html

Challenges in the development

The negotiations were tough. There were many strong interests, and some suspicion of other countries' intentions. Some delegations saw the exercise as just another way the West wanted to get information to protect themselves from disease from the East and the South. The new paradigm of detecting and stopping outbreaks at the source, not at the frontiers, was not easily accepted by everyone.

One particular challenge was Article 2 on purpose and scope of the IHR. This article had no predecessor in the 1969 revision. Almost every word of this article was hotly negotiated, testifying to the importance of the article.

Article 2 Purpose and scope

The purpose and scope of these Regulations are 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.

I will point to three major shifts in the IHR (2005).

1. The IHR (2005) introduces event-based surveillance, to replace the old list of three diseases. This means that the notifiable condition is «an event», not a disease case. This was one of the major difficulties during the negotiations, because many delegations wanted to keep a list of notifiable diseases. A separate expert meeting, which I had the privilege of chairing, had to hammer out a compromise.

Three major shifts

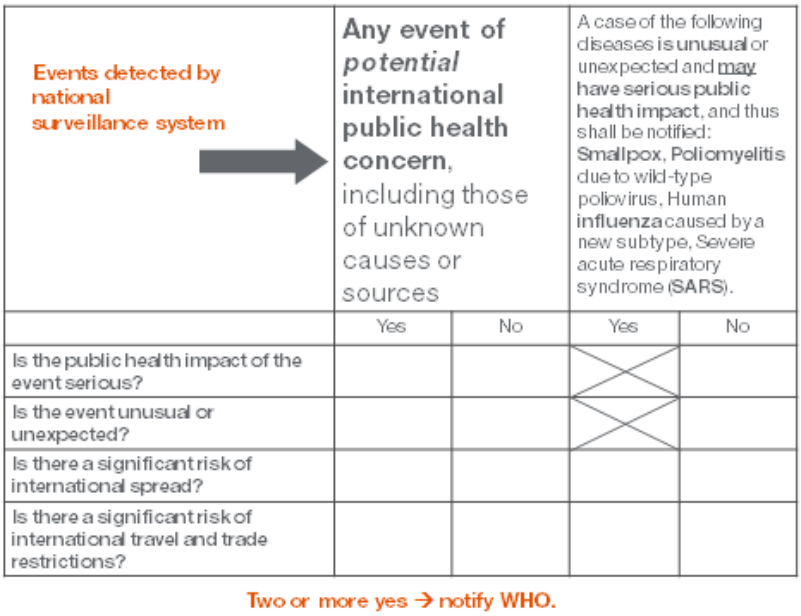
1. Event-based surveillance
2. Transfer of power from Member States to WHO
3. Member States' obligations to build capacities

We suggested that any potential public health event of international concern, including those of unknown causes or sources, should be notified if two or more of these criteria were fulfilled:

- The event had a serious public health impact
- The event was unusual or unexpected.
- The event led to a significant risk of international spread.
- The event led to significant risk of international travel and trade restrictions.

In addition, we kept a small list of four diseases, namely

smallpox, SARS, poliomyelitis and new influenza, arguing that these by default fulfilled the criteria for a notifiable event.



The change from case-based to event-based surveillance was rational, for several reasons.

Firstly, the change underscores that it is the sum of the disease and the circumstances that determines the potential for spread. For instance, a case of cholera in a traveller to Oslo, may not be problematic. A case of cholera in a survivor of the Philippine hurricane signals a potential disaster.

Secondly, an epidemic may be serious even if the causative organism has not been identified yet. There is no reason to suspend notification until laboratory confirmation is available.

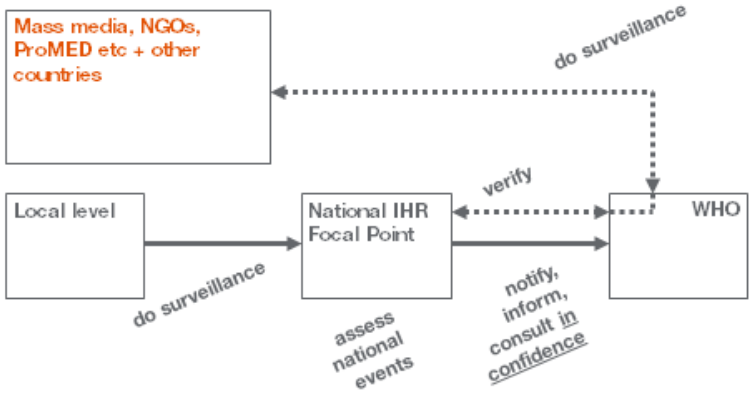
And thirdly, a list of diseases cannot include new, unknown diseases, like SARS or MERS.

It is worth noticing here that the basis for the IHR surveillance system is the national surveillance systems. They will feed in events to be assessed for possible notification. The IHR surveillance is thus integrated in national surveillance.

2. With the new IHR (2005), Member States trusted WHO with more power. WHO can now utilise other sources of information than only the official notifications from the affected Member State. And it is the Director General of WHO who determines whether an event really constitutes a public health emergency of international concern, a so-called pheic. This means that it is the event itself - not the official notification of it - that is the basis of WHO's determination of pheic.

And, finally, it is WHO that decides on recommendations to

control and prevent the international spread of an event.



So, the implications of notification have changed. Notification does not imply that an event is a public health emergency of international concern. Notification has no immediate consequences for the Member State. Notification can be seen as a start of a dialogue between the Member State and WHO, usually ending with no declaration of a public health emergency of international concern.

The incentives for the Member State are that the IHR provides some protection against unjustified measures, such as travel restrictions or trade embargoes, against the Member State, and that the IHR provides for WHO and other countries assisting the Member State in question.

So, whereas prior to the current IHR, the Member State itself decided whether WHO and the international community should be informed about and act upon a cholera outbreak, today this power rests with WHO. The organisation can use all information sources to verify the outbreak and give recommendations for stopping its international spread.

3. The Member States have signed up to their obligations to build capacities for detecting and preventing international spread of disease. Articles 5, 13 and 20 and annex 1 of the IHR give details of these obligations. They are, firstly, the capacity to detect, report, assess, notify and respond to events, and, secondly, the capacity to provide certain services at the points of entry into the country, including access to medical service, access to facilities for quarantine and isolation, and the ability to disinsect or disinfect when needed.

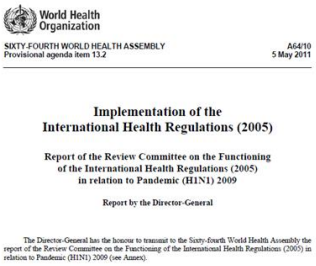
The WHO is monitoring Member States' progress with this capacity building, and reports to the World Health Assembly.

Challenges in implementation of the IHR (2005)

The IHR (2005) contains rather radical changes in the views of many countries. It requires a change of mind-set to a new paradigm of early information sharing and fighting outbreaks at their source, not at the frontiers. There is still a lot of emphasis on border controls, ship inspections and documents for ships, aircrafts and people. There is a risk that the IHR will be seen as an administrative instrument, a system for the exchange of documents at borders. Then, not much has been gained.

In 2010-2011, the IHR (2005) underwent their first scheduled external review, by a committee led by Harvey Fineberg. I was part of his committee. Out first conclusion was:

> *«The IHR helped make the world better prepared to cope with public-health emergencies. The core national and local capacities called for in the IHR are not yet fully operational and are not now on a path to timely implementation worldwide.»*


World Health Organization

SIXTY-FOURTH WORLD HEALTH ASSEMBLY
Provisional agenda item 13.2

A64/10
5 May 2011

Implementation of the International Health Regulations (2005)

Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009

Report by the Director-General

The Director-General has the honour to transmit to the Sixty-fourth World Health Assembly the report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 (see Annex).

The report of the Review Committee is here: http://apps.who.int/iris/bitstream/10665/75235/1/9789241564335_eng.pdf

We had observed that many Member States lacked the core capacities to detect, assess and report potential health threats, that some national IHR focal points lacked the authority to communicate information related to public-health emergencies to WHO in a timely manner, and that the IHR lacks enforceable sanctions for a countries that fail to explain why they have adopted more restrictive traffic and trade measures than those recommended by WHO.

From this followed our recommendations:

> *«Accelerate implementation of core capacities required by the IHR.»*

Recommendations from Review

1. Accelerate implementation of core capacities
2. Enhance the WHO Event Information Site
3. Reinforce evidence-based decisions on international travel and trade
4. Ensure necessary authority and resources for all National IHR Focal Points

We noted that donor countries and organizations could take advantage of the IHR Annex 1A as a priority list for development support and also seize opportunities to share specialized resources, such as laboratories, across countries.

> *«Enhance the WHO Event Information Site.»*

This is the secure web site where event related information is shared between national focal points and WHO.

> *«Reinforce evidence-based decisions on international travel and trade.»*

We encouraged WHO to energetically seek to obtain the public-health rationale and relevant scientific information from Member States who introduce measures beyond WHO recommendations.

Also, WHO should review and assess the effectiveness and impact of border measures taken during the 2009 pandemic to support evidence-based guidance for future events.

> *«Ensure necessary authority and resources for all National IHR Focal Points. States Parties should ensure that designated National IHR Focal Points have the authority, resources, procedures, knowledge and training to communicate with all levels of their governments and on behalf of their governments as necessary.»*

Currently, WHO is struggling with understanding and stopping the international outbreak of MERS. From the outside, it looks as though information sharing between affected Member States and WHO is suboptimal. This means that after more than a year, we still do not definitively know the reservoir, the source, the mode of transmission and the clinical spectrum of the disease. This state of affairs underscores the need for more sharing of information.

Towards the end here, I will sum up my three personal recommendations to Member States concerning implementation of IHR:

- Transparency – early sharing of information
- Follow WHO's recommendations on measures
- Build capacities – annex 1a

First, Member State should adapt principles of transparency and early sharing of information. The early notification to WHO and the continued sharing of information with WHO should be decided by the public health authorities, not by politicians. Thus, the national IHR focal point should be in the institute that conducts national surveillance, not in the Ministry. This is about changing mind-set from the old IHR where notification to WHO was determined by the Minister of Health or even by the Prime Minister.

Secondly, Member States should follow recommendations from WHO concerning international disease spread. This means that countries should not unilaterally introduce trade measures, restrictions of traffic or elaborate border measures. There is an opening in Article 43 of IHR for measures beyond WHO recommendations, but they need a good public health rationale and scientific basis. The fear is that such measures may undermine the whole IHR, especially if the measures are poorly justified and targeted at poorer countries. Then they will be an effective disincentive for early notification from other affected countries.

And thirdly, Member States should continue building capacities for detecting and responding to disease outbreaks, integrated in their public health system. These capacities should not only serve IHR purposes, but improve national public health in general. The annex 1 is a fine priority list. The needs are better surveillance systems, better field epidemiology capacity, improved laboratory capacity, and improved facilities for

treatment and isolation. In short, a functioning public health system.

The relevance for this meeting, is that IHR asks Member States to assist and collaborate with other countries in building the capacities. Article 44 asks for technical cooperation, logistical support and financial resources for the countries in need. Annex 1 is the priority list, and I would especially point to annex 1a on the surveillance and response, and less so to annex 1b on points of entry facilities.

Article 44, 1 (b), (c), (d)

1. States Parties shall undertake to collaborate with each other, to the extent possible, in: (…)

(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;

(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and

(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.

Conclusion

In conclusion, I will say that the 2005 revision of IHR was long overdue, that the new IHR is a good instrument for global health preparedness, that all countries should work hard to make it a success, and that donor countries will find in the IHR many reasons for and ways to investing in public health systems.

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