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INTERNATIONAL HEALTH REGULATIONS – REVISION PROCESS

A number of disease outbreaks of international concern during the 1990s focused attention on the International Health Regulations (IHR) which currently deal only with three designated diseases - cholera, plague and yellow fever. The resurgence of infectious diseases and the heightened risk of international spread caused by the growth of commercial air transport led in 1995 to World Health Assembly resolution WHA48.7, requesting the Director-General to take steps to revise and broaden the scope of IHR. A series of consultations of experts and working group meetings were held between 1995 and 1997 to secure agreement on the direction of the revision process.

Resolution WHA54.14, adopted by the Fifty-fourth World Health Assembly in 2001, supported the ongoing revision, including criteria to define what constitutes a *public health emergency of international concern* so as to facilitate reporting by Member States of all such events. These criteria have been incorporated into a notification instrument and tested internally. They are now being formally tested with participating Member Countries. The resolution also urged Member States to designate a focal point for IHR. By May 2003, 138 out of 192 Member States of WHO had nominated national focal points for IHR revision and operations.

WHO has put in place a global system for epidemic alert and response. A major outcome of this approach is an increasing tendency for countries to report outbreaks early and seek WHO's assistance in rapidly mobilizing and coordinating appropriate international support. The management and control of SARS recently has clearly demonstrated WHO's systematic approach to global epidemic alert and response requirements.

In line with the IHR Revision Project, in-depth workshops were held in three countries of the SEA Region - India, Sri Lanka and Thailand. All three workshops recommended refinements to the notification instrument as well as a critical evaluation of national capacities in key sectors, including epidemiological surveillance, laboratory diagnostics, and points of international arrival and departure. To further support implementation of the revised Regulations, operational guidelines including (a) design and implementation of early warning systems for disease surveillance, (b) guide to ship sanitation, and (c) guide to hygiene and sanitation in aviation, are being developed or updated.

The first technical composite draft was planned to be completed before May 2003. Due to the SARS outbreak, the publication of this key document was delayed in order to incorporate the crucial lessons learnt during the response to SARS. Finally, resolution WHA56.28, adopted by the Fifty-sixth World Health Assembly in May 2003, sets out the process to finalize the revision proposals. Regional consensus meetings are to be convened in 2003 to provide a forum for the Member States to evaluate the revised legal draft. Following this an intergovernmental working group will be established to finalize the revised Regulations for submission to the Fifty-eighth World Health Assembly in 2005.

This paper is presented to the Regional Committee for noting the progress in the revision process.

CONTENTS

Page

1. BACKGROUND

The *International Sanitary Regulations* were adopted by the Fourth World Health Assembly in 1951 as the first single international code of measures for preventing the international spread of designated infectious diseases and of requirements for reports and notifications of cases of these diseases.[1] The measures established in the Regulations were designed to ensure the maximum security against the international spread of disease with a minimum interference in world traffic. They were replaced in 1969 by the *International Health Regulations* (IHR), which were subsequently amended in 1973 with additional provisions for cholera, and revised in 1981 to exclude smallpox.

The three diseases that remain subject to the current regulations - cholera, plague and yellow fever - are of considerable importance to the countries of the South-East Asia Region Cholera sporadically affects many countries of the Region and is regularly reported from a small number and, although plague is restricted to a few endemic foci in the Region, the potential consequences of even limited outbreaks of human diseases are well known. While, thankfully, yellow fever has not appeared in Asian countries, the presence of suitable arthropod vectors in many countries and an almost completely non-immune population mean that international efforts to counter any risk of spread to Member Countries of the South-East Asia Region are of great concern.

Following a number of high profile international responses to disease outbreaks, including the outbreak of plague in India in 1994, the Forty-eighth World Health Assembly expressed the need for further substantial revision to take account of the resurgence of infectious diseases and the heightened risk of their international spread caused, in particular, by the growth of commercial air transport. World Health Assembly resolution WHA48.7 requested the Director-General to take steps to prepare a revision and urged broad participation and cooperation in this process. A series of consultations by experts and working group meetings were held between 1995 and 1997 to secure agreement on the direction of the revision process.

A report on the progress of the revision summarized the results of these consultations and working groups, including the proposal that the reporting of specific diseases be replaced by the immediate reporting of a number of defined clinical syndromes that are of international importance.[2] The approach was subsequently field-tested in 22 countries, including India, Sri Lanka and Thailand from the South-East Asia Region. The results, reported to the Fifty-fourth World Health Assembly, supported the conclusion that syndromic reporting, although valuable within a national system, was not appropriate for use in the context of a regulatory framework.[3]

The report noted that the Regulations serve as the framework for WHO's outbreak alert and response activities, and defined an approach to the revision process based on three main challenges that had been identified during alert and response activities.[4] The approach goes beyond notification of specific diseases, though reporting by disease remains possible when the diagnosis is known. In adopting resolution WHA54.14, the Health Assembly supported the

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[1] WHO Regulations No. 2, adopted in accordance with Article 21 of the Constitution.

[2] See document EB101/12.

[3] See document A54/9.

[4] These challenges are: ensuring that only public health risks (usually caused by an infectious agent) that are of urgent international importance are reported under the Regulations; avoiding stigmatization and unnecessary negative impact on international travel and trade of invalid reporting from sources other than Member States, which can have serious economic consequences for countries; making sure that the system is sensitive enough to detect new or re-emerging public health risks.

ongoing work on the revision of the Regulations in the context of WHO's outbreak alert and response activities, and inclusion of criteria to define a *public health emergency of international concern*. It also urged Member States to designate a focal point for the Regulations.

One of the major obstacles hindering effective implementation of the current Regulations arises from the reluctance of countries to promptly and frankly report outbreaks. This reluctance to report is often due to fear of the economic repercussions in the form of lost trade and tourism. WHO has put in place a global system for epidemic alert and response, and developed the operational framework for epidemic intelligence, event verification, risk assessment, coordination of response and information management, in partnership with the global outbreak alert and response network, to support the Regulations. One positive consequence of the prompt support WHO now offers, through its outbreak alert and response activities, is an increasing tendency for countries to report outbreaks at an early stage and seek WHO's assistance in mobilizing and coordinating appropriate international support. For example, during an outbreak of an unknown disease in Bangladesh, the network was able to coordinate support for the Ministry of Health through a team that drew upon both global and regional expertise to investigate the outbreak. The benefits of the procedures now established were also seen when India experienced a small cluster of human plague cases in February 2002. The timely provision of authoritative information and advice by both the Ministry of Health and WHO in collaboration resulted in minimal disruption to international traffic in contrast to the events of 1994 when many countries around the world imposed inappropriate and damaging restrictions.

2. PROGRESS

WHO has identified criteria to define *public health emergencies of international concern* as directed by World Health Assembly resolution WHA54.14. These criteria have been incorporated into a notification instrument to guide all Member States in identifying those emergencies that should be notified to WHO. This instrument has been tested internally in WHO in the context of outbreak alert and response activities and is now being formally tested with participating Member States through the designated focal point for the Regulations.

World Health Assembly resolution WHA48.7 acknowledged the strengthening of epidemiological surveillance and disease control activities at the national level as the main defence against the international spread of infectious diseases. The revised Regulations will describe the basic minimum capacities needed by Member States in a number of areas in order to fully implement the Regulations. These core capacities are needed to operate national systems for disease surveillance and response and to perform specific activities at international airports, seaports and major frontier crossings. It is expected that these core capacities will serve as both a driving force for strengthening national systems for disease surveillance and response and a benchmark for measuring progress. Such an internationally agreed target will also provide a clear focus for support provided by bodies other than WHO.

Since January 2001, when the Director-General wrote to all Member States requesting the nomination of official national focal points to engage in the revision process, 138 out of 192 Member States have done so. In the South-East Asia Region, 9 of the 11 Member States have designated national focal points.

The effectiveness of the Regulations as an international instrument depends primarily on the extent to which countries accept the legal framework and are able to work within it. Consultation with Member States on proposed technical amendments is therefore of central importance to successful revision of the Regulations. A series of meetings with selected Member States at country, subregional, regional and interregional levels has been held

throughout 2001 and 2002 to validate permanent routine measures contained within the existing Regulations, and to test the new proposals.[5]

In the South-East Asia Region, three countries have organized and participated in in-depth workshops on the IHR revision project. These meetings were held in Thailand (July 2002), Sri Lanka (October 2002) and India (November 2002). All three meetings considered the key changes proposed to the Regulations, including the role of the national IHR focal point, routine measures at points of international entry and departure as well as reviewing the notification decision instrument and the proposed national core capacities in disease surveillance and response. The workshops were attended by a wide group of national public health officials, including representation from those responsible for health services at ports and airports and food safety.

Refinements to the notification instrument were recommended by all the workshops and many of these have already been incorporated in the version currently being evaluated. The meetings identified public health laboratory capacity as a key area for attention in strengthening national surveillance and response and also drew attention to the need for greater clarity regarding the role of the national IHR focal point and the political nature of notifications of *public health emergencies of international concern.*

In addition, the workshop in Thailand encouraged the revision project to provide Member States with an assessment of the impact that adopting the revised Regulations would have on different national sectors.

The workshop in Sri Lanka identified the need to build surveillance and response capacity and ensuring effective coordination of services at points of international arrival and departure.

The workshop in India highlighted the need to continue the current routine measures, including appropriate proof of vaccination and disinsection of aircraft to prevent the introduction of yellow fever to Asia. This workshop also supported the concept of establishing international sanitary airports and ports. The proposed broadening of IHR to encompass all *public health emergencies of international concern*, including those potentially related to food and animals, was supported, as was the mandate for the Organization to make recommendations for the protection of public health during such emergencies.

The implications that the proposed revisions might have for disease surveillance in the Region were considered as part of the Intercountry Consultation on the Regional strategy for Integrated Disease Surveillance, held in Myanmar in August 2002, in which 10 Member States from the Region participated.[6]

The conclusions and recommendations from these meetings, as well as from those held in other regions, have been taken forward in the process of writing the first technical composite draft, which, although currently under internal review, will be available to Member States in September 2003.

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[5] Information on workshops and meetings is available in Global crises – global solutions. Managing public health emergencies of international concern through the revised International Health Regulations. Document WHO/CDS/CSR/GAR/2002.4, Appendix 2, and at http://www.who.int/emc/IHR/int_regs.html

[6] See document SEA-CD-130

To further support implementation of the revised Regulations, WHO is preparing guidelines on the design and implementation of early warning systems as an essential component of national disease surveillance.

The existing Regulations make a direct reference to the *Guide to ship sanitation* and the *Guide to hygiene and sanitation in aviatio*n. Current editions of these guides date back to 1967 and 1977 respectively. They are undergoing substantial revision to ensure that they fulfil their role in providing up-to-date and evidence-based support to the implementation of the revised Regulations. Revision of both guides, involving a broad consultation, is under way and new editions should be published in 2003.

3. PLANS FOR COMPLETING THE REVISION PROCESS

The report to the Fifty-fourth World Health Assembly set out the main steps envisaged to complete the revision of the Regulations. The first technical composite draft, which includes the commentary provided by participating Member States, will be completed before May 2003, marking the end of the initial consultation phase. At the same time, this draft will provide the basis for an appropriate legally worded text. It is planned to convene a workshop to consider issues such as compliance, possible conflicts with other international instruments and resolution of disputes.

The conclusions reached by the revision process must now be extended from the technical to the political level. This will be fostered through a series of regional consensus meetings to be convened in 2003 under the guidance of the Regional Directors. These meetings will provide Member States with a forum to examine and question the first technical composite draft in detail. It is anticipated that Member States will wish to include a number of national sectors in addition to public health in their review of this document prior to the consensus meeting.

This extensive consultation process is felt to be the best method for arriving at a worldwide governmental consensus on the revised Regulations. The degree of consensus achieved following the regional meetings will determine the extent of any subsequent global level meetings. After reviewing the progress attained, the Executive Board can agree to the convening of an open-ended Intergovernmental working group of interested Member States to finalize the draft revised Regulations for submission to the Health Assembly. It is expected that the revised Regulations will be ready for submission to the Fifty-eighth World Health Assembly in 2005.

These plans were submitted to the Executive Board for consideration during its 111th session in January 2003 and were fully endorsed. Board Members expressed their satisfaction with the direction of the revisions, particularly the broadening of scope to include *public health emergencies of international concern*, as this would link the revised Regulations to WHO's outbreak alert and response activities and thus give the Regulations greater flexibility and relevance. Implementation of the Regulations would, in turn, help countries to intensify their preparedness and response measures. Board Members strongly supported plans for broad engagement of Member States in the revision process as this would help ensure that countries would accept and implement the Regulations. The Fifty-sixth World Health Assembly adopted an amended version of the EB resolution (EB111.R13) that sets out the process to finalize the revision proposals.

4. CONCLUSIONS

The difficult process of revising the International Health Regulations is entering a critical phase: the Secretariat is now in a position to present the first draft of the revised Regulations to its Member States and partners. The process for finalizing and adopting the revision has been agreed by the Executive Board. There has been universal support for the proposed wide-scale consultation. Such a process requires heavy investment of resources in time and expertise from the Secretariat, Member States and other partners in implementing the Regulations. It is important at this stage that all Member States be actively engaged in the revision process in order to maintain the momentum achieved and attain the goal of adopting the revised Regulations by the current target of 2005.