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INTERNATIONAL HEALTH REGULATIONS: PERSPECTIVES FROM THE REGION OF THE AMERICAS

The International Health Regulations (IHR) are being revised in accordance with a resolution adopted by the World Health Assembly in 1995 (WHA48.7) to address the threat posed by the emergence and resurgence of infectious diseases and the heightened risk of their international spread caused, in particular, by the growth of commercial air transport and trade. The experiences following the emergence and rapid international dissemination of severe acute respiratory syndrome (SARS) in 2003 have given concrete expression to these threats and risks and challenged the current Regulations to adequately orient the international public health partners on specific actions to be undertaken.

Expert consultations and working groups held since 1995 developed a consensus on the direction of the IHR revision process. They proposed notification criteria and possible response actions to address “public health emergencies of international concern” and the designation of a national center as a focal point for the IHR. In 2001, the 43rd Directing Council of PAHO adopted Resolution CD43.R13 in support of the revision of the IHR urging Member States to participate actively in the review process both nationally and through regional integration systems. PAHO has successfully taken the opportunities presented by the Southern Common Market (MERCOSUR) and the Andean Community countries to get comments on the changes being proposed.

In 2004, an extensive consultation process has been organized for arriving at a consensus on the first regulatory draft of the revised IHR distributed to Member States in January 2004. Subregional consultation meetings have taken place between April and June 2004. WHO will consolidate the feedback from all Regions and an intergovernmental working group will convene in Geneva in November 2004 to draft the final version of the revised International Health Regulations to be submitted to the Fifty-eighth World Health Assembly in May 2005. This process aims to ensure that all essential concerns of Member States regarding public health implications of the revised IHR are addressed so that their obligations can be met.

This progress report is submitted to the Directing Council for information.

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Revision of the International Health Regulations: Perspectives from the Region of the Americas

Background

1. The purpose of the International Health Regulations (IHR) is to ensure maximum security against the international spread of diseases with minimum interference from world traffic. Their origins date back to the mid-nineteenth century when cholera epidemics overran Europe between 1830 and 1847.
2. On 14 November 1924, at the VII Pan American Sanitary Conference in Havana, Cuba, the governments of 21 American republics signed and ratified the Pan American Sanitary Code (Code). The objectives of the Code include: the prevention of the international spread of communicable infections; the promotion of cooperative measures between governments; the stimulation of the mutual exchange of information to improve public health and combat diseases and the standardization of the measures employed at points of entry. The Code was amended by the Additional Protocol to the Pan American Sanitary Code (1952) to eliminate several articles.
3. In 1948, the WHO Constitution came into force and in 1951 WHO Member States adopted the International Sanitary Regulations, which were renamed the International Health Regulations in 1969. The Regulations were modified in 1973 with additional provisions for cholera control and in 1981 to exclude smallpox. The IHR were originally intended to help monitor and control six serious infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever, and typhus. Today, only cholera, plague, and yellow fever are reportable diseases.
4. The World Health Assembly (WHA) requested the revision of the IHR in 1995 (Resolution WHA48.7), to address the threat posed by the emergence and resurgence of infectious diseases and the heightened risk of their international spread caused, in particular, by the growth of commercial air transport and trade. The experiences following the emergence and rapid international dissemination of severe acute respiratory syndrome (SARS) in 2003 have given concrete expression to these threats and risks and challenged the current Regulations to adequately orient WHO and its international partners on specific actions to be undertaken.
5. A series of expert consultations and working groups has been held since 1995 to develop a consensus on the direction of the IHR revision process. In 2001, Resolution WHA54.14 set out WHO's "global health security: epidemic alert and response" strategy and stressed the need for all Member States to work together with WHO and with other technical partners revising the IHR. Together they were to define notification criteria and

possible response actions to address “public health emergencies of international concern” and to designate a national focal point for the IHR. That same year, the 43rd Meeting of the Directing Council of PAHO adopted Resolution CD43.R13 in support of the revision of the IHR urging Member States to participate actively in the review process both nationally and through regional integration systems.

6. An extensive consultation process has been organized for arriving at a consensus on the revised IHR. The revised IHR, which were developed following a series of technical consultations, were distributed to Member States in January 2004 in order to give them sufficient time to review the text prior to the subregional consultation meetings that have taken place between April and June 2004. WHO will consolidate the feedback from all Regions and an intergovernmental working group will convene in Geneva in November 2004 to draft the final version of the revised International Health Regulations to be submitted to the Fifty-eighth World Health Assembly in May 2005.

Revised International Health Regulations

7. The framework for the revised IHR is based on the understanding that the best way to prevent the international spread of diseases is to detect and contain them while they are still a local problem. Outbreaks and epidemics repeatedly challenge national health services and disrupt routine control programs, diverting attention and funds. International coordination is necessary since many countries may need technical cooperation with disease containment activities during serious disease events.

8. In the present world of new and re-emerging diseases, any disease list becomes obsolete the day after it is printed. Also, a case of a disease does not always pose a danger of international spread or impact. The disease must be coupled with circumstances, such as place, time, size of outbreak, closeness to an international border (or an airport), speed of spread and mode of transmission, etc. Consequently, cholera would no longer be reportable unless an outbreak was 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, unusual severity, or if trade and travel restrictions were applied by other Member States.

9. The core concept of the revised IHR—and one that will require substantial change in the way countries interact with WHO at global, regional, and country levels—is that all events that may constitute a public health emergency of international concern should be notified to WHO. A set of criteria was developed to define such events and to cooperate with Member States in the decision to notify. The decision instrument consists of four criteria—seriousness of public impact, unusual/unexpected nature of the illness, potential

for international spread and for travel and trade restrictions—and a set of indicators in the form of support questions, which help to define each criterion.

10. When there is an event with possible international repercussions, national administrations (with input from several sectors) will be required to determine whether the event fulfills the criteria, and, therefore, whether it must be reported to WHO.

11. In order to ensure that urgent national events of international concern are picked up early, each country will require that their surveillance system gather information on unusual and unexpected events expeditiously. Moreover, the system must have the capacity for rapid analysis, so that decisions for action on such data can be made at the local level. The revised IHR will contain a recommended set of core capacity requirements for surveillance and response in Member States.

12. In many countries, surveillance- and action-oriented decision-making capacity may already be in place. Other countries may need a grace period to fulfill this IHR requirement, and technical cooperation and additional funding may become necessary.

13. Today, when an outbreak in one country can constitute a health emergency of concern for the entire world, a collaborative effort among countries is needed to guarantee global health security. Surveillance and response networks must contribute towards global health security by pooling resources of technical institutions regarding epidemiological, laboratory, and clinical management, research, and communications, and by collaborating to rapidly contain threats.

14. The main changes proposed in the revised IHR relate to four key areas: the scope of risk/disease notification; the legal framework for epidemic alert and response; appointment of national focal points and definition of core capacities required in surveillance and response; and public health capacity to implement recommended measures at points of entry. Risk and disease notification is extended to encompass all public health emergencies of international concern, and is connected to established mechanisms for rapid action both by national authorities and by the Organization.

15. Information other than official notifications can be used by WHO to help identify and control urgent international events. There will be an obligation on Member States to respond to requests from the Organization to verify the reliability of such information. 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 ‘round the clock’.

16. Events not meeting the criteria in the decision instrument may also be shared with WHO through a consultation process. National focal points should be appointed with defined responsibilities for official information exchange with WHO during urgent events. In most cases, such information may have to be distributed nationally to hospitals, health officials, ports, and airports very quickly. The communication will in most instances have to be by electronic means, and there needs to be a back-up system within each Member State, so that information always reaches someone who is available. A single contact point is vital to ensuring that the Member State can protect itself in the emergency.

17. The requirements for core surveillance and response capacity in countries and more specifically at points-of-entry (ports, airports, and ground border crossings) proposed in the IHR creates a benchmark for national health-service capacity-building and will require a process of assessment and development of national plans of action to be supported by technical cooperation.

18. At the regional level, there will be an obligation on PAHO/WHO to rapidly provide technical cooperation to Member States in assessing and controlling outbreaks. The established Emerging and Reemerging Infectious Diseases Surveillance Networks are an asset for close collaboration with the Member States. PAHO/WHO will have to proactively provide technical cooperation as well as react and assist in outbreaks, especially if there are multiple outbreaks occurring simultaneously. Some activities already being developed include: training on surveillance, outbreak investigation and laboratory techniques, enhancement of laboratory capacity, improved interaction among partners in epidemiology and laboratory services, and dissemination of epidemiological alerts and technical information on epidemic-prone diseases.

19. With the changes being proposed in the revised IHR, there will be increased demands on country and regional offices. This point merits serious consideration in the planning of the program budget so the Organization fulfills the assigned responsibilities.

Challenges

20. In the present era of rapid electronic communication—i.e. the Internet—news about many urgent international events will become public before even the most efficient health administration has had time to react and notify. Such news, even if unverified, may quickly lead to restrictions on travel and trade from other countries feeling threatened. Information drawn from a wide range of formal and informal sources about the occurrence of outbreaks will need to be verified by national authorities to ascertain its international relevance.

21. Response to threats presented by epidemic-prone and emerging diseases, have often been late or insufficient. Some countries have failed to strengthen their national surveillance and response capacities due to lack of understanding of the need, lack of commitment, lack of funds, or competing priorities. Currently, almost all countries have some kind of system for the surveillance of communicable diseases, but these systems often lack an early warning element and fail to elicit efficient and effective action in response to the surveillance data collected.

22. Political commitment and a core of technical competence and infrastructure is needed for effective epidemic alert and response at the country level. Such national capacity should build on existing communicable disease surveillance systems; should be dynamic and adaptable to changing national and regional priorities; should link common resources to avoid duplication; and should exploit synergies where possible in order to make better use of a country's laboratory and clinical capacities and epidemiological skills. National capacity includes competent managerial and technical staff whose work is guided by policies and procedures which are clearly set out and shared across the system. Sufficient financial resources must be available for the ongoing maintenance of the system and need to be rapidly accessible for outbreak responses.

23. A major challenge is how to organize international resources to respond to an outbreak which threatens to overwhelm the national capacity, or to contain a disease about which little is known. The response to this challenge will entail international cooperation to strengthen partnerships, which in turn enables countries to access logistical, epidemiological, and laboratory resources and communications capabilities.

Regional Technical Cooperation Developments

24. PAHO/WHO has provided technical cooperation for building national and subregional capacity to detect, investigate, and control events related to epidemic-prone diseases. The *Regional Plan of Action for Combating New, Emerging, and Reemerging Infectious Diseases in the Americas* was published in 1995 and provides the framework within which actions in this area take place.

25. In 1998, the initial PAHO/WHO regional meeting for the revision of the IHR involved the participation of national staff from all Member States. Since then, PAHO has been working with Member States to obtain their comments on the proposed revisions and to keep them informed on the progress made. Following Resolution CD43.R13, PAHO has discussed the IHR in working groups on health that have been formed within subregional integration systems.

26. An important component of epidemic control across borders has been the exchange of information and mechanisms of communication between various national public health institutions at all levels of public health and health care delivery services.

27. In collaboration with other agencies and governments, these efforts have resulted in the following:

- Subregional surveillance networks have been established in the Amazon Basin, Southern Cone, Central American subregion, and most recently the Caribbean. These networks bring together epidemiologists, clinicians, and laboratory scientists to share information, complement each country's strengths, and collaborate in responding to events that are beyond individual country capacity.
- Argentina, Bolivia, and Brazil have embarked on a comprehensive reorganization of their surveillance systems, with emphasis on local capacity to detect and respond to infectious diseases outbreaks.
- PAHO has been working with its Member States to strengthen their epidemiological and laboratory capabilities for the surveillance and control of communicable diseases through several of its technical cooperation programs, and has organized networks of laboratories for specific pathogens and for emerging and reemerging diseases. The laboratory capacity to confirm the infectious etiology of outbreaks has become an integral part of the aforementioned surveillance networks, which stresses the use of reference centers of excellence.
- With regard to antimicrobial resistance, there is a functional network for identification of bacteria and quality control of antimicrobial sensitivity testing for *Salmonella*, *Shigella*, *Vibrio cholerae*, *Haemophilus influenzae* and *Streptococcus pneumoniae*, and other bacteria of nosocomial and community importance.

28. One of the most active groups participating in the IHR review to date has been the Southern Common Market (MERCOSUR), which includes the Southern Cone countries (Argentina, Brazil, Paraguay, and Uruguay, with Bolivia and Chile as observers). This group has provided PAHO/WHO with insight into proposed changes and has taken concrete steps regarding the IHR, such as the following:

- Including the Regulations as a priority topic of its Surveillance Working Group.
- Pledging unanimous support to the revision process, especially as it refers to border health and its trade components.

- Conducting four workshops resulting in resolutions and agreements signed by the Ministries of Health.
- Carrying out country activities including the revision of national norms for port-of-entry sanitation and travelers' health certificates; testing syndromic surveillance at the national level; and testing the "decision tree" for reporting events of international public health concern.

29. The *Organismo Andino de Salud*, comprising the Andean countries (Bolivia, Chile, Colombia, Ecuador, Peru, and Venezuela), has included the IHR revision on its health agenda. Through a cooperative agreement with PAHO, it has organized two workshops on the subject to inform the countries about the revision of the IHR; to initiate a national process to bring together interested parties; and to obtain national views regarding the proposed changes. Two ministerial resolutions emerged from these discussions. The first one established national technical task forces, and the second urged countries to review and strengthen epidemiological surveillance, especially in border areas.

30. In North America, the United States established a national working group for the review of the revised IHR with broad institutional representation; it includes the participation of the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention, the Food and Drug Administration, Department of Agriculture, Immigration and Naturalization Services, Customs, and others. HHS has been a major contributor to the IHR revision process providing continuous feedback on each step with specific suggestions for adjustment. More recently, two sets of comments with regard to the first draft of the revised IHR have been submitted to PAHO/WHO and are available on the WHO IHR web page. Building on the Global Public Health Intelligence Network and the experience with the outbreak of SARS, Canada has also reinforced the importance of the IHR. Canada has made a commitment to strengthen its public health capacity with particular emphasis on dealing with events of international public health concern. Shortly after the SARS outbreak in Canada, Health Canada commissioned an analysis of how well the situation was handled, what worked, and what did not. The report recommended the need for a new public health agency, and their government is now actively engaged in the planning and design of such an agency.

31. The experiences following the emergence and rapid international spread of severe acute respiratory syndrome (SARS) gave concrete expression to the magnitude of the challenges faced by Member States and PAHO/WHO to implement the revised IHR. This considerable public health threat prompted national authorities to request PAHO/WHO's assistance. The situation involved an unknown agent, presenting unusual clinical features and an unknown mode of transmission; and the index case was linked to international travel with major hubs affected, resulting in restrictions on international travel for

tourism and business. Extensive use was made of unofficial information sources. WHO Headquarters, together with its Regional Offices, coordinated the global response using laboratory, clinical, and epidemiology networks to establish technical guidelines (infection control, clinical, laboratory, airlines, and ships), case definition, and travel advisories; to update information provided to airports, health authorities, and the general public about actual risk; and to clarify trade questions about restrictions regarding risk of transmission by goods.

32. Member States have actively participated in subregional consultation meetings with delegations that were mostly comprised of ministry of health officials. In some instances representatives from transport, agriculture, foreign affairs, and food safety sectors were present. Preparation for the meetings with extensive national consultation was performed by half of the participant States. Several key areas of concern to Member States were identified during the subregional meetings. One was the need to incorporate into the IHR the necessary commitment from Member States and WHO regarding resources and deadlines to establish core capacities requirements for surveillance and response, and for designated airports, ports, and ground crossings. There were also reservations with public health jurisdictional authority in implementing recommended measures at points of entry. The chain of communication among the national center-focal point (NC-FP) for the IHR, the health administration, and WHO should be redefined to ensure that the NC-FP obtains clearance from the health administration before communicating with WHO. The decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern (PHEIC) should be adjusted to ensure a sensitivity that permits timely actions of prevention and control while minimizing the overload of the national and global alert and response systems. A list of diseases should be considered to supplement the decision instrument. The decision process for epidemic alert and response needs to be transparent while ensuring the independence of the emergency and review committees. In addition, it was requested that the affected State be able to make representations to these committees to assist them in their deliberations. Finally, some countries requested that the health authority have the right to charge a fee for vaccination and other prophylaxis. Summary reports of each meeting are available on PAHO's web page.

Future Activities

33. To ensure full country participation in the final stages of the IHR revision process, resources will also be devoted to collaborating with countries in preparing for the implementation of the IHR through strengthening PAHO/WHO technical cooperation in communicable-disease surveillance, alert, and response. PAHO will continue to provide technical cooperation to countries in their process of expanding the awareness and participation of other relevant sectors besides health. Two major objectives were established for the current biennium: to consult Member States on the proposed revised

text of the IHR, and to strengthen the capacity of the Region of the Americas to detect and respond to disease outbreaks.

34. Having conducted the four subregional consultation meetings as mentioned above (paragraph 32), PAHO has summarized the regional contributions for the Inter-Governmental Working Group, which will meet in Geneva, in November 2004. PAHO will continue to hold the IHR as a priority topic on the health agenda of the countries and the subregional integration systems.

35. Activities to improve the regional capacity for alert and response will be geared to strengthening existing subregional surveillance of emerging diseases as well as mechanisms for alert and response at PAHO Headquarters and in country offices. The latter includes improving procedures for rapid epidemic intelligence, verification, and secure communications of essential/sensitive information in coordination with the Global Alert and Response Network (WHO/GOARN); expanding communications and information exchange concerning public health emergencies of international concern with ministries of health in real time through the subregional surveillance of emerging infectious diseases networks, coordinating regional outbreak investigation and response; and supporting national interventions through stand-by arrangements, logistic support, and standardized protocols.

36. At the national level, countries will be encouraged to assess their public health services (laboratory, epidemiology, hospital, and others) preparedness to detect and respond to emergencies caused by infectious disease epidemics using standardized guidelines. This will include development of plans of action for national capacity-building (disease detection, investigation, confirmation, and response).

37. Strengthening the existing national alert-and-response system at country level will require linking, expanding, and integrating epidemiology, laboratory, and preparedness-planning activities, especially in less developed countries. The most relevant outcome of this activity will be the preparation of contingency plans to deal with gaps and strengths identified in the assessment.

Action by the Directing Council

38. The Directing Council is requested to formulate comments and observations and issue recommendations on the IHR revision process on its implications for the Region of the Americas and on programmed activities related to the future implementation of the IHR.