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Implementation of the International Health Regulations (2005) in the WHO European Region

At the Fifty-eighth World Health Assembly in 2005, by resolution WHA58.3, WHO Member States adopted the current International Health Regulations (2005) (IHR), which entered into force in June 2007. Since then, the States Parties and WHO have reiterated their commitment and taken important steps towards meeting the legally binding IHR requirements. Between June 2007 and July 2009, the national focal points and the WHO IHR Contact Point were in contact in respect of over 200 public health events in more than 40 States Parties in the WHO European Region.

Implementation of the IHR is a continuous process that will be guided by reviews of the implementation and functioning of the Regulations. In line with the mandate received from the World Health Assembly, the WHO Regional Office for Europe has been working on implementation of the above-mentioned resolution.

This document attempts to summarize the progress made at both global and regional levels in implementing the IHR and draws on the lessons learned and challenges related to the current pandemic (H1N1) 2009.

Its structure follows the order of the areas of work as outlined in the WHO publication *International Health Regulations (2005): Areas of work for implementation*, published in 2007 (WHO/CDS/EPR/IHR/2007.1).

This document should be read in conjunction with the paper prepared for the technical briefing at the fifty-ninth session of the WHO Regional Committee for Europe on "Pandemic (H1N1) 2009: overview and role of the WHO Regional Office for Europe in preparedness and response", which provides an update on the current status, actions taken and challenges faced to date.

A draft resolution is submitted for consideration by the Regional Committee.

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The International Health Regulations

1. Recognizing the need for improved tools to respond effectively and collectively to international public health risks, WHO Member States tasked an intergovernmental working group to revise the previous International Health Regulations (IHR (1969)).[1] As a result, during the Fifty-eighth World Health Assembly in 2005, WHO Member States adopted the current IHR (2005), which entered into force in June 2007.[2]

2. The purpose and scope of the IHR 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" (IHR, Article 2).

3. Hence, the IHR adopt a multisectoral approach and encompass a broad range of public health hazards (biological, chemical, radionuclear and of unknown etiology). Implementation of the IHR represents a unique opportunity to mobilize resources and develop sustainable public health capacities, serving both domestic and global public health.

4. Since their entry into force, States Parties to the IHR and WHO have reiterated their commitment and taken important steps towards meeting their legally binding IHR requirements,[3] which is a challenge that requires time, commitment and a willingness to change. The WHO Regional Office for Europe has been providing assistance to States Parties to implement the IHR, and the wide range of activities carried out have generally corresponded to the areas of work outlined in the WHO document *International Health Regulations (2005): Areas of work for implementation*, published in 2007.[4] The account below is structured accordingly. It takes into account the issues that have emerged, the lessons learned and the challenges posed during the initial stages of the current public health emergency of international concern, as determined by the WHO Director-General on 25 April 2009 on the occasion of the emergence and rapid spread of a novel influenza virus – the pandemic (H1N1) 2009 virus – and the subsequent declaration of pandemic alert level 6 on 11 June 2009, after receipt of convincing evidence of sustained community-wide transmission of the virus.

5. At this stage, the momentum of implementation of the IHR must be sustained by taking into account the challenges posed by the current pandemic (H1N1) 2009 and drawing on the lessons learned so far. There is a need for States Parties and WHO to focus on harmonizing their interpretation of the scope and provisions of the IHR and related practices in keeping with principles inspiring the IHR. This would facilitate achievement of full political commitment, together with mobilization of the necessary resources, both of which are critical prerequisites to move the implementation of the IHR forward at all levels in order to enjoy its full benefits.

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[1] World Health Assembly resolutions WHA54.14. *Global health security: epidemic alert and response*, WHA55.16. *Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health*, and WHA56.28. *Revision of the International Health Regulations*, Geneva, World Health Organization, 2001, 2002 and 2003, (http://apps.who.int/gb/archive, accessed 27 July 2009).

[2] World Health Assembly resolution WHA58.3. *Revision of the International Health Regulations*. Geneva, World Health Organization, 2005, (http://apps.who.int/gb/eebwha/pdf_files/WHA58/WHA58_3-en.pdf, accessed 10 August 2009).

[3] World Health Assembly resolution WHA61.2. *Implementation of the International Health Regulations*. Geneva, World Health Organization, 2008, (http://apps.who.int/gb/or/e/e_wha61r1.html, accessed 27 July 2009).

[4] *International Health Regulations (2005). Areas of work for implementation*. Geneva, World Health Organization, 2007 (document WHO/CDS/EPR/IHR/2007.1).

Foster global partnerships

6. Global and regional partnerships are essential to the successful implementation of the IHR. Different sectors (e.g. health, agriculture, travel, trade, education, defence) must work in partnership to build coherent alert and response systems that cover all public health threats and, at the time of an event, are able rapidly to mobilize the required resources in a flexible and responsive way.

7. WHO's public health mandate and its relations with partners, as well as its national, regional and global networks, also play an important role in implementation of the Regulations. The WHO Regional Office for Europe has been engaged at regional level with various national institutes, international initiatives, intergovernmental and regional economic integration organizations, donor agencies, development banks and technical agencies to support implementation of the IHR. International networks and projects involved include the project on Response to Emerging infectious disease: Assessment and Development of Core capacities and Tools (REACT), EpiNorth and EpiSouth, Ship Sanitation Programme and Coordinated Action for the Control of Communicable Diseases in Cruise Ships and Ferries (SHIPSAN), and the Stability Pact Initiative for South-Eastern Europe.

8. In the 2009 States Parties report, 79% (23/29) of States Parties in the WHO European Region reported that they participated in bilateral or multicountry groups that meet regularly to prepare for and respond to cross-border public health events.

9. In the WHO European Region, WHO staff at regional and country levels have received training in the IHR to enable them to advise national authorities. The Regional Office organized four subregional meetings of national IHR focal points (NFPs) to raise awareness, facilitate international collaboration and support IHR-related capacity-building. These meetings have often been organized jointly by the Regional Office with essential contributions from national institutes, international initiatives, intergovernmental and regional economic integration organizations, and donor agencies such as the European Commission and European Union institutions, the Asian Development Bank and its Central Asia Regional Economic Cooperation (CAREC) Program, the World Bank, the United States Agency for International Development (USAID), the United States Centers for Disease Control and Prevention (CDC), the Hamburg Port Health Centre of the Central Institute for Occupational and Maritime Health in Germany, the National Institute for Public Health and the Environment in the Netherlands, and the United Kingdom Health Protection Agency.

10. In particular, the contributions of States Parties with well developed capacities are valuable, in combination with the commitment of those with less developed capacities, ensuring the same level of core capacities throughout the WHO European Region. To this effect, the Regional Office has often mobilized national experts and authorities to promote the spirit of the IHR and to facilitate the exchange of experiences among States Parties during meetings, workshops and country missions.

Challenges

- Taking account of the heterogeneity between and within the Member States in the Region in terms of capacities, languages, institutional arrangements, public health background, agendas of stakeholders involved, and resources available;
- ensuring commitment of countries and, within countries, of all relevant sectors required to provide technical support and, where needed, mobilize the resources required for effective implementation of the IHR;

- at a time of global economic crisis, ensuring solidarity and mutual commitment of States Parties with and without sufficient resources to build up their capacity, in order to channel resources to where the need is the greatest;
- optimizing collaboration and coordination between the Regional Office and other global, regional organizations and networks; and
- ensuring regional coordination mechanisms that accommodate the national and regional diversities and needs of Member States while promoting the IHR through initiatives at the global level.

Strengthen national disease prevention, surveillance, control and response systems

11. Strengthening countries' disease surveillance and response systems is central to improving public health security in each country and globally. The IHR requires well established core capacities to detect unusual health events in a timely manner, leading to responses commensurate with risks. In this respect, the aim is ideally to contain the event at source and thus prevent further international spread. States Parties should assess and maintain core capacities for surveillance and response at local/community, intermediate and national public health levels (IHR, Annex 1A). States Parties should have assessed their core capacities and developed national IHR action plans addressing identified gaps by June 2009. Implementation of these action plans should ensure that the core capacities for surveillance and response are present by June 2012. Nevertheless, each national IHR action plan should be conceived as a living document that should be updated after June 2009, if the need arises, to secure its smooth implementation.

12. In the 2009 States Parties report, 93% (28/30) of States Parties in the WHO European Region reported that they had made an assessment of their capacities for surveillance and early warning regarding public health events, while 90% (27/30) had assessed their capacities to respond to urgent public health events. Fifty-four per cent (17/31) of States Parties reported having developed plans of action as set out in paragraph 2 of Annex 1A to the IHR.

13. The Regional Office regards capacity-building efforts within the framework of the IHR as an opportunity to maximize synergies among ongoing and planned technical projects and initiatives. The IHR framework for strengthening capacities is also expected to make it easier to mobilize resources in a cost-effective manner at both national and regional levels. At this juncture, it is essential that capacity-building is based on prior and ongoing efforts related to avian influenza, as well as on the momentum generated by the pandemic (H1N1) 2009, by prioritizing those components that are critically important to ensure an adequate response as the pandemic evolves.

14. Since 2007, the Regional Office has supported and facilitated workshops and training at subregional, national and subnational levels, to strengthen both the early warning and response functions as well as laboratory capacities. The Regional Office has developed one generic IHR assessment tool and three hazard-specific assessment tools (for communicable diseases, chemical hazards and radionuclear hazards), which have been shared with NFPs in the Region.

15. Additional technical guidance and other information on assessing and building up core capacity to implement the IHR are progressively being made available at regional and global levels, relying heavily on the contributions of experts from the WHO European Region.

Challenges

- Securing the continuous commitment of both national authorities and partners, together with WHO, to ensure that the necessary resources are mobilized to facilitate the implementation of national IHR action plans;
- using the national IHR action plans to mobilize human and financial resources, in order to strengthen core capacities;
- giving full consideration to synergies between existing resources, structures and initiatives, in order to avoid unnecessary duplication and maximize the cost–effectiveness of partnerships, in particular during development and implementation of national IHR action plans;
- translating core capacity requirements as specified in Annex 1A to the IHR into tangible and useful capacities in diverse local contexts; and
- having national authorities endorse the national IHR action plans and recognize that development and implementation of the plan are subject to needs-driven adjustments.

Strengthen public health security in travel and transport

16. States Parties also need to assess and maintain core capacities at designated points of entry (IHR, Annex 1B). Points of entry include airports, ports and ground crossings, the designation of the latter being explicitly voluntary under the IHR. This area of work truly underlines the multisectoral approach of the IHR.

17. In the 2009 States Parties report, different proportions of States Parties reported having designated ports (59%, 16/27) airports (52%, 14/27) and ground crossings (11%, 3/28) for development of the core capacities set out in Annex 1B of the IHR. Fifty-seven per cent (16/28) of States Parties had conducted some assessment of the related capacities. States Parties have adopted different strategies when designating points of entry for development of the core capacities set out in IHR Annex 1B. The range includes States Parties that have designated no or few ports, airports and ground crossings, as well as others who have designated large numbers. Based on available information from the 2009 report, there were 124 designated ports in 14 States Parties, 91 designated airports in 13 States Parties and 150 designated ground crossings in three States Parties.

18. In addition to the designation of ports, States Parties can authorize additional or the same ports to issue and extend ship sanitation certificates. The list of authorized ports included over 600 ports in 29 States Parties in the WHO European Region as of 23 July 2009.

19. To assist in the development of IHR-related capacities at ports, the Regional Office, in collaboration with competent national authorities in Germany and the Netherlands, designed a workshop on IHR implementation at ports that has been held at two occasions. Guidance materials related to points of entry have also been made available to NFPs in the Region. The Regional Office has also facilitated a limited number of country missions related to this area of work.

20. At global level, significant efforts have been invested by national experts and WHO into setting standards and developing standard operating procedures for activities under the IHR framework related to ports and ships. In this area of work, the contributions and leadership of national experts in the WHO European Region have been invaluable assets.

21. The current pandemic (H1N1) 2009 has highlighted the need for WHO guidance in order to build up a common understanding of relevant IHR provisions among States Parties and

stakeholders. WHO should guide the implementation process in a coherent manner according to the deadlines set out in the Regulations, especially with regard to giving effect to recommendations issued by the Emergency Committee. Similarly, the current pandemic has highlighted the need to clarify the respective roles of the World Trade Organization (WTO) and WHO in relation to the adoption and implementation of measures by States Parties that might unnecessarily interfere with trade.

Challenges

- Clarifying the often uncertain and overlapping responsibilities of port health authorities (or their equivalents), and unclear protocols for communication with NFPs, which may require coordination or adjustment of (sub)national administrative structures;
- defining and bringing clarity to the principles, procedures and guidance for the designation and certification of points of entry, the latter applying only to airports and ports;
- collaborating to create synergies between existing resources, structures, initiatives and organizations (e.g. the International Air Transport Association (IATA), the International Civil Aviation Organization (ICAO), WTO) in order to ensure a coherent and cost-effective approach to implementation of the relevant IHR provisions;
- mobilizing human and financial resources at all levels to ensure efficient links between sectors/disciplines, in order to benefit prevention, detection and response pertaining to public health events.

Strengthen WHO global/regional alert and response systems; and strengthen the management of specific risks

22. The NFP is the principal functional entity for the IHR at country level and each State Party must designate one, while the six WHO regional offices have WHO IHR contact points. The NFP must be accessible at all times to communicate and exchange information with the WHO IHR Contact Point and other national stakeholders.

23. Since April 2008, all 54 States Parties in the WHO European Region have designated an NFP. States Parties have chosen different operational structures for their NFPs, although he or she is typically located within the Ministry of Health or at a national public health institute. The division of IHR-related tasks between the NFP and other national stakeholders is usually determined by their respective decision-making mandates and technical expertise.

24. In the 2009 States Parties report, 86% (24/28) of States Parties reported having held information meetings in the context of IHR implementation, with or without the active participation of WHO. Moreover, 72% (21/29) of States Parties had developed plans of action for IHR implementation, 93% (25/27) had translated the IHR and 43% (12/28) had developed or revised standard operating procedures for “IHR operations”. Eighty-four per cent (26/31) of States Parties reported that they had used the decision instrument in Annex 2 of the IHR as a guide for the notification of public health events to WHO.

25. A number of States Parties in the WHO European Region have overseas territories and the like, which poses additional challenges when defining roles and responsibilities (e.g. for information-sharing) throughout the process of detecting and managing a public health event.

26. The Regional Office supports the operation of channels of communication with NFPs by engaging in interactions with them about public health events, including simulation exercises at national, subregional and global levels and IHR-related administrative tasks.

27. In tests performed by the Regional Office, the proportions of accessible NFPs were 82% (36/44) by telephone (November 2007), 70% (38/54) by e-mail (June 2008, during a global exercise), and 48% (23/48) by fax (January 2007).

28. From June 2007 to July 2009, NFPs and the WHO IHR Contact Point for the European Region were in constant communication regarding over 200 public health events in over 40 States Parties. For two thirds of the events considered, interactions were initiated by WHO as a result of routine screening of informal sources of information. The largest proportion of events considered could be attributed to communicable diseases (~45%), followed by zoonoses (~20%), food products (~20), chemicals (10%), radiation (<5%) and pharmaceuticals (<5%). These categories are not mutually exclusive but rather reflect organizational and operational arrangements.

29. Activation of IHR communication mechanisms initiates a joint NFP-WHO risk assessment to determine whether any action is needed. Depending on the nature of the event, the Regional Office also initiated joint NFP-WHO risk assessments involving other WHO regions, other specialized agencies of the United Nations and European Union institutions. These event-related risk assessments led to a broad range of international public health actions, such as information-sharing at the international level, facilitation and coordination of interactions between national counterparts, provision of technical advice and deployment of experts to the field.

30. Since 2006, the Regional Office has organized and run national intersectoral workshops in a number of countries, to raise awareness of the IHR and engage national stakeholders from different sectors.

31. The current pandemic (H1N1) 2009 has demonstrated that direct channels of communication between WHO and States Parties are functioning well. The arrangement of having a single “entry point” in WHO (i.e. the WHO IHR Contact Point) and in States Parties (i.e. the NFP) has proved to be extremely valuable for supporting information-sharing and securing coordinated responses involving many stakeholders. For example, in terms of sharing information, WHO has provided its Member States with updates about the rapidly evolving pandemic situation at international level in order to inform response activities and strategies at national level. Joint risk assessments were also valuable when defining priorities from the perspective of the Regional Office, for example for the deployment of WHO’s regional and global stockpiles of oseltamivir to Member States most in need.

Challenges

- Ensuring continued and enhanced transparent and timely communication, collaboration and coordinated actions between NFPs and the WHO IHR Contact Point;
- defining institutional arrangements that will ensure efficient communication between WHO and State Parties with territories in more than one WHO region in relation to events of potential international concern occurring in their overseas territories;
- defining clear approaches and procedures for communication, risk assessment and management of public health events associated with food, chemical and radionuclear hazards, (both among WHO-coordinated networks such as the International Food Safety Authorities Network (INFOSAN), the Global Chemical Incident Alert and Response Network (CHEMINET) and the Radiation Emergency Medical Preparedness and Assistance Network (REMPAN), as well as other international organizations, such as the International Atomic Energy Agency (IAEA), and networks (e.g. the EU Rapid Alert System for Food and Feed (RASFF));

- defining mechanisms to secure a coherent, evidence-based and risk assessment-driven response at all levels commensurate with the risk during a public health emergency of international concern, as stipulated under the IHR;
- introducing mechanisms facilitated by WHO for sharing information, to extract and build on the lessons learned from real events to inform and improve event management, risk assessment and capacity-building;
- analysis of the potential benefits of WHO's involvement in the management of public health events of potential international concern, in order to define where WHO should focus its resources and efforts.

Sustain rights, obligations and procedures

32. The IHR are legally binding, so States Parties must ensure that their national legislation is compatible with them. A number of States Parties in the WHO European Region have taken the opportunity of the entry into force of the IHR to review and amend their national legislation and/or public health law. The Regional Office has mobilized expertise and resources within and to States Parties to support the revision of national legislation.

33. In the 2009 States Parties report, 52% (16/31) of States Parties reported that an assessment of all relevant national legislation, regulations or administrative requirements had been carried out to determine whether they facilitate full implementation of the IHR. Fifty-three per cent (16/30) of States Parties had adopted new or revised legislation to facilitate full implementation of IHR. These results indicate that further review, and possibly amendment, of national legislative frameworks are warranted in some instances, to facilitate and formalize IHR-related structures and capacities. The EU legislative framework is also being adapted to reflect relevant aspects of the IHR.

34. The IHR set out rules with defined procedures and responsibilities for WHO and States Parties to the Regulations. On the other hand, some Member States also have to fulfil their obligations through different arrangements and frameworks with other organizations. IHR-related coordination with intergovernmental and regional economic organizations and with regional and global networks poses specific challenges as a result of the different obligations of Member States and the specific mandates of the respective organizations, which can lead to confusion and duplication at times. Lack of full recognition of the legal mandates and obligations of WHO and States Parties under the IHR undermines efficient direct and bilateral communication between WHO and States Parties and hinders effective technical collaboration between the Regional Office and other organizations in areas of work relevant for implementation of the Regulations.

Challenges

- Identifying and mobilizing expertise at the intersection of law and public health, in order to adjust the national legislative framework to accurately reflect public health principles in line with IHR obligations and in the best interests of public health;
- overcoming the division of legislative actions between different subnational and national levels. This issue is particularly relevant in federal states, where the subnational level can have far-reaching health-related responsibilities;
- interpreting and translating the provisions of the IHR into national legislation, acknowledging that a legal text cannot cover every possible occurrence;

- ensuring that some States Parties, such as EU Member States, have a common understanding of their IHR-related obligations towards WHO, which are independent from other legally binding frameworks;
- clarifying the coordination mechanisms between different organizations in respect of their mandates, without compromising the obligations of States Parties and Member States towards the different organizations;
- promoting a better understanding of the procedures and modus operandi of the Emergency Committee, (including the formulation of temporary recommendations), which was convened for the first time on the occasion of determination of the public health emergency of international concern related to the pandemic (H1N1) 2009.

Conduct studies and monitor progress

35. Giving effect to the IHR is a continuous process that will be guided by review of the implementation and functioning of the Regulations. In 2009, as in 2008, WHO invited all 194 States Parties to complete a questionnaire, to help them meet their obligation to report to the World Health Assembly on implementation of the IHR. The 2009 questionnaire was completed and submitted by 57% (31/54) of States Parties in the WHO European Region before the deadline for consideration of the report by the World Health Assembly. The submitted data are highly useful for monitoring purposes. The status of implementation of the key components in the IHR is presented in Table 1.

36. The IHR implementation process depends on the tireless engagement of professionals from different disciplines and sectors at subnational, national and international levels. The implementation process will also be supported by the extraction and documentation of lessons learned, so that these can lead to change and serve to optimize event management and capacity strengthening under the IHR framework.

Challenges

- Maintaining a balance between theoretical monitoring exercises and the spirit of the IHR, to improve domestic and international public health capacities;
- facilitating mechanisms to extract and build on the lessons learned from practice in a continuous, consultative and systematic fashion, in order to harmonize interpretation of the IHR and related practices, and ultimately to further improve the application of the IHR and maximize their anticipated benefits;
- reviewing the tools, mechanisms and provisions outlined in the IHR, building on the lessons learned, and without jeopardizing the spirit of the IHR and those provisions that efficiently serve the interests of public health.

Table 1. Status of components of the IHR implementation process,
States Parties report to the Sixty-second World Health Assembly, WHO European Region, 2009

Component	**Proportion of States Parties answering "yes" (Total respondents = 31)**
Has the State Party held information meetings for IHR advocacy purposes?	86% (24/28)
Have you developed a plan of action for IHR implementation?	72% (21/29)
Have you translated the IHR?	93% (25/27)
Have you developed or revised standard operating procedures for IHR operations?	43% (12/28)
Has an assessment of all relevant national legislation, regulations or administrative requirements been carried out to determine whether they facilitate full implementation of the IHR?	52% (16/31)
Has any new or revised legislation been adopted to facilitate full implementation of IHR?	53% (16/30)
Does the State Party participate in bilateral or multicountry groups that meet regularly to prepare for and respond to cross-border public health events?	79% (23/29)
Is the decision instrument in Annex 2 of the IHR used to guide notification of public health events to WHO?	84% (26/31)
Has the State Party assessed the national capacities for surveillance and early warning of public health events?	93% (28/30)
Has the State Party assessed the national capacities for response to urgent public health events?	90% (27/30)
Has the State Party developed plans of action to ensure that core capacities are present and functioning throughout its territories as set out in paragraph 2 of Annex 1A of the IHR?	57% (17/31)
Has the State Party designated ports for development of the core capacities set out in Annex 1B of the IHR?	59% (16/27)
Has the State Party designated airports for development of the core capacities set out in Annex 1B of the IHR?	52% (14/27)
Has the State Party designated ground crossings for development of the core capacities set out in Annex 1B of the IHR?	11% (3/28)
Has the State Party assessed the national capacities of designated airports, ports and ground crossings?	57% (16/28)
Has the State Party developed an implementation plan to ensure that point of entry capacities will be present and functioning by 2012?	40% (12/30)