World Health Organization

SIXTY-NINTH WORLD HEALTH ASSEMBLY **A69/20**
Provisional agenda item 14.1 **18 May 2016**

Implementation of the International Health Regulations (2005)

Annual report on the implementation of the International Health Regulations (2005)

Report by the Director-General

1. In accordance with paragraph 1 of article 54 of the International Health Regulations (2005) and resolution WHA61.2 (2008), States Parties and the Director-General report annually to the Health Assembly on the implementation of the Regulations. An earlier version of this report was considered by the Executive Board at its 138th session in January 2016.[1] The document has been extensively revised and includes new text to reflect recent developments. It gives an account of actions taken by the Secretariat within the framework of the Regulations regarding the international response in 2015, and to date in 2016, to public health events and emergencies – in particular, Ebola virus disease, Middle East respiratory syndrome (MERS), poliomyelitis, avian influenza and Zika virus infection, with associated microcephaly and Guillain-Barré syndrome. The report also includes information about the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, and the first amendment to the International Health Regulations (2005) regarding yellow fever vaccination. It also describes the proposed shift from the country self-reporting of core capacities under the Regulations to a more complete assessment of national capabilities using, inter alia, external evaluations.

KEY PUBLIC HEALTH EVENTS AND EMERGENCIES IN 2015

2. From 16 October 2015 to 15 March 2016, 167 "public health events" were recorded in WHO's Event Management System. During that period, WHO posted 141 updates, including regional updates and updates on meetings of the Emergency Committee, on the event information site for National IHR Focal Points, relating to 69 public health events. Most updates concerned Zika virus disease and human cases of MERS or avian influenza.

Ebola virus disease

3. Since the declaration of a Public Health Emergency of International Concern in 2014, the IHR Emergency Committee regarding the Ebola outbreak in West Africa has met nine times. The most

[1] Document EB138/19; see also summary records of the Executive Board at its 138th session, first meeting (section 4) and second meeting (section 1) (document EB138/2016/REC/2).

recent meeting was held by teleconference on 29 March 2016. The Committee noted that, since its last meeting, Guinea, Liberia and Sierra Leone had met the criteria for confirmed interruption of their original chains of Ebola virus transmission; they had now completed the 42-day observation period and additional 90-day enhanced surveillance period since their last case that was linked to the original chain of transmission twice tested negative. Guinea reached this milestone on 27 March 2016. These achievements were considered not affected by the report of limited clusters of cases associated with the resurgence of the virus in a small number of individuals who had previously recovered from the disease. The Committee concluded that the Ebola situation in West Africa no longer constituted a Public Health Emergency of International Concern and that the corresponding Temporary Recommendations issued by the Director-General should be terminated. Based on the advice of the Emergency Committee, and her own assessment of the situation, the Director-General terminated the Public Health Emergency of International Concern and the Temporary Recommendations and supported the public health advice provided by the Committee.[1]

4. The Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, established and convened by the Director-General pursuant to decision WHA68(10) (2015), held its first meeting on 24 and 25 August 2015, intersessional meetings in October 2015, November 2015, December 2015 and February 2016, and its second and final meeting from 21 to 24 March 2016. The report of the first meeting of the Review Committee, as well as reports of intersessional meetings are available on the WHO website.[2] The final report of the Committee has been forwarded to the Sixty-ninth World Health Assembly in the accompanying document A69/21.

Middle East respiratory syndrome

5. The MERS coronavirus has been circulating in the Arabian Peninsula − years after it was first identified. By March 2016, laboratory-confirmed cases of infection had been reported to WHO from 26 countries in the Middle East, North America, Europe and Asia. Major hospital outbreaks occurred in the Republic of Korea in the period May–August 2015 and in Saudi Arabia in August 2015.

6. Since 2013, the IHR Emergency Committee concerning Middle East respiratory syndrome coronavirus has met 10 times, most recently in September 2015.[3] At the latest meeting, the Committee advised that the situation still did not constitute a Public Health Emergency of International Concern. However, the virus continued to be transmitted from camels to humans, and from humans to humans in health-care settings. Continuing challenges included ensuring: the reporting of asymptomatic cases that had tested positive for the virus, rapid information-sharing, implementation of infection control measures and appropriate research studies. The Committee emphasized that there was no public health justification for restricting trade or travel to prevent the spread of MERS coronavirus; screening at points of entry was considered unnecessary. However, raising awareness about MERS and its symptoms among travellers, particularly in light of the hajj, was strongly advised.

[1] See http://www.who.int/mediacentre/news/statements/2016/end-of-ebola-pheic/en/ (accessed 22 April 2016).

[2] See http://www.who.int/ihr/review-committee-2016/en/ (accessed 31 March 2016).

[3] See http://www.who.int/mediacentre/news/statements/2015/ihr-emergency-committee-mers/en/ (accessed 22 April 2016).

Poliomyelitis

7. Since the declaration of a Public Health Emergency of International Concern on 5 May 2014, the IHR Emergency Committee regarding the international spread of poliovirus has met eight times to date. In February 2016, the Committee agreed that the epidemiological situation still constituted a Public Health Emergency of International Concern and advised the extension of the revised Temporary Recommendations, focusing on large-scale population movements and increasing vaccination coverage among refugees, travellers and cross-border populations. The Committee noted the continued spread of poliovirus between Afghanistan and Pakistan, and outbreaks of vaccine-derived poliovirus elsewhere, and urged regular review of the risk of international spread in high-risk areas. The Director-General endorsed the Committee's conclusions and issued Temporary Recommendations under the Regulations.[1]

8. By decision WHA68(9) (2015), the Sixty-eighth World Health Assembly requested the Director-General to report to the Sixty-ninth World Health Assembly on progress towards reduction in the risk of international spread of wild poliovirus.[2]

Zika virus, microcephaly and Guillain-Barré syndrome

9. On 1 February 2016, the Director-General convened the first meeting of the Emergency Committee on Zika virus under the International Health Regulations (2005), regarding clusters of cases of microcephaly and other neurological disorders in some areas affected by Zika virus. Based on the advice of the Emergency Committee, the Director-General declared that the cluster of cases of microcephaly and other neurological disorders reported in Brazil, following a similar cluster in French Polynesia in 2014, constitutes a Public Health Emergency of International Concern and issued corresponding Temporary Recommendations. At its second meeting (Geneva, 8 March 2016), the Emergency Committee reviewed the latest evidence showing a link between Zika virus infection and microcephaly and agreed that, although the evidence for a causal link was stronger than in February 2016, additional research was still needed. This conclusion prompted the Committee to provide additional advice which the Director-General issued as Temporary Recommendations.[3]

10. From 1 January 2007 to 30 March 2016, Zika virus transmission has been documented in a total of 61 countries and territories. As at 26 March 2016, the virus is actively spreading in 38 countries and territories. Six countries have also reported locally-acquired infection in the absence of any known mosquito vectors, probably through sexual transmission. Based on observational, cohort and case-control studies there is a growing scientific consensus that the virus is a cause of increased cases of Guillain-Barré syndrome, microcephaly and other neurological disorders being reported in a number of countries where Zika virus is circulating. WHO launched a Strategic Response Framework encompassing surveillance, response activities and research.[4] WHO is working closely with regional offices and affected countries on an integrated response including mosquito surveillance and control, promotion of personal protective measures, support for pregnant women living in or returning from

[1] Available at http://www.who.int/entity/mediacentre/news/statements/2016/8th-IHR-emergency-committee-polio/en/index.html (accessed 22 April 2016).

[2] See document A69/26.

[3] Available at http://www.who.int/entity/mediacentre/news/statements/2016/2nd-emergency-committee-zika/en/index.html (accessed on 22 April 2016).

[4] See http://www.who.int/emergencies/zika-virus/strategic-response-framework.pdf (accessed 22 April 2016).

Zika virus-affected countries, and management of additional complications related to Zika virus infection. Increased investments are essential to combat the spread of Zika virus and manage its complications. To date, WHO and partners have identified funding requirements for the period through June 2016.

Avian influenza A(H5N1) and A(H7N9) viruses

11. The threat of an influenza pandemic is persistent owing to the constantly evolving nature of influenza viruses. The epidemiological pattern of avian influenza A(H7N9) infection in humans so far in 2016 seems similar to that of 2015. Highly pathogenic avian influenza A(H5) viruses in various subtypes, including H5N1, H5N2, H5N6, H5N8 and H5N9, continue to circulate and spread in birds and cause, or have the potential to cause, sporadic human infections. Virological and epidemiological assessment of influenza A(H5) viruses shows that the associated risk has remained unchanged since the 2015 assessment.

12. With the continuous spread of influenza A(H5) virus in western Africa, the epidemic of influenza A(H7N9) virus infections in poultry and the virus' continuous reassortment with influenza A(H9N2) virus, and repeated zoonotic infections, the threat posed by avian influenza viruses, as shown by influenza A(H5), influenza A(H7N9) and influenza A(H9N2) viruses, is stark.

13. Influenza A(H1N1) and A(H3N2) viruses, with different characteristics than seasonal influenza viruses circulating in humans, are enzootic in swine populations in many regions of the world and have the potential to infect humans. A few human infections with swine influenza A(H1) viruses have been documented again since September 2015.

14. Through the Global Influenza Surveillance and Response System, covering 113 countries, WHO is closely monitoring the evolution and emergence of influenza viruses of potential public health significance.

PROGRESS ON IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005)

Capacity-building

15. The IHR core capacity monitoring framework used a self-assessment questionnaire by States Parties since 2010 to report to the Health Assembly on the status and development of the minimum core public health capacities required by the International Health Regulations (2005). In 2015, States Parties have continued to provide information to the Secretariat.[1] As at 5 April 2016, 126 of 196 States Parties had completed the self-assessment questionnaire sent in April 2015. Analysis of information from countries' annual reporting of IHR core capacity provided to the Secretariat by the States Parties suggests that progress has been made in the following areas: appropriate legislation and policy in place for implementation of the Regulations; coordination and collaboration with other sectors for capacity-building; functional and improved detection capacities with early warning; coordinated preparedness and emergency response capacities; and improved communication to the public and to stakeholders. However, the actual level of capacity is uncertain in some countries and efforts to ensure that these

[1] See IHR Capacity Scores for all reporting States Parties for 2015 available at http://www.who.int/gho/ihr (accessed 22 April 2016).

capacities remain operational will require continuous strengthening of infrastructure, procedures and human resources. In addition, detection and response capacities for chemical and radiological events are often not yet in place. Details of 2015 scores provided by countries can be consulted on the WHO website.[1]

16. The International Health Regulations (2005) require the development, strengthening and maintenance of core capacities for surveillance and response, and at designated points of entry. The initial deadline for developing core capacities was 2012, with potential extensions until 2016. Progress has been made, but these capacities have not been established in many countries. The Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation recommended in 2014 that "the Director-General consider a variety of approaches for the shorter- and longer-term assessment and development of IHR core capacities".[2]

17. WHO has developed a new IHR monitoring and evaluation framework for core capacities. In addition to the annual reporting, the framework includes after-action reviews, simulation exercises and independent (external) evaluation (see Annex). The Secretariat's initial focus has been on the development of the independent evaluation component. In February 2016, the IHR (2005) Joint External Evaluation Tool[3] was finalized and, together with partners and experts, voluntary joint external evaluation missions to countries have begun. Preliminary experiences have shown positive results and partners have expressed interest in supporting this approach and in benefitting from joint external evaluation in the development or improvement of national action plans for improved country health emergency preparedness. The three other components of the new IHR monitoring and evaluation framework are being finalized, together with all relevant guides and tools. These will be posted on the WHO website. Reporting to the Health Assembly using a new format is planned for 2017; data for 2016 will be collected, starting in June 2016, subject to approval by the Health Assembly of the new IHR monitoring and evaluation framework.

18. On 8 and 9 October 2015, the health ministers of the seven leading industrialized nations met in Berlin and discussed health topics, including Ebola virus disease. Their broad-ranging final Declaration drew attention inter alia to the central mandate and "committed leadership of the WHO" and the fact that the legally binding "International Health Regulations (2005) are the primary international instrument designed to help protect countries from the international spread of disease, including public health risks and public health emergencies". The ministers supported the International Health Regulations (2005) "in expressly requiring countries to collaborate with each other in developing and maintaining the core capacities for implementation [of the Regulations]", noting that "full compliance [with the Regulations] is ultimately each country's responsibility".[4]

19. WHO and the Government of South Africa jointly convened a high-level partner and stakeholder meeting on "Building health security beyond Ebola" in Cape Town, South Africa, from 13 to 15 July 2015. The meeting brought together over 200 participants, including representatives of countries affected by Ebola virus disease. Its goal was to agree on priority actions to boost health security, with the aim of strengthening health systems and capacities for implementing the

[1] See http://www.who.int/gho/ihr/en/(accessed 26 April 2016).

[2] See document A68/22 Add.1, paragraph 43.

[3] JEET available at http://www.who.int/ihr/publications/WHO_HSE_GCR_2016_2/en/ (accessed 1 April 2016).

[4] http://www.bmg.bund.de/fileadmin/dateien/Downloads/G/G7-Ges.Minister_2015/G7_Health_Ministers_Declaration_AMR_and_EBOLA.pdf (accessed 22 April 2016).

International Health Regulations (2005). Participants agreed on the need for collective action on national and global health security, and set out expectations regarding future steps in aligning multistakeholder initiatives. There was broad agreement on WHO's role as a convenor of countries and partners. WHO proposed a collaborative approach between international and national stakeholders to strengthen and sustain the health system capacities needed to implement the Regulations. A follow-up meeting is planned to review the achievements and challenges encountered in the implementation of country health emergency preparedness, to agree on a road map, including through a multisectoral approach, to build priority capacities for country health emergency preparedness and to obtain further commitments from Member States and partners.

20. The Government of Finland hosted a Senior-level Meeting on Establishing an Alliance for Country Assessments for Global Health Security and IHR Implementation (Geneva, 14 March 2016). The meeting brought together more than 20 countries as well as representatives from multilateral institutions and donors in order to propose an alliance for assessment through joint external evaluations of core capacities under the International Health Regulations (2005). It was proposed that this alliance include a small secretariat within WHO and an advisory group to be established in support of the country assessment process.

21. The French Ministry of Social Affairs, Health and Women's Rights and the European Commission organised a High Level Conference on Global Health Security (Lyon, France, 22 and 23 March 2016). The event was cosponsored by WHO and the European Commission under the patronage of The Netherlands' Presidency of the Council of the European Union. The main outcome of the Conference was the commitment to reinforce global health security through the implementation of the International Health Regulations (2005). By bringing together many institutions, as well as private and public partners and the human and animal health sectors, the Conference increased awareness about the Regulations and the need to accelerate their implementation. Participants reaffirmed key principles of the Regulations: a multisectoral approach, the accurate assessment of capacities, the fundamental aspects of health systems strengthening and human resources and inter-country cooperation.

First amendment to the International Health Regulations (2005): vaccination against yellow fever

22. The International Health Regulations (2005) were amended for the first time in 2014. The amendment was proposed by the Director-General in light of a recommendation from the Strategic Advisory Group of Experts on immunization that a single dose of yellow fever vaccine confers life-long protection. The Sixty-seventh World Health Assembly accordingly adopted resolution WHA67.13 (2014) to update Annex 7 of the Regulations, revising the period of effectiveness of vaccination against yellow fever and the validity of the related certificate from 10 years to the life of the person vaccinated.[1] This amendment will enter into force in July 2016.

23. In response to a request by the Sixty-eighth World Health Assembly, which noted that vaccination against yellow fever may be required of any traveller leaving an area where WHO has determined that a risk of yellow fever transmission is present, the Director-General has started to publish an updated online list of countries that accept a certificate of vaccination against yellow fever

[1] See document WHA67/2014/REC/1, resolution WHA67.13 and Annex 5.

for life, and has established a scientific and technical advisory group to map the risk of yellow fever and provide guidance on vaccination for travellers.[1]

OPPORTUNITIES AND CHALLENGES IN THE IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005)

24. The Review Committee on the Role of International Health Regulations (2005) in the Ebola Outbreak and Response has concluded that it is imperative to prioritize the implementation of the Regulations in all countries and to strengthen the Secretariat's capacity and partnerships to support States Parties.[2] The Committee made 12 recommendations to ensure implementation of the Regulations based on new proposals and to improve compliance with the Regulations by: developing a global strategic plan; financing implementation of the Regulations; increasing awareness about them; introducing and promoting the external assessment of core capacities; improving the Secretariat's risk assessment and risk communication work; enhancing compliance with requirements for Additional Measures and Temporary Recommendations; strengthening National IHR Focal Points; prioritizing support measures to the most vulnerable countries; and boosting core capacities under the International Health Regulations (2005) within the broader health systems strengthening agenda.

Preparedness and coordination between multiple initiatives to implement the Regulations

25. The Ebola crisis has prompted the international community to reassess its global priorities and to appreciate fully the importance of the Regulations as a multilateral instrument capable of guiding countries, international organizations and partners, in their preparedness for major public health emergencies. This renewed interest in the Regulations as a global public good for health has spawned numerous new initiatives to assess existing public health capacities within health systems and to support their development and strengthening through incentives and collaboration. Examples include initiatives for health systems strengthening, pandemic preparedness efforts, including the Pandemic Influenza Preparedness Framework, strengthening of core capacities under the International Health Regulations (2005), preparedness for natural disasters (for instance, safe hospitals), the One Health Initiative, emergency preparedness programmes for the transport and biosecurity sectors, and the integration of country health emergency preparedness and preparedness for natural disasters and humanitarian crises. These initiatives require coordination and represent important opportunities for global public health and the Secretariat.

CONCLUSION

26. The Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response has made recommendations to improve the functioning of the Regulations. Effective implementation of the Regulations is more important than ever, considering the public health challenges in a world in which borders do not contain disease and other public health threats. Global public health security remains high on the international agenda; the Regulations are central both to achieving global public health security and to avoiding unnecessary interference with travel and trade. The inadequacy of core surveillance and response capacities in many countries continues to hamper

[1] See resolution WHA68.4 (2015).

[2] See document A69/21.

the ability of the Regulations to protect their populations and the world from public health emergencies such as the outbreak of Ebola virus disease, a new subtype of human influenza, and the Zika virus-associated clusters of microcephaly and Guillain-Barré syndrome. Ensuring compliance with the Regulations, especially in preventing inappropriate measures related to trade and travel, remains a significant challenge. Renewed and sustained commitment to and compliance with the Regulations on the part of their main stakeholders are critical for their successful and effective implementation. In this regard, the reform of WHO's work in health emergencies and the recommendations of the IHR Review Committee on the Role of International Health Regulations (2005) in the Ebola Outbreak and Response, together with a renewed commitment by States Parties and relevant partners, constitute essential elements for the effective implementation of the Regulations.

ACTION BY THE HEALTH ASSEMBLY

27. The Health Assembly is invited to note the report.

ANNEX

The International Health Regulations (2005)

Monitoring and Evaluation Framework

Principles of the new IHR Monitoring and Evaluation Framework

1. The new IHR Monitoring and Evaluation Framework combines qualitative and quantitative approaches in an objective review process of the countries' actual capacities. It is proposed to conduct this monitoring and evaluation process through a four-year cycle anchored in the national health system review cycle and budget planning.

2. The new framework should promote accountability and transparency through accurate and timely reporting on the status of IHR implementation which will foster dialogue, trust and accountability among States Parties. Opportunities for improvements identified as a result of applying this framework should be translated into a national plan of action with timelines and resources for implementation. The national plan of action for IHR core capacity and country health emergency preparedness should be incorporated into the national budget cycle and aligned with the national strategic plan, rather than being independent of institutional planning. This continuing cycle of review process must facilitate linkages with other relevant sectors and ensure compatibility within existing national strategic plans; promote partnership at national and international levels; and engage with current and prospective donors and partners to complement domestic investment in health security.

The four components of the new IHR Monitoring and Evaluation Framework

3. The framework comprises four interrelated components, which are designed to identify gaps and opportunities for improvement. It is proposed that, within a four-year period, States Parties will systematically conduct the following activities.

Annual reporting

4. Annual reporting on implementation of the Regulations to the Health Assembly by States Parties is required under Article 54 of the Regulations. These reports must be made in accordance with resolution WHA61.2 (2008) on implementation of the Regulations. Annual reporting seeks to give a quantitative snapshot of the status of the core capacities across all countries. Recognizing the limitations of any self-administered tool, the current IHR monitoring questionnaire is to be complemented as frequently as possible by the other three elements. The questionnaire is also being revised to make it simpler and aligned with the Joint External Evaluation Tool.

Joint external evaluation

5. Joint external evaluation is intended to assess country capacity to prevent, detect, and rapidly respond to public health events under the Regulations. The purpose of the external evaluation is to introduce an independent expert measurement of a country's capacity and to measure progress in achieving capacities required under the Regulations.

6. External evaluation allows countries to identify the most urgent needs within their national plans; to prioritize opportunities for enhanced preparedness, detection and response capacity building including setting national priorities and allocating resources on the basis of objective findings; and to engage with current and prospective donors and partners, as appropriate. Transparency is an important element to attract and direct resources to where they are needed most.

7. Countries are encouraged, on a voluntary basis, to conduct at least one joint external evaluation every four years.

8. To conduct joint external evaluations in a standardized manner across States Parties, a Joint External Evaluation Tool has been designed by the Secretariat in collaboration with experts, States Parties and partners. The tool is organized so as to assess 19 technical areas.

After-action review and/or simulation exercise(s)

After action review

9. It is imperative to complement annual reporting by reviewing real-life experience of a public health event which can offer an opportunity to draw lessons and identify opportunities for improvement. The health event(s) for after-action review should be selected by States Parties, although technical advice can be provided by the Secretariat upon request. The information that is captured through the after-action review will be primarily qualitative and functional, and will be used to identify any areas for improvement through a national plan of action. This review can be a self-review (IHR national implementers) or a joint review (IHR national implementers and external national or international partners in partnership with a peer group from another country or with the Secretariat).

Simulation exercise(s)

10. When there is no suitable public health event to review, simulation exercises can serve as an alternative for testing the actual functioning of IHR core capacities. Exercises (national, regional or subregional) could also be specially designed when there is a need to test the performance of a particular functionality or technical area.

11. Countries are encouraged to conduct an after-action review or conduct simulation exercises at least once every four years.

Reporting to the World Health Assembly on progress in implementing the Regulations

12. According to the transparency and mutual accountability principles underlying the Regulations, it is proposed that the relevant reporting to the Health Assembly by the Secretariat will provide a summary of each country's assessment based on the new IHR Monitoring and Evaluation Framework. The Secretariat will establish dedicated pages on the WHO website to provide access, with the agreement of the country concerned, to the information contained in the annual report and/or in respect of any joint external evaluation mission, after-action review and/or simulation exercise conducted.

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