Implementation of the International Health Regulations (2005)

Report by the Director-General

1. In resolution WHA61.2, the Health Assembly decided that States Parties to the International Health Regulations (2005) and the Director-General shall report to the Health Assembly on the implementation of the Regulations annually. In resolution WHA65.23, the Health Assembly requested the Director-General to report on progress made by States Parties and the Secretariat in implementing this resolution. In January 2014, the Executive Board at its 134th session considered an earlier version of this report.¹

2. The present report gives an account of key actions taken by the Secretariat within the framework of the Regulations in response to the emergence of Middle East respiratory syndrome coronavirus (MERS-CoV), the second event – after pandemic (H1N1) 2009 – for which an Emergency Committee has been convened under the Regulations. The report also describes the process of consultation with Member States on the criteria to be used by the Director-General when making decisions about the granting of extensions to the target date by which States Parties shall develop, strengthen and maintain core capacities as set out in Articles 5 and 13 of the Regulations. Further, the report summarizes information received by the Secretariat regarding implementation of the Regulations by States Parties in 2013. It also gives an account of activities undertaken by the Secretariat under the areas of work for implementation established in 2007.² One of those areas of work concerns the systematic management of specific risks, including those posed by yellow fever. In the light of recent recommendations on the matter made by the Strategic Advisory Group of Experts on immunization, the Secretariat proposed revisions to Annex 7 of the International Health Regulations (2005); these are contained in the draft resolution recommended to the Health Assembly in resolution EB134.R10.³

¹ See document EB134/32 and the summary records of the Executive Board at its 134th session, eleventh meeting, section 2 (document (EB134/2014/REC/2).


³ See document EB134/2014/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.
SECRETARIAT ACTIONS IN RESPONSE TO MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS

3. Following the emergence of a novel coronavirus in 2012 (since named Middle East respiratory syndrome coronavirus (MERS-CoV)), the Secretariat has been working closely with Member States, National IHR Focal Points and partners to monitor and respond to the epidemic within the framework of the Regulations. The Secretariat has played a highly visible role in the provision of information, risk assessments and guidance. The WHO Regional Office for the Eastern Mediterranean has been involved in all MERS-CoV activities.

4. The Secretariat has provided direct support to Member States, particularly with the following activities: investigating new cases; enhancing surveillance and laboratory practices; undertaking biorisk management and sampling procedures; preventing and controlling infection; and providing training and guidance for the clinical management of MERS-CoV infections and suspected cases. Since the beginning of the epidemic, the Secretariat has deployed missions to countries in order to support health ministries in investigating the epidemic and in developing and adapting protocols and response plans for dealing with MERS-CoV, in the context of building sustainable alert and response capacities under the Regulations.

5. The Secretariat is facilitating global surveillance of MERS-CoV for early detection of changes in the epidemiology of the virus and for investigation and reporting of cases; and it continues to make global risk assessments and information rapidly available through the Event Information Site for National IHR Focal Points, Disease Outbreak News, press releases and other reports. The Secretariat has also regularly updated guidance on international travel and health, including specific advice and information for the umrah and hajj pilgrimages, as well as advice on surveillance for countries to which the pilgrims would return.

6. The Secretariat is committed to collaborative investigation and management of the epidemic and has been working closely with Member States affected by MERS-CoV and partners at the human–animal interface, including FAO and OIE; it has also been active in other collaborative mechanisms, such as the International Food Safety Authorities Network. The Secretariat continues to share information with partners in order to optimize surveillance and risk assessments, improve understanding of the zoonotic aspects of the disease and enhance preparedness and response.

7. The Secretariat has coordinated technical networks and the Global Outbreak Alert and Response Network in order to provide Member States with access to additional international resources. In January and June 2013, the WHO Regional Office for the Eastern Mediterranean hosted consultative meetings of health experts and public health researchers on MERS-CoV. Scientific findings were made available through public web updates, expert networks, and published literature summaries and updates. In June 2013, participants in an intercountry meeting also hosted by the Regional Office made recommendations on surveillance and response, mass gatherings, clinical management, laboratory capacity, infection prevention and control, media and risk communication, and implementation of the International Health Regulations (2005).

8. Investigations have, in several countries, identified MERS-CoV in camels. A number of camels are linked to confirmed human cases, showing that camels are a reservoir of the virus. Further research is therefore urgently needed in order to understand how the virus passes between camels and humans.

9. In December 2013, WHO convened a consultative meeting with countries affected by MERS-CoV in order to close critical knowledge gaps related to human exposure risk, transmission
and spread of the virus.\textsuperscript{1} In particular, countries agreed: to participate in an international multi-country case-control study in order to identify risk factors and exposure leading to infection; to implement national sero-epidemiological studies, in collaboration with WHO and international health partners; and to conduct animal studies in collaboration with FAO and OIE. Further consultations and meetings have taken place with countries affected by MERS-CoV and partners in order to review the guidance and tools, foster coordination among countries, and ensure availability of WHO and international technical support, if required, for preparing and implementing the studies.

10. The Regulations have provided the legal framework for managing the response to MERS-CoV. For the second time since their entry into force in June 2007, the Director-General convened a meeting of the Emergency Committee in order to elicit advice on key questions relating to the event, including whether it constituted a public health emergency of international concern, and on health measures that might be required to respond effectively to the event. The Emergency Committee has met on four occasions since July 2013.\textsuperscript{2} Based on the information supplied and the deliberations conducted at the four meetings, the Committee advised the Director-General that the conditions for a public health emergency of international concern had not been met. The Director-General agreed with the advice of the Committee. In addition to the public health advice given to the Director-General at the three previous meetings, at its fourth meeting, the Committee strongly advocated conducting investigative studies to improve the current understanding of risk factors and the epidemiology. The Committee further recommended continuing to review and strengthen such tools as standardized case definitions and surveillance, and placing further emphasis on infection control and prevention.

**GRANTING OF EXTENSIONS IN 2014–2016**

11. The Executive Board at its 132nd session considered the criteria proposed by the Secretariat to be used by the Director-General when deciding on requests for extensions to the target date by which States Parties shall implement the core capacities under the Regulations for the period 2014–2016.\textsuperscript{3} The Executive Board noted that there were no objections to the proposed criteria, but that the latter would benefit from further consideration by Member States at WHO regional committee sessions in 2013, with the final criteria to be provided to the Executive Board at its 134th session. At the regional committee sessions, Member States generally supported the criteria. However, further recommendations and suggestions were made, including: that requests for extensions could be submitted up to two months, rather than four, before the deadline in June 2014;\textsuperscript{4} and that a criterion should be included requiring that advice given by the IHR Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009 should be considered – such a requirement is already part of the decision-making process for extension requests. The possibility of the Review Committee giving consideration to other issues concerning core public health capacities, including implementation indicators, was also mentioned.


\textsuperscript{3} See EB132/15 Add.1 and the summary records of the Executive Board at its 132nd session, ninth meeting, section 3.

\textsuperscript{4} See decision CD52(D5) adopted by the 52nd Directing Council (65th session of the Regional Committee for the Americas).
12. At its 134th session, the Executive Board considered the Secretariat’s report, contained in document EB134/32, and further discussed the proposed criteria, together with a summary of the recommended adjustments to the criteria that had been submitted by the Regional Office for the Americas. In its report, the Secretariat’s proposed that the current criteria should be considered as final, on the understanding that the process of granting extensions will include the provision of advice by the IHR Review Committee to the Director-General, in accordance with the Regulations. The Board discussed the matter and noted the report. It is therefore intended that a meeting of the Review Committee will be convened by the Director-General before the Sixty-seventh World Health Assembly.

INFORMATION RECEIVED FROM STATES PARTIES TO THE INTERNATIONAL HEALTH REGULATIONS (2005)

13. With regard to requests for extensions for the period 2012–2014, 118 of the 196 States Parties concerned have requested and obtained extensions. Forty-two States Parties indicated that they did not need an extension.

14. States Parties have continued to provide information to the Secretariat on implementation of the Regulations in relation to the national capacity requirements set out in Annex 1 of the Regulations. As at 11 March 2014, the self-assessment questionnaire sent to States Parties in March 2013 had elicited 122 responses, representing 62% of the 196 States Parties. The data show States Parties making good progress in strengthening several core capacities, notably in the areas of zoonotic diseases (with a global average score of 82%), surveillance and response (both at 80%), laboratory capacity (76%), coordination and risk communication (75% and 74%, respectively), and legislation and food safety (both at 73%). On the other hand, States Parties reported relatively low capacities in handling radiological and chemical events (55% and 56%, respectively), points of entry and human resources (58% and 61%, respectively). The latest capacity scores, by WHO region, of all States Parties that submitted a completed questionnaire will be made available before the Sixty-seventh World Health Assembly.

GLOBAL PARTNERSHIPS

15. WHO has continued to strengthen its relationships with other international and intergovernmental organizations during the period under review, including FAO, ICAO, WMO, IAEA, OIE, the International Air Transportation Association and the World Bank. During significant public health events and emergencies, WHO’s Strategic Health Operations Centre and WHO’s regional operations centres have served as hubs for coordinating information and activities across multiple organizations and jurisdictions. WHO has established a public health emergency operations centre network (EOC-NET) to further promote communication and collaboration in, and between, Member States and international organizations.

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1 See document EB134/32.
3 A State Party shall make a formal request in writing to the Director-General at least four months in advance of the target date. Any such request must be accompanied by a new implementation plan. See document A66/16.
4 See the summary record of the Executive Board at its 134th session, eleventh meeting, section 2.
STRENGTHENING NATIONAL CAPACITY

16. All levels of the Organization continue to support States Parties in fulfilling their core capacity requirements as laid down in the Regulations, under the leadership of the regional offices, which provide technical support to countries through regional initiatives in a number of key areas. These initiatives include the continued enhancement of laboratory quality systems and diagnostic capacity through the development and translation of tools and guidelines, provision of external quality assessment, and organization of training sessions, workshops and on-site assessment or technical assistance missions in all regions. A new training course on leadership and management skills for public health laboratory directors is being prepared for implementation. Together with FAO and OIE, WHO continues to be responsible for implementation of the IDENTIFY project.¹

17. In the specific area of implementation of the Regulations in national legislation, following a series of subregional workshops in 2011, 2012 and 2013 in several WHO regions, the Secretariat has conducted individual legislative assessment missions to States Parties in the South-East Asia and European regions. In the area of implementation of the Regulations at points of entry, technical support missions to assess country capacity have been conducted by the Secretariat. Consultations, training courses, meetings and workshops have also been held to further develop competencies and provide technical guidance for public health professionals at points of entry in several WHO regions. Such activities have included the development of a learning programme covering: inspection of ships and the issuance of ship sanitation certificates; advice on managing public health events occurring on ships and affecting air travel; and vector surveillance and control using a multisectoral approach. Additionally, the Secretariat supported the establishment of WHO procedures for airport and port certification as required by the Regulations. With a view to facilitating an exchange of information, the Secretariat has hosted the Ports, Airports and Ground Crossing Network (PAGnet) on its website² and is supporting an initiative to designate WHO collaborating centres for points of entry, in order to build core capacities.

18. In the area of national surveillance, the Secretariat, with the support of technical experts from the six WHO regions, has started to draw up global guidance on early warning and response, including event-based surveillance. The Secretariat is also preparing a guide on coordinated surveillance between points of entry and national surveillance systems. In order to facilitate and speed up weekly transmission of surveillance data from remote health facilities to the central level, WHO is also developing an electronic tool partly based on mobile telephone technologies. Finally, the Secretariat has developed and tested a training toolkit targeted at epidemiologists, to be used by course organizers, programme coordinators and trainers in relevant institutions such as field epidemiology training programmes and schools of public health. This will provide them with a common learning framework and standard quality materials, thereby contributing to harmonized understanding and implementation of the Regulations.

19. In terms of the application of the Regulations to specific risks, significant progress has been made (in collaboration with FAO and OIE) in developing references for good governance across the animal and human health sectors. Consistent material has been produced in recent years by WHO and OIE in their respective sectors to help countries objectively evaluate their situations, address gaps and build capacities, in order to improve their operational capability and comply with international

¹ As described in document A66/16.

requirements. In order to tackle problems at the human–animal interface, a joint OIE–WHO programme of work was established in April 2013. In particular, it focuses on adjusting the framework for monitoring progress in the implementation of core capacities in States Parties to more accurately reflect the interface, and on improving the WHO laboratory assessment tool to improve compatibility with the corresponding OIE instrument. In partnership with the World Bank and OIE, WHO is developing a joint methodological guide for countries, which combines the updated tools, in order to strengthen national human and animal health systems governance.

20. The Secretariat has continued to provide support to countries hosting mass gatherings. Preparedness for mass gatherings and the public health legacies of such events have strengthened capacity-building efforts under the Regulations. The Secretariat has built a network of collaborating centres for mass gatherings and is undertaking a revision of its guidance based on lessons learnt.

21. In the area of response, the Secretariat is committed to supporting Member States in building or improving capacities through the Public Health Emergency Operations Centre Network (EOC-NET). It has conducted a systematic review of public health emergency operations centres in order to provide evidence for national decision-makers and support further development of standards and guidance on building and using the centres. The Secretariat continues to work with Member States and other partners to ensure effective transfers of technology, knowledge and skills in four agreed emergency operations centre priority areas: communications technology and infrastructure; minimum data sets and standards; procedures and plans; and training and exercises.

22. The Secretariat continues to focus attention on supporting States Parties in assessing their needs, and on the investments required to establish and maintain their core capacities. The prototype of a costing tool was developed by WHO and its partners in 2013 and is currently being tested in selected countries. It is adapted to the existing monitoring framework for the Regulations and takes account of previously developed tools, analyses and methodologies.

23. The Global Polio Eradication Initiative continues to use the framework of the Regulations to publish information about the international spread of wild poliovirus, including the detection of wild poliovirus and new outbreaks in previously polio-free countries, on the Event Information Site for National IHR Focal Points. All such events are published in parallel in Disease Outbreak News on WHO’s public website. Since April 2013, this has included the publication of several event updates on a developing poliomyelitis outbreak in the Horn of Africa and the Middle East. The Executive Board, at its 134th session, discussed whether the Director-General should convene a meeting of an Emergency Committee to address developments relating to poliomyelitis eradication.\(^1\)

24. A meeting of the Global Health Security Initiative Chemical Events working group, and a seminar on chemical events and the International Health Regulations (2005) were held in Lyon, France, in April 2013, to review tools and steps taken by countries participating in the Initiative in order to enhance compliance of States Parties with the Regulations in the context of chemical incidents. Since the Strategic Approach to International Chemicals Management\(^2\) and the Regulations share some common objectives, for example improving multisectoral coordination and strengthening capacities to detect and manage chemical exposures, WHO is raising awareness about potential synergies in both the chemical safety and International Health Regulations (2005) communities through regional workshops on core capacities and information materials.

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\(^1\) See document A67/38.

\(^2\) See document WHA59/2006/REC/1, Annex 1.
25. In order to strengthen national, regional and WHO’s emergency response capacities in the context of radiation hazards, in November 2013 the Secretariat worked with FAO, IAEA, ICAO, WMO and other international organizations on an international exercise (ConvEx-3(2013)) that simulated a terrorist attack in Morocco. It tested the notification mechanism under the Regulations as well as WHO’s capability to respond to a radiation emergency. The Secretariat maintains the Radiation Emergency Medical Preparedness and Assistance Network, whose 14th coordination and planning meeting will be held in Würzburg, Germany, from 7 to 9 May 2014. Jointly with Network members, the Secretariat is developing technical guidelines and training tools to equip countries to deal with radiation emergencies. In addition, the Secretariat continued to contribute to the Global Health Security Initiative Radio-Nuclear Threats working group, and, at the request of the Government of Mexico, contributed to the second Conference on the Humanitarian Impact of Nuclear Weapons (Nayarit, Mexico, 13 and 14 February 2014). The Secretariat held the third coordination meeting of the WHO BioDoseNet laboratory network in Leiden, Netherlands, in March 2013, in support of strengthening national laboratory capacities. The primary purpose of the network is to (i) build national biodosimetry capacities in Member States; and (ii) support laboratory services’ surge capacity in response to a radiation emergency. Finally, in 2013, the Secretariat provided technical support for the development of the South-East Asia Region’s strategy for a public health response to chemical and radiation events in the context of the Regulations, through technical consultations held in Sri Lanka and Thailand.

PREVENTION OF, AND RESPONSE TO, INTERNATIONAL PUBLIC HEALTH EMERGENCIES

26. The network of National IHR Focal Points and WHO IHR Contact Points has been increasingly used for rapid communication of public health information between WHO and States Parties, including on MERS-CoV and human infection with avian influenza A(H7N9) virus. The number of users of the National IHR Focal Points network with access to the Event Information Site currently stands at 749, representing 185 States Parties.

27. WHO continues to detect, track and respond to public health risks and emergencies in a timely manner and in close collaboration with countries, within the framework of the Regulations. In addition to MERS-CoV-related events (see above), between 26 October 2013 and 28 February 2014, 81 events were recorded in the Event Management System. Of these, 33 (41% of the total) were substantiated as real events needing to be monitored, six (7%) were discarded as false rumours after verification, and 14 (17%) were real events that did not meet the definition of an outbreak. No final classification has been attributed to 28 events (35%). In summary, 65% of the events recorded completed a verification process during the period.

28. Such routine international surveillance and response activities have been enhanced by a new version of the Event Information Site for communication with National IHR Focal Points in order to improve access to information related to acute public health events. The updated technology will ensure that the site can be further extended to accommodate future needs and expanded information-sharing. A hazard detection and risk assessment system has been developed in collaboration with the Joint Research Centre of the European Commission, to complement the Event Management System in identifying potential public health risks and monitoring ongoing public health risks. The hazard detection and risk assessment system supports an all-hazards approach that fosters collaboration across all levels of the Organization and with external partners and initiatives. The first version of the system is currently being pilot-tested in headquarters and introduced in regional offices.
29. The fourteenth meeting of the Global Outbreak Alert and Response Network Steering Committee, (Chavannes de Bogis, Switzerland, 9–11 December 2013), reviewed the following matters: the role and scope of the Network’s operations; greater regional involvement; further development of technical and operational capacity; and the Network’s contribution in developing and supporting sustainable response capacities. The Steering Committee collaborated with Member States in reviewing the support given to countries for risk assessments and outbreak response missions, and in major humanitarian emergencies.

30. WHO maintains stockpiles of medicines, vaccines and medical and non-medical equipment, which are mobilized to respond to epidemics and pandemics. The composition, mobilization and use of the global stockpiles are agreed through defined processes. They are kept in a network of warehouses worldwide. WHO has deployed equipment, medicines and vaccines to support emergency response in Central African Republic, Nigeria, Pakistan, Philippines, South Sudan and Syrian Arab Republic. WHO is collaborating with national institutions in the prepositioning of outbreak response equipment in order to improve both the timeliness of the response and geographical coverage. In collaboration with the Bioforce Institute in Lyon, France, WHO has developed a training course on outbreak response logistics, and a pilot training course has been conducted. Trainees have since been deployed in Central African Republic, Philippines and South Sudan. The Secretariat will expand the training course to WHO country offices and national institutions and networks.

31. Two web-based tutorials were launched to train National IHR Focal Points in the use of Annex 2 of the Regulations. Their purpose was to provide continuous support to staff in all National IHR Focal Points so as to increase the sensitivity and consistency of the assessment and notification process. The tutorials are based on the recommendations of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to pandemic (H1N1) 2009. The tutorials present scenarios in which National IHR Focal Point personnel assess whether events must be notified to WHO. Following the completion of each module, the user is provided with the responses proposed by an expert panel, as well as explanations. The tutorials are accessible on the WHO website.

32. With regard to food-related events, the links between the emergency contact points in countries for the International Food Safety Authorities Network and their National IHR Focal Points continue to be strengthened, through sustained efforts by the Secretariat to ensure that at national level both groups are informed when responding to an event. The International Food Safety Authorities Network’s secretariat has offered ongoing advice and support to States Parties requesting an extension of the deadline under the Regulations for ensuring core capacities in the area of food safety, as set out in the monitoring framework.

YELLOW FEVER VACCINATION OR REVACCINATION

33. Yellow fever is the only disease specified in the International Health Regulations (2005) for which countries may require proof of vaccination from travellers as a condition of entry under certain circumstances and may take certain measures if an arriving traveller is not in possession of such a certificate. The Regulations stipulate that vaccination with an approved yellow fever vaccine provides protection against infection for 10 years, and that the certificate of vaccination or re-vaccination is

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1 See document A64/10.
accordingly valid for 10 years. Following the conclusion by the Strategic Advisory Group of Experts on immunization that a single dose of yellow fever vaccine is sufficient to confer sustained immunity and life-long protection against yellow fever disease and that a booster dose of yellow fever vaccine is not needed, WHO has endorsed this conclusion. In its report, the Strategic Advisory Group of Experts on immunization also recommended that WHO should revisit the provisions in the International Health Regulations (2005) relating to the period of validity for international certificates of vaccination against yellow fever.

34. A number of Member States have requested guidance from WHO on implementation of this advice under the International Health Regulations (2005). Initial steps have been taken by the Secretariat to inform Member States of the conclusions reached by the Strategic Advisory Group of Experts on immunization and to urge them to consider accepting certificates of vaccination against yellow fever based on vaccination with approved vaccine at any time (provided it is at least 10 days since administration of the vaccine prior to arrival).

35. As a consequence, the Director-General proposed that Annex 7 of the International Health Regulations (2005) should be updated (see paragraph 39 below).

CONCLUSION

36. The procedures contained in the International Health Regulations (2005) for the management of major public health events and emergencies, including the convening of Emergency Committee meetings, continue to be implemented, allowing WHO to apply the lessons learnt from pandemic (H1N1) 2009 in a new context. The value of timely reporting and the sharing of information has once again been demonstrated.

37. Significant gains have been made in implementation of the Regulations at national level during the period under review. At all levels of the Organization, the Secretariat has intensified its technical support to States Parties in all areas. Effective and timely implementation of the Regulations, however, has been compromised by institutional and resource challenges, including uneven levels of support by various stakeholders for specific capacities, hazards and WHO regions or geographical areas. In that context, the focus of donor support should be aligned with the priorities of the Secretariat and the needs of the most vulnerable Member States. Although some capacities have improved globally, namely, surveillance, laboratory and risk communication, they remain at a critical level and efforts

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3 The International Health Regulations (2005) also stipulate that vaccination certificates must include the expiry date based on the date of administration of the vaccine; additionally, every worker at a point of entry in an area where WHO has determined that a risk of yellow fever transmission is present and every member of a crew of a conveyance using any such point of entry shall have a valid certificate of vaccination.
should be sustained over time. The relatively low level of capacities for handling radiological and chemical events reflects a gap that can be dealt with through the systematic mapping of stakeholders working in those areas, some of whom might not necessarily have yet built strong relations with health ministries. Capacities at points of entry remain a challenge, but several guidelines have been developed and are available in different languages to facilitate additional awareness-raising and training. One of the key capacities that remains low is human resources, and only Member States can commit to build and maintain the human resources needed for each capacity under the Regulations. Based on available information, it is anticipated that many States Parties will apply for an additional two-year extension from June 2014 to June 2016, in line with Article 5 and Article 13 of the Regulations.

38. At all levels of the Organization, and in all areas, the Secretariat has intensified the technical support it provides to States Parties. In addition, the Director-General has been appealing to countries in order to obtain their additional commitment to organize a series of high-level events that will help to maintain the momentum to build capacities, emphasizing the importance of national engagement and multisectoral approach. A renewed effort is required to accelerate global capacity to prevent, detect and rapidly respond to infectious disease threats and other risks, whether naturally occurring, intentionally produced or accidentally released. States Parties and partner international organizations from all sectors should make concrete commitments to achieving progress towards that goal.

**ACTION BY THE HEALTH ASSEMBLY**

39. The Health Assembly is invited to note the report and adopt the draft resolution recommended by the Executive Board in resolution EB134.R10.