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Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005)

Interim progress report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response

Report by the Director-General

Pursuant to requests made by the Health Assembly in resolutions WHA73.1 and WHA73.8 (2020), the Director-General has the honour to transmit to the Executive Board at its 148th session the interim progress report of the Review Committee on the functioning of the International Health Regulations (2005) during the COVID-19 Response (at Annex).

ANNEX

INTERIM PROGRESS REPORT OF THE REVIEW COMMITTEE ON THE FUNCTIONING OF THE INTERNATIONAL HEALTH REGULATIONS (2005) DURING THE COVID-19 RESPONSE

BACKGROUND

1. The Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response was convened by the Director-General on 8 September 2020 at the request of Member States in resolution WHA73.1 (2020), and in line with Article 50 of the International Health Regulations (2005) (IHR or Regulations). The Committee is composed of 21 members selected and nominated by the Director-General from the IHR Roster of Experts, comprising a wide range of expertise and with adequate gender and geographical representation. It is Chaired by Professor Lothar H. Wieler (Germany), supported by a Vice-Chair, Professor Lucille Blumberg (South Africa) and Rapporteur, Dr Preben Aavitsland (Norway).
2. The Committee's mandate is to review the functioning of the IHR during the COVID-19 response, to review the status of implementation of the relevant recommendations of previous IHR Review Committees, and ultimately to make technical recommendations to the Director-General regarding the functioning of the Regulations and the possible need for amendments. This report summarizes the work of the Review Committee up to 8 December 2020.

PROCESS

3. The Committee holds virtual three-hour plenary meetings on a weekly basis and is supported by the WHO IHR Secretariat. In addition, the Committee conducts its works through three subgroups, on preparedness, alert and response, which meet virtually every week for an hour. The subgroups, led respectively by Dr Jean-Marie Okwo-Bele, Dr Mark Salter and Professor James LeDuc, deliberate on specific issues, conduct interviews and report back during the weekly plenary meeting. In accordance with provisions of Article 51.2 of the International Health Regulations (2005), the Committee also holds monthly open meetings, which are attended by more than 100 designated representatives from Member States, United Nations entities and non-State actors in official relations with WHO. So far, designated representatives from 33 Member States have submitted statements to the Committee, either individually or as part of specific groups of Member States, as well as four representatives of United Nations entities and non-State actors in official relations with WHO.
4. The Committee coordinates its work with the work of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (IOAC) and the Independent Panel for Pandemic Preparedness and Response through their respective Secretariats and through monthly calls between the Chairs.
5. The Committee has interviewed the Chairs of previous Review Committees, the Chairs of current and previous Emergency Committees, the Chair and Vice-Chair of the Global Outbreak Alert and Response Network (GOARN), the Chief of the Universal Periodic Review Branch of the United Nations Office of the High Commissioner for Human Rights, the Chair of the IOAC, researchers in the area of travel measures, 14 national IHR focal points, and WHO staff from headquarters and regional and country offices. Additional interviews are planned.

6. The WHO IHR Secretariat has provided relevant background and supporting documents to the Committee. More in-depth analyses in relation to preparedness capacities, travel measures and national legislation are planned.

PRIORITIES

7. The Committee is examining the following key questions:

- How well, overall, have the IHR functioned during COVID-19 so far? How have the Regulations contributed to the global response?
- How are the roles and responsibilities of the WHO Secretariat and States Parties under the IHR understood and fulfilled?
- How well were Member States prepared to respond to the COVID-19 response?
- How can the current tools and approaches for preparedness assessment and monitoring better help countries to respond more effectively? How can universal peer reviews be used to help improve IHR implementation?
- How was information shared during the early days of the outbreak under the IHR? Does the WHO Secretariat need a stronger and clearer mandate to react if information is not provided by States Parties? If yes, how should this mandate be better formulated and implemented?
- Are the criteria for the determination of a public health emergency of international concern (PHEIC) and the consequences of declaring a PHEIC clear and understood? What are the advantages and disadvantages of an intermediate level of alert? How could an intermediate level of alert be implemented? Which alternatives may be considered?
- How did the WHO Secretariat and States Parties implement their obligations with regard to additional health measures in relation to international traffic?
- How are the current mechanisms of collaboration and coordination for global outbreak alert and response functioning? What needs to be changed or improved?

PRELIMINARY FINDINGS

Overall assessment

8. Member States and experts have expressed overwhelming support for the Regulations as a cornerstone of international public health and health security law. However, there is also agreement that several areas need improving in order for the world to be better prepared for the next pandemic.

9. More clarity is needed regarding the respective roles and responsibilities of the WHO Secretariat and States Parties, as well as a clearer understanding of the limitations faced by the WHO Secretariat under the provisions of the International Health Regulations (2005).

10. High-level political support and resources for implementation of the Regulations are insufficient and irregular at both national and international levels. The Committee has requested documentation in regard to funding of all activities and staff contributing to implementation at WHO (headquarters and

regional and country offices). In addition, information is being collected from national IHR focal points on their structure, functioning and interactions across governments and regionally, as well as national political support and funding for implementation of the Regulations.

11. Article 54 requires States Parties and the Director-General to report to the World Health Assembly on the implementation of the Regulations. It also requires the Health Assembly to review periodically the functioning of the Regulations. The annual reports by the IHR Secretariat to the World Health Assembly include extensive reporting on core capacities implementation, based on self-reporting through the States Parties' Annual Report, and additional voluntary mechanisms such as the Joint External Evaluation, after-action reviews and simulation exercises. The Regulations do not establish a stand-alone mechanism for monitoring and evaluating the general compliance by State Parties or WHO with all their obligations, beyond core capacities implementation.

12. The lack of a robust compliance evaluation and accountability mechanism was identified during the interviews as reducing incentives for adequate preparedness and cooperation under the Regulations and as deterring timely notifications of events and public health information. Such criticism was raised in particular with regard to the adoption of additional health measures in view of their transboundary social and economic consequences. A robust system of compliance evaluation built into the Regulations was cited during the interviews as a potential approach to strengthening the overall framework of the Regulations and its credibility as a legal instrument; such an approach could include consideration of a universal peer review mechanism.

13. Another area for improvement identified by the Committee is strengthening global efforts for outbreak alert and response, including through considering increased coordination and cooperation with GOARN. At the Committee's request, GOARN is conducting a survey to identify the challenges to and support required for more effective engagement in alert and risk assessment activities and in response operations.

14. The Committee is conducting an article-by-article analysis of the Regulations to examine whether the perceived shortcomings in their effectiveness during the COVID-19 response stem from the design of the Regulations or from challenges in their implementation.

15. The Committee is considering whether the Regulations can be made more effective through specific targeted amendments and annexes, or if there are other ways to create a common understanding on expected actions by WHO and States Parties.

Preparedness

IHR core capacities: assessment, monitoring and reporting

16. The COVID-19 pandemic has revealed significant gaps in pandemic preparedness in countries across the world, including in the areas of: surveillance, health systems, equipment and training, essential public health functions and the role of national IHR focal points, emergency legislation, risk communication and coordination.

17. The Committee has examined the extent to which the current tools and methods for assessing and monitoring IHR core capacities, such as State Party Self-Assessment Annual Reporting tools, Joint External Evaluations and Intra-Action Reviews, cover all the necessary capacities, including those at subnational level and those related to whole-of-government and One Health approaches. The Committee

has also examined how the current tools for preparedness assessment and monitoring could be strengthened to better help countries implement a more effective response.

18. A peer-review mechanism, based on the Universal Periodic Review used by the Human Rights Council, may be useful in improving preparedness and response, as well as compliance with States Parties' legal obligations under the Regulations. For example, the Universal Periodic Review has been shown to foster intersectoral coordination and whole-of-government approaches, to encourage good practices, and to link implementation of its recommendations with the Sustainable Development Goals and other government agendas – all of which are vital to strengthening IHR core capacities. More deliberation of the details is necessary by the Committee. The Committee's findings in this area will inform the Director-General's initiative, announced at the resumed Seventy-third World Health Assembly in November 2020, to establish and pilot a new Universal Health and Preparedness Review in early 2021.

19. The Committee has reviewed the role of national IHR focal points, and how their scope and mandate as provided by the Regulations is functioning in practice. Previous Review Committees noted that, while the Regulations require all countries to have a national IHR focal point as a "centre" accessible 24/7 for communication with WHO, not all countries have designated such a centre; in some countries the national IHR focal point is just one person.

20. The Committee noted that effective implementation of the International Health Regulations (2005) requires many functions that are not within the narrow mandate of the national IHR focal point, such as multisectoral coordination for preparedness and response and collaborative risk assessment. The absence of a dedicated national entity, with sufficient authority and a clear mandate to take ownership of and leadership on implementation, is considered a significant limitation to effective implementation of the Regulations at national and subnational levels. At country level, legislation establishing the national IHR focal point institution should formalize its inclusion in the national emergency plan as well as its participation in the national health committee or similar body.

Preparedness for a pandemic or an "unexpected" event

21. Many countries have been using the Pandemic Influenza Preparedness (PIP) Framework as a foundation for their COVID-19 response. While some areas of IHR core capacities have been improved under PIP, others have not. Although the health ministry is the responsible authority, effective preparedness and response measures require a whole-of-government approach. Response measures are often led by non-health ministries, with little consultation. Another challenge is that pandemic preparedness planning is generally not an integral part of public health system strengthening and primary health care.

22. Influenza pandemic preparedness can help broaden the approach for respiratory illnesses preparedness. Disease-specific plans and other relevant plans, however, are often not integrated with national action plans for health security as part of a single platform for all activities related to the International Health Regulations (2005) and health security in the country.

Alert

Notification and outbreak alert mechanisms

23. In recognition of the importance of timeliness in identifying, assessing and sharing information about an outbreak, as well as agreements and obligations under the Regulations, it is crucial to

understand how the communication between States Parties and the WHO Secretariat unfolded in the days and weeks following initial reports of atypical pneumonia. WHO requires flexibility and agility to rapidly inform the world on public health events with risk of international spread; any practices relating to the Regulations that led to delays, for example in the verification process, need to be addressed.

24. The Alert subgroup has explored how the communication between States Parties and the WHO Secretariat unfolded in the very early days of the pandemic and examined practices relating to the Regulations that may have led to delays.

25. Initial alerts between China and WHO were based on several sources of information, including ProMED, part of the Epidemic Intelligence from Open Sources (EIOS) initiative, media reports, Chinese television and social media. An announcement made by the Wuhan Health Commission of a cluster of pneumonia cases of unknown cause was identified by the Chinese Center for Disease Control and Prevention and the WHO country office through routine epidemic intelligence activities. WHO requested verification of these reports on 1 January 2020 and received a response from the China National IHR Focal Point on 3 January 2020. Such response timings do not seem to be any different in scope and duration from other similar delays (beyond the 24 hours required by the IHR) reported by WHO and some of the national IHR focal points interviewed by the Committee.

26. The Committee considers that the timelines required by the Regulations for States Parties' notification are not realistic given that the speed and ubiquitous presence of social media results in information reaching the public domain before countries have concluded a comprehensive risk assessment. The limited authority and status of the national IHR focal points often leads to delays in notification. Another consideration is that countries may be reluctant to report on events if they perceive consequences, mainly related to travel and trade, deriving from early notification. The current IHR requirements for notification and verification, as well as information sharing by WHO, need further examination.

Risk assessment and provision of information

27. WHO plays an important role in the early phase of any outbreak, by gathering information and conducting risk assessments. WHO's risk assessments are provided regularly to the IHR Emergency Committees. The process for determining a public health emergency of international concern (PHEIC) also considers WHO's risk assessments. The Review Committee is studying aspects of this early phase, including the timeliness of the provision of basic epidemiological data by the affected countries, and the involvement of the WHO Secretariat.

28. WHO provided the Review Committee with details about its approach for conducting rapid risk assessments for events that may require the convening of an IHR Emergency Committee or any other response action from WHO. The template and methodology were shared with the Committee, together with examples of rapid risk assessments for past events and all such assessments conducted for COVID-19. The first rapid risk assessment was issued by WHO on 5 January 2020. Official information as well as media, social media and informal sources are useful for surveillance. WHO-provided rapid risk assessments for events that may pose a risk of international spread are of vital importance. Rapid risk assessments in countries are also relevant but need further review and discussion by the Committee.

The Emergency Committee and PHEIC declaration

29. More transparency could benefit WHO's decision-making processes with respect to convening the IHR Emergency Committee, the selection of external experts, the determination of a PHEIC and the

issuance of guidance and recommendations. The issue of transparency was discussed by previous Review Committees and requires further assessing by this Review Committee.

30. Further clarity is needed on the indicators used by the IHR Emergency Committee in its assessment of the severity of an event, beyond the definition currently provided by the Regulations.¹ Such indicators may include, for example, the epidemiological situation, infection dynamics, burden of disease, and available public health and health services capacities. The link between the determination of the PHEIC and the declaration or characterization of an event as a pandemic, which is not mentioned in the Regulations, needs to be also further examined.

31. In addition, the declaration of a PHEIC by the Director-General following the advice of the IHR Emergency Committees is often misinterpreted beyond its definition of a “risk”, as a trigger for mobilizing resources and to implement actions beyond WHO recommendations. There may be scope for WHO to communicate more clearly what should happen when an event is declared a PHEIC (beyond the issuance of temporary recommendations).

32. Another area of concern is the rigid binary nature of declaring a PHEIC. This binary nature was also noted by the IHR Emergency Committee for COVID-19 at its first meeting on 22 January 2020 as a constraint to raising awareness globally of the importance of events that do not immediately meet the criteria for a PHEIC, but that require an immediate global response, specifically to prevent the event from becoming a PHEIC.

33. The Review Committee is assessing the advantages and disadvantages of an intermediate level of alert, such as a “yellow stage” of the PHEIC as an initial warning signal, and whether different types of PHEIC are required, such as a regional PHEIC declaration for events that pose a public health threat to a region/continent only. The Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response in 2016 recommended that an intermediate level of alert be introduced, but this was not endorsed by Member States.

34. For events that may not meet the criteria for a PHEIC but may nonetheless require an urgent escalated public health response, the Committee considers that WHO should actively alert the global community. This could include sharing WHO risk assessments publicly in a manner consistent with Article 11, making recommendations and outlining steps required to prevent a PHEIC, including an increased response from the international community (Article 44). It may also include a specific designation of the event as an Intermediate Public Health Alert, or a specific risk communication procedure, to be developed and implemented by the Director-General.

Response

International travel, including the use of digital technology

35. The Committee is considering whether the international spread of COVID-19 was due to inconsistent implementation of health measures by States Parties or insufficient WHO recommendations in relation to international traffic. The Committee is reviewing aspects of WHO’s advice and recommendations on international travel and States Parties’ implementation of additional health

¹ Under Article 1 of the International Health Regulations (2005), a “‘public health emergency of international concern’ means an extraordinary event which is determined, as provided by these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require coordinated international response”.

measures, including: evidence on the effectiveness and timeliness of both WHO's travel advice and the travel restrictions implemented by States Parties; compliance with States Parties' and WHO's reporting obligations under Article 43 on additional health measures; and the absence of an enforcement mechanism to hold States Parties to account for lack of compliance with their obligations under the International Health Regulations (2005).

36. The Committee recognizes that States Parties have sovereign rights and can implement measures under national laws or regulations, which may interfere with international traffic. The relationship between national legislation and obligations under international law needs to be examined. There may be insufficient incentives for States Parties to comply with temporary recommendations. Nuanced enforcement options may be needed, targeting early and late phases of the pandemic. WHO should work on identifying the minimal essential information required from States Parties to serve as a foundation for further guidance to help all States Parties prepare and respond most efficiently.

37. The Committee is looking into the possible applications of digital technology to enable safe international travel, including for documentation at points of entry (arriving and departing travellers), travel history, testing and contact tracing, and possibly vaccination requirements. Caution will be needed to ensure that individual privacy considerations are respected.

38. There remain many scientific questions to be resolved regarding vaccine efficacy and duration of immunity following natural infection as well as what constitutes durable immunity. Nonetheless, there will be a global need to document safe traveller status, once validated preventive or prophylactic measures are available. The Committee is assessing whether options for developing and standardizing ways to document proof of vaccination or other prophylaxis are within its remit (linked to Article 36 of the Regulations) and should be considered.

39. The Response subgroup is also considering how to address the unique challenges associated with outbreaks on international cruise ships. The growing global cruise ship industry has created conditions that may involve thousands of diverse international passengers and crews residing in close quarters and potentially exposed to a pathogen such as the coronavirus responsible for COVID-19 that may necessitate implementation of isolation of patients and quarantine of those exposed (contacts). This represents novel challenges to States Parties and conveyance operators on a scale not envisioned in the International Health Regulations (2005). Consideration should be given to clearly defining the limits of States Parties' responsibilities under the Regulations for implementing isolation and quarantine measures on international cruise ships. Another issue is how to classify cases in relation to national surveillance systems.

Collaboration and coordination

40. Many sectors of society, including those outside of health, are impacted by the pandemic and are involved in the global response. The Regulations include detailed provisions about the identification of and communication about a serious international health threat. However, they are not specific when it comes to response, other than the issuance of temporary recommendations if the event constitutes a PHEIC, and these recommendations usually refer only to travel measures as per Article 18.

41. Article 44 provides for collaboration and assistance but does not go into the detail of practical ways to facilitate this. The Regulations could be more relevant by providing for the coordination of national and international response measures – beyond issuing temporary recommendations. The Committee will further examine the relations between the Regulations and the WHO's Emergency Response Framework, as well as the coordination of global response through the UN Crisis Management

Team, activated at the request of the United Nations Secretary-General on 4 February 2020, under WHO leadership.

42. Early response actions highlighted the need to optimize procedures for efficient, timely sharing of pathogens, specimens and sequence information essential for development of effective countermeasures. Emergence of a novel pathogen requires the rapid development of diagnostic assays, therapeutic interventions, vaccine development and prophylactic measures. In order to engage the global scientific community in these response efforts, it is critical that pathogens, their genomic sequence, and relevant clinical samples be rapidly made available to the global medical research community. The Committee is considering how the Regulations could facilitate the rapid sharing of scientific findings and samples within the global scientific community under Article 6. Lessons learned from pandemic influenza preparedness planning may offer a useful model for further development.

Communication and information sharing

43. The global COVID-19 pandemic has impacted every corner of the world and will continue to do so for the foreseeable future. Meeting critical information requirements with timely, accurate guidance must be sustained throughout the duration of the pandemic. Mass media, social media, risk communication and community engagement have during the past decade become extremely relevant to a health emergency response, yet for obvious reasons are not reflected in the International Health Regulations (2005).

44. WHO is playing a critical role in providing accurate, timely, scientific information and in providing tools to manage the overabundance of information and misinformation in the fight against COVID-19. WHO should remain agile in adapting to global information needs to counter inaccurate information and unsubstantiated rumours.

CONCLUSION

45. The Committee will continue its deliberations with the aim to present a final report to the Director-General for the Seventy-fourth World Health Assembly in May 2021. However, noting that the review of the event is taking place while the event is still unfolding, the Committee may not have all the elements necessary to conclude its deliberations by then.

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