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Preview

Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009

For discussion at the meeting of the Review Committee, 28 March 2011

INTRODUCTION

In January 2010, at its 126th session, WHO's Executive Board welcomed the Director-General's proposal to convene a Review Committee provided for in Chapter III of Part IX of the International Health Regulations 2005 (IHR). The Director-General's proposal included a request for the Committee to review the experience gained in the global response to the influenza A (H1N1) 2009 pandemic, in order to inform the review of the functioning of the Regulations; to help assess and, where appropriate, to modify the ongoing response; and to strengthen preparedness for future pandemics. The Committee's remit follows:

> **The assessment of the global response to the pandemic H1N1 will be conducted by the International Health Regulations Review Committee, a committee of experts with a broad mix of scientific expertise and practical experience in public health. The members are some of the leading experts in the world in their respective fields.**
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> **The International Health Regulations (IHR) is an international legal agreement that is binding on 194 States' Parties across the globe, including all of the Member States of WHO. The basic purpose of the IHR is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. In January 2010, the WHO Executive Board requested a proposal from the Director-General on how to assess the international response to the pandemic influenza, and then approved her suggestion to convene the IHR Review Committee to review both the pandemic response and the functioning of the IHR.**
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> **The pandemic H1N1 is the first Public Health Emergency of International Concern to occur since the revised IHR came into force. The IHR played a central role in the global**

response to the pandemic and so review of the IHR and review of the global handling of the pandemic influenza are closely related.

The IHR facilitate coordinated international action by requiring countries to report certain disease outbreaks and public health events to WHO so that global reporting of important public health events is timely and open.

The IHR were first implemented (i.e. "entered into force") worldwide in 2007 and the Health Assembly determined that a first review of its functioning is to take place by the Sixty-third World Health Assembly in May 2010.

Objectives

The review has three key objectives:

- **Assess the functioning of the International Health Regulations (2005);**
- **Assess the ongoing global response to the pandemic H1N1 (including the role of WHO); and**
- **Identify lessons learnt important for strengthening preparedness and response for future pandemics and public health emergencies.**

Members of the Review Committee are listed at the end of this document.

METHOD OF WORK

The Review Committee conducted a major portion of its work through plenary meetings at WHO's headquarters in Geneva. For transparency, these meetings were open to the media. The Committee heard testimony from individuals representing States Parties, National IHR Focal Points,

intergovernmental organizations, nongovernmental organizations, United Nations agencies, industry, health professionals, experts, members of the media, chairs of relevant committees and the WHO Secretariat.

The full Committee and its working groups also met for deliberative sessions in Geneva, open only to members of the Committee and its immediate support staff. Further consultations took place among the support staff, the chair and working groups of the Committee by means of telephone conferences and e-mail exchange.

While operating independently, the Review Committee frequently sought information from WHO's Secretariat, asking for clarification of issues that arose during the information-gathering and report-writing periods. WHO staff provided written responses to many questions posed by the Committee and spoke informally with Committee members. WHO provided the Committee with unfettered access to internal documents and Committee members signed non-disclosure agreements in order to review confidential legal documents.

The WHO Secretariat developed a series of briefing notes for the Committee, providing background on issues such as: the IHR; pandemic preparedness; pandemic phases; pandemic severity; pandemic vaccine; antiviral drugs; virological monitoring; disease monitoring; laboratory response; public health measures; and the Open-ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. The Committee had access to a series of studies that evaluated the functioning of Annex 2 of the IHR (i.e. the decision instrument for States Parties' assessment and notification of public health events) as well as progress reports on the implementation of the IHR. At the Committee's request, the WHO Secretariat devised a matrix of the key public health functions of the IHR and identified a broad range of non-pandemic events that had been notified to WHO since the IHR came into force. The Committee

selected 18 events and directed the Secretariat to prepare a summary of each event to facilitate its assessment of the public health functions of the IHR.

The Committee sought to document WHO's role and management in response to the pandemic and to evaluate the effectiveness of the IHR. This required a thorough investigation of events and decisions in the course of the pandemic, an examination of criticisms of the Organization and an assessment of its achievements. The goal from the outset has been to identify the best ways to protect the world in the next public health emergency. Throughout its deliberations, the Committee has aimed to be thorough, systematic, open and objective. The final report will provide a full description of the evidence presented to the Committee in interviews and documents, and the Committee's assessment and interpretation of that evidence.

ORGANIZATION OF THE FINAL REPORT

The final report will have three main components. The first section describes the development and functions of the IHR. It also assesses pandemic preparedness in the context of earlier infectious outbreaks, such as severe acute respiratory syndrome (SARS) and avian influenza A (H5N1), and how these historic events shaped the global response to the pandemic in 2009.

The second section includes a chronology of the events of the pandemic. It provides a snapshot of decision-making in the early days of the outbreak.

Section three assesses the public health functions of the IHR in relationship to the pandemic and other events. It describes the global response to the pandemic and evaluates how WHO and the IHR performed in light of the first Public Health Emergency of International Concern, as defined by the IHR.

BACKGROUND AND CONTEXT

The IHR establish a regime for the routine protection of public health and provide for the management of disease threats, both in countries and at their borders. They also provide a framework for coordinated and proportionate responses to significant emerging disease threats. Such threats may range from public health events affecting one or more countries to events of global public health significance. The provisions of the IHR are legally binding on States Parties and WHO. The IHR introduced a number of key innovations, including the replacement of a list of notifiable diseases with a decision instrument (Annex 2), to assist countries to determine whether an event may constitute a Public Health Emergency of International Concern. The 2009 pandemic was the first major test of the IHR.

A review of the functioning of the IHR and how successfully WHO performed in response to the pandemic requires an understanding of the context of the pandemic. The Review Committee identified five factors that framed the events and help explain what happened in the pandemic response. Expressed simply, they are:

- the core values of public health;
- the unpredictable nature of influenza;
- the threat of avian influenza A (H5N1) and how it shaped general pandemic preparedness;
- WHO's dual role as a moral voice for health in the world and as a servant of its Member States;
- the limitations of systems that were designed to respond to a geographically focal, short-term emergency, rather than a global, sustained, long-term event.

105 The core values of public health shaped the response of public health leaders around the world
106 to the pandemic. The main ethos of public health is one of prevention: to prevent disease and avert
107 avoidable deaths. The response of WHO and many countries to the pandemic was a reflection of this
108 mindset. This was affirmed in the sentiments expressed by many Member States to the Review
109 Committee: in the face of uncertainty and potentially serious harm, it is better to err on the side of
110 safety. Public health officials believe and act on this conviction. It is incumbent upon political leaders
111 and policy-makers to understand this core value of public health and how it pervades thinking in the
112 field.

113 Influenza pandemics will continue to occur, if history and science are any guide. In this sense,
114 influenza is grossly predictable. However, exactly when, where and how severe the next influenza
115 pandemic will be, no one can predict. Because pandemics occur infrequently, there is a tendency to
116 over-interpret the patterns of the past. For example, it may be tempting when considering the
117 pandemics of 1918, 1957, 1968 and 2009 to conclude that successive pandemics tend to decline in
118 severity. However, four observations are too few to support this conclusion. Research, especially on
119 genetic markers of the virus and on host factors, may eventually increase the accuracy of predictions,
120 but at present, lack of certainty is an inescapable reality when it comes to influenza. One key
121 implication is the importance of flexibility to accommodate unexpected and changing conditions. The
122 ability to take action in the face of uncertainty and to adapt rapidly to new circumstances are hallmarks
123 of sound public health practice and emergency management.

124 The response to the emergence of pandemic influenza A (H1N1) 2009 was the result of a
125 decade of pandemic planning, largely centred on the threat of an avian influenza A (H5N1) pandemic.
126 However, H5N1 and H1N1 have markedly different characteristics. H5N1 infection in humans results
127 in about 60% mortality among confirmed cases, yet it is only sporadically transmitted to humans and
128 even less often between humans. When thinking about a potential H5N1 pandemic, large numbers of

fatalities could be assumed because the virus had proved itself to be highly lethal. Since H5N1 was not easily transmissible from human to human, suppression of an outbreak through the use of antiviral drugs and other measures could be thought feasible. WHO's web site has described the prospect of severe disease in a possible pandemic, which was understandable in the context of expectations about H5N1. But the reality of H1N1 was quite different. Because H1N1 caused illness that did not require hospitalization in the vast majority of cases, the question of severity of the pandemic and how to characterize it became a key challenge. As the H1N1 virus spread to several countries within days, the possibility of rapid containment, a tenet of planning in WHO's multi-stage response, was never really feasible.

Another reality that shaped the response to the pandemic is the nature of WHO itself. WHO has a dual character and mission: as a moral voice for global health, and as a servant of its Member States. As the directing and coordinating authority on international health within the United Nations system, WHO is well-positioned to be a champion for health as a human right. Its policy and technical leadership can help countries cope with an array of public health concerns. At the same time, WHO is a servant of its 193 Member States, which meet every year at the World Health Assembly in Geneva to set policy for the Organization, approve the Organization's budget and plans, and, through the Assembly's Executive Board, elect the Director-General every five years. WHO's scientific and technical aspirations for global health are constantly conditioned by the multiplicity of views, needs and preferences of its Member States.

WHO's internal response capacities to health emergencies are geared towards relatively short-term, geographically focal events, a type that WHO confronts many times each year. By contrast, the pandemic required a worldwide response lasting one to two years. Before the pandemic, SARS was the only global emergency in recent decades that provided WHO with a foretaste of the demands that a pandemic might entail. However, SARS lasted but a few months and affected only about two dozen countries.

CONCLUSIONS AND RECOMMENDATIONS

154 With this background and context, the Review Committee offers three overarching conclusions:

155 **Summary conclusion 1**

156 ***The IHR helped make the world better prepared to cope with public health emergencies. The core***
157 ***national and local capacities called for in the IHR are not yet fully operational and are not now on***
158 ***a path to timely implementation worldwide.***

159 **Summary conclusion 2**

160 ***WHO performed well in many ways during the pandemic, confronted systemic difficulties and***
161 ***demonstrated some shortcomings. The Committee found no evidence of malfeasance***.

162 **Summary conclusion 3**

163 ***The world is ill-prepared to respond to a severe influenza pandemic or to any similarly global,***
164 ***sustained and threatening public health emergency. Beyond implementation of core public health***
165 ***capacities called for in the IHR, global preparedness can be advanced through research,***
166 ***strengthened health-care delivery systems, economic development in low- and middle-income***
167 ***countries and improved health status.***

168 The remainder of this document summarizes the Committee's findings and reasoning and the
169 recommendations that follow each conclusion.

Summary conclusion 1

The IHR helped make the world better prepared to cope with public health emergencies. The core national and local capacities called for in the IHR are not yet fully operational and are not now on a path to timely implementation worldwide.

Development of the IHR required more than a decade of complex deliberations. While the IHR are not perfect, they significantly advance the protection of global health. The Committee has focused its recommendations on how ongoing implementation of the IHR can be strengthened. The IHR seek to balance the sovereignty of individual States Parties with the common good of the international community, and take account of economic and social interests as well as the protection of health. The Committee's recommendations acknowledge these inherent tensions and focus on actions that can enhance the shared goal of global public health security.

The Committee commends the following provisions of the IHR:

- The IHR oblige WHO to obtain expert advice on the declaration and discontinuation of a Public Health Emergency of International Concern.
- The IHR strongly encourage countries to provide each other with technical cooperation and logistical support for capacity building.
- The IHR encourage establishment of systematic approaches to surveillance, early warning systems and response in Member States.
- The IHR required the establishment of National IHR Focal Points to create a clear two-way channel of communication between WHO and Member States.

- The IHR led a number of countries to strengthen surveillance, risk assessment, response capacity and reporting procedures for public health risks.

- The IHR introduced a decision instrument (Annex 2) for public health action that has proved more flexible and useful than the list of notifiable diseases it replaced.

- The IHR require countries to share information relevant to public health risks.

- The IHR require States Parties that implement additional health measures significantly interfering with international traffic and trade to inform WHO about these measures, and to provide the public health rationale and relevant scientific information for them.

Despite these positive features of the IHR, many States Parties lack core capacities to detect, assess and report potential health threats and are not on a path to complete their obligations for plans and infrastructure by the 2012 deadline specified in the IHR. Continuing on the current trajectory will not enable countries to develop these capacities and fully implement the IHR. Of the 194 States Parties, 128, or 66%, responded to a recent WHO questionnaire on their progress. Only 58% of the respondents reported having developed national plans to meet core capacity requirements, and as few as 10% of reporting countries indicated that they had fully established the capacities envisaged by the IHR. Further, as documented by external studies and a WHO questionnaire, in some countries, National IHR Focal Points lack the authority to communicate information related to public health emergencies to WHO in a timely manner.

The most important structural shortcoming of the IHR is the lack of enforceable sanctions. For example, if a country fails to explain why it has adopted more restrictive traffic and trade measures than those recommended by WHO, no legal consequences follow.

To remedy a number of these problems, the Committee recommends the following:

Recommendation 1

Accelerate implementation of core capacities required by the IHR. WHO and States Parties should refine and update their strategies for implementing the capacity-building requirements of the IHR, focusing first on those countries that will have difficulty meeting the 2012 deadline for core capacities. One possible way to support and accelerate implementation would be for WHO to enlist appropriate agencies and organizations that would be willing to provide technical assistance to help interested countries assess their needs and make the business case for investment. Making the case for investment in IHR capacity building and subsequent resource mobilization would increase the likelihood that more States Parties could come into compliance with the IHR.

Recommendation 2

Enhance the WHO Event Information Site. WHO should enhance its Event Information Site to make it an authoritative resource for disseminating reliable, up-to-date and readily accessible international epidemic information. States Parties should be able to rely on the Event Information Site as a primary source for such information.

Recommendation 3

Reinforce evidence-based decisions on traffic and trade. When States Parties implement traffic and trade measures more restrictive than those recommended by WHO, IHR Article 43 provides that the States Parties shall inform WHO of their actions. WHO should energetically seek to obtain the public health rationale and relevant scientific information, share it with other States Parties, and, where appropriate, request reconsideration, as stipulated under Article 43. WHO should convene an expert panel to review and assess the effectiveness and impact of border measures taken during the pandemic to support evidence-based guidance for future events.

Recommendation 4

Ensure necessary authority and resources for all National IHR Focal Points. States Parties should ensure that designated National IHR Focal Points have the authority, resources, procedures, knowledge and training to communicate with all levels of their governments and on behalf of their governments as necessary.

Summary conclusion 2

WHO performed well in many ways during the pandemic, confronted systemic difficulties and demonstrated some shortcomings. The Committee found no evidence of malfeasance.

As noted in testimony by States Parties, WHO provided welcome leadership in coordinating the global response throughout the pandemic. WHO's epidemic intelligence functions have strengthened in recent years as a result of the Event Management System, increases in Regional Office capacity, and the Global Outbreak Alert and Response Network.

The Committee commends the following actions by WHO and other partners:

- Development of influenza preparedness and response guidance to help inform national plans. Pandemic preparedness plans were in place in 74% of countries when the pandemic began.
- Effective partnering and interagency coordination (with the United Nations Children's Fund and the United Nations Office for Project Services), including close cooperation with the animal health sector (the World Organisation for Animal Health, and the Food and Agriculture Organization) on technical and policy issues.
- Rapid field deployment and early guidance and assistance to affected countries.

- Timely detection, identification, initial characterization and monitoring of the pandemic (H1N1) 2009 virus through the Global Influenza Surveillance Network.

- Selection of the pandemic vaccine virus and development of the first-candidate vaccine reassortant virus within 32 days of declaration of the Public Health Emergency of International Concern.

- Vaccine seed strains and control reagents made available within a few weeks.

- Early policy recommendations on target groups and dosage of vaccines by the WHO Strategic Advisory Group of Experts (SAGE).

- Weekly collation, analysis and reporting of global epidemiological, virological and clinical surveillance data.

- Prompt appointment of an Emergency Committee with well-qualified individuals, which was convened within 48 hours of activation of IHR provisions.

- Efficient distribution of more than 3 million treatment courses of antiviral drugs to 72 countries.

- Establishment of a mechanism to help countries monitor their development of IHR core capacities.

The Committee also noted systemic difficulties that confronted WHO and some shortcomings on the part of WHO:

- The absence of a consistent, measurable and understandable depiction of severity of the pandemic. Even if the definition of a pandemic depends exclusively on spread, its degree of severity affects policy choices, personal decisions and the public interest.

What is needed is a proper assessment of severity at national and sub-national levels. These data would inform WHO's analysis of the global situation as it evolves, allowing WHO to provide timely information to Member States. The Committee does, however, recognize that characterization of severity is complex and difficult to operationalize.

- Inadequately dispelling confusion about the definition of a pandemic. One online WHO document described pandemics as causing "enormous numbers of deaths and illness", while the official definition of a pandemic was based only on the degree of spread. When, without notice or explanation, WHO altered some of its online documents to be more consistent with its intended definition of a pandemic, the Organization invited suspicion of a surreptitious shift in definition rather than an effort to make its descriptions of a pandemic more precise and consistent. Reluctance to acknowledge its part in allowing misunderstanding of the intended definition fuelled suspicion of the Organization.

- A pandemic phase structure that was needlessly complex. The multi-phase structure contains more stages than differentiated responses. Defined phases leading to a pandemic are more useful for planning purposes than for operational management.

- Weekly requests for specific data were overwhelming to some countries, particularly those with limited epidemiological and laboratory capacity. Country officials were not always convinced the data they submitted were being analysed and used, particularly as the epidemic progressed. Continued counting of cases yielded less useful information than would have been provided by rates of hospitalization, complications and death in countries affected early on in the pandemic.

- The decision to keep confidential the identities of Emergency Committee members. Although confidentiality represented an understandable effort to protect the members from external pressures, this paradoxically fed suspicions that the Organization had something to hide. While the decision was consistent with WHO practices for other expert committees, whose identities are normally divulged only at the end of what is often a one-day consultation, this practice was not well-suited to a Committee whose service would extend over many months.

- Lack of a sufficiently robust, systematic and open set of procedures for disclosing, recognizing and managing conflicts of interest among expert advisers. In particular, potential conflicts of interest among Emergency Committee members were not managed in a timely fashion by WHO. Five members of the Emergency Committee and an Adviser to the Emergency Committee declared potential conflicts of interest. None of these were determined sufficiently important to merit the members' exclusion from the Emergency Committee. The relationships in question were published, along with the names of the members of the Emergency Committee, when the pandemic was declared over on 10 August 2010. Before this information was published, however, assumptions about potential ties between Emergency Committee members and industry led some to suspect wrongdoing. The Review Committee recognizes that WHO is taking steps to improve its management of conflicts of interest, even as this review has proceeded.

- At a critical point of decision-making about the pandemic (moving from Phase 4 to 5), conferring with only a subset of the Emergency Committee rather than inviting input from the full Emergency Committee.

- The decision to diminish proactive communication with the media after declaring Phase 6 (for example, by discontinuing routine press conferences focused on the evolving pandemic) was ill-advised.

- Failure to acknowledge legitimate reasons for some criticism, in particular, inconsistent descriptions of a pandemic, or the lack of timely disclosure of relationships potentially constituting a conflict of interest among experts who advised on plans and response to the pandemic. In such instances, WHO may have inadvertently contributed to confusion and suspicion.

- Responding with insufficient vigour to criticisms that questioned the integrity of the Organization.

- Despite the ultimate deployment of 78 million doses of pandemic influenza vaccine to 77 countries, numerous systemic difficulties impeded WHO's ability to achieve a timely distribution of donated vaccines. Negotiations over legal agreements with manufacturers were protracted and in some cases unsuccessful. Excessive complexity in donor and recipient agreements hindered timely execution. Obtaining regulatory approvals, dealing with liability concerns over vaccine used in recipient countries, assuring maintenance of the cold chain throughout vaccine distribution and securing plans for local vaccine administration added to the delays. These difficulties proved daunting in the midst of a pandemic; some could have been reduced by more concerted preparation and arrangements in advance of a pandemic.

- Lack of timely guidance in all official languages of WHO.

- Lack of a cohesive, overarching set of procedures and priorities for publishing consistent and timely technical guidance resulted in a multiplicity of technical units

within the Organization individually generating an unmanageable number of documents.

Critics assert that WHO vastly overstated the seriousness of the pandemic. However, reasonable criticism can be based only on what was known at the time and not on what was later learnt. The Committee found that evidence from early outbreaks led many experts at WHO and elsewhere to anticipate a potentially more severe pandemic than subsequently occurred. The degree of severity of the pandemic was very uncertain throughout the summer of 2009, well past the time, for example, when countries would have needed to place orders for vaccine. An observational study of 899 patients hospitalized in Mexico between late March and 1 June 2009, showed that pandemic (H1N1) 2009 disproportionately affected young people. Fifty-eight patients (6.5% of those hospitalized) became critically ill, with complications including severe acute respiratory distress syndrome and shock. Among those who became critically ill, the mortality rate was 41% (1). These statistics were alarming. Even a reported mortality rate of one third that level among critically ill patients in Canada was worrisome (2). In August 2009, the President's Council of Advisors on Science and Technology in the United States of America released a report positing a possible scenario of 30 000–90 000 deaths from pandemic (H1N1) 2009 in the United States alone (3). The mid-point and upper level of this scenario turned out to be five times higher than the post-pandemic estimates of the actual number of deaths (4). Even so, 87% of deaths occurred in those under age 65, with the risk of death among children and working adults seven times and 12 times greater, respectively, than during typical seasonal influenza (4).

Some commentators accused WHO of rushing to announce Phase 6 and suggested the reason was to enrich vaccine manufacturers, some of whose advance-purchase agreements would be triggered by the declaration of Phase 6. Far from accelerating the declaration of Phase 6, WHO delayed declaration until evidence of sustained community spread in multiple regions of the world was undeniably occurring. As far as the Review Committee can determine, no critic of WHO has produced

any direct evidence of commercial influence on decision-making. In its interviews with staff and advisory committee members, including the Strategic Advisory Group of Experts and the Emergency Committee, and with representatives of industry, and through its review of internal and external documents, the Review Committee found no evidence of attempted or actual influence by commercial interests on advice given to or decisions made by WHO. In the Committee's view, the inference by some critics that invisible commercial influences must account for WHO's actions ignores the power of the core public health ethos to prevent disease and save lives.

The Review Committee offers the following recommendations:

Recommendation 5

Strengthen WHO's internal capacity for sustained response. WHO should strengthen its internal capacity to respond to a sustained Public Health Emergency of International Concern, such as a pandemic, identifying the skills, resources and internal arrangements to support a response that extends beyond a few months. Among the internal arrangements that WHO should reinforce are:

- Identify the skills, resources and adjustments needed for WHO to carry out its role in coordination and global support.
- Establish an internal, trained, multi-disciplinary staff group who will be automatically released from their normal duties for an unspecified duration, with a relief rotation after a designated interval.
- Ensure a 24/7 capacity to meet the personal needs for accommodation, meals, transportation and childcare of WHO staff enlisted in a sustained emergency response.

- Establish an event management structure that could be maintained throughout a future pandemic or other sustained global public health emergency.

Recommendation 6

Improve practices for appointment of an Emergency Committee. WHO should adopt policies, standards and procedures for the appointment and management of an Emergency Committee that assure an appropriate spectrum of expertise on the committee, inclusive consultation and transparency with respect to freedom from conflicts of interest.

- As provided for in Article 48 of the IHR, WHO should appoint an Emergency Committee with the spectrum of expertise appropriate for each event. For an influenza pandemic, this expertise includes virology, laboratory assessment, epidemiology, public health field and leadership experience, risk assessment and risk communication.

- To ensure that the full range of views is presented, WHO should invite all members of an Emergency Committee to participate in all of its major deliberations.

- WHO should clarify its standards and adopt more transparent procedures for the appointment of members of expert committees, such as the Emergency Committee, with respect to potential conflicts of interest. The identity and relevant background, experience and relationships of Emergency Committee members should be publicly disclosed at the time of their proposed appointment, with an opportunity for public comment. WHO should have clear standards for determining when a conflict of interest exists that warrants disqualifying an individual, and have clear procedures to determine when and on what basis exceptions may be made to obtain necessary expertise or balance. The Review Committee appreciates the need for expert consultations to be held in confidence so that the Director-General will have the benefit of candid

discussion and advice. The desirability of confidential consultation heightens the burden of transparency on standards for appointment.

- As part of a more proactive and rigorous approach to managing conflicts of interest, WHO should appoint a designated ethics officer.

Recommendation 7

Revise pandemic preparedness guidance. WHO should revise its Pandemic Preparedness Guidance in order to: simplify the phase structure (one possible paradigm would include only three phases – baseline, alert phase, pandemic); emphasize a risk-based approach to enable a more flexible response to different scenarios; and include further guidance on risk assessment.

Recommendation 8

Develop and apply measures to assess severity. WHO should develop and apply measures that can be used to assess the severity of every influenza epidemic. By applying, evaluating and refining tools to measure severity every year, WHO and Member States can be better prepared to assess severity in the next pandemic. Assessing severity does not require altering the definition of a pandemic to depend on anything other than the degree of spread. Rather, while not part of the definition of a pandemic, measured and projected severity are key components of decision-making in the face of a pandemic.

The Committee recognizes that estimating severity is especially difficult in the early phase of an outbreak, that severity typically varies by place and over time, and that severity has multiple dimensions (deaths, hospitalizations and illness, with each varying by age and other attributes, such as pre-existing health conditions and access to care; burden on a health system; and social and economic factors). Descriptive terms used to characterize severity, such as mild, moderate and severe, should be quantitatively defined in future WHO guidelines so that they may be used consistently by different

observers and in different settings. The Committee urges consideration of adaptive measures that would move as rapidly as possible from early counts of cases, hospitalizations and deaths to population-based rates. Severity should be assessed as early as possible during a pandemic and continually re-assessed as the pandemic evolves and new information becomes available. Severity might be assessed using a basket of indicators in a pre-agreed minimum data set (e.g. hospitalization rates, mortality data, identification of vulnerable populations and an assessment of the impact on health systems). Estimates of severity should be accompanied by expressions of confidence or uncertainty around the estimates.

Recommendation 9

Streamline management of guidance documents. WHO needs a strategy and document management system to cope with the development, clearance, translation and dissemination of guidance and other technical documents in a timely and consistent way during a public health emergency. Interim guidance should be revised as data become available. When feasible, if the guidelines have potential policy implications, WHO should make every effort to consult with Member States.

Recommendation 10

Develop and implement a strategic, organization-wide communications policy. WHO should develop an organization-wide communications policy and a strategic approach to improve routine and emergency communications. A strategic approach entails matching the content, form and style of communication with selected media, timing and frequency in order to reach the intended audience and serve the intended purpose. WHO should be prepared to sustain active, long-term communications outreach when circumstances require, to acknowledge mistakes and to respond professionally and vigorously to unwarranted criticisms. Web publishing procedures should be clarified so that changes

in web pages can be historically tracked and archived. WHO should invest in a robust social media presence for rapid communication to a wider, more diverse audience.

Recommendation 11

Set up advance agreements for vaccine distribution and delivery. In concert with efforts by Member States, and building on existing vaccine distribution systems, WHO should set up advance agreements with appropriate agencies and authorities in Member States, vaccine manufacturers and other relevant parties that would facilitate approval and delivery of pandemic vaccines to low-resource countries, to increase equity in supply and support advance planning for administration of vaccines.

Summary conclusion 3

The world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained, and threatening public health emergency. Beyond implementation of core public health capacities called for in the IHR, global preparedness can be advanced through research, strengthened health-care delivery systems, economic development in low and middle-income countries and improved health status.

Despite the progress that the IHR represent and WHO's success in mobilizing contributions from the global community, the unavoidable reality is that tens of millions of people would be at risk of dying in a severe global pandemic. Unless this fundamental gap between global need and global capacity is closed, we invite future catastrophe.

Beyond the specific measures recommended above to complete implementation of the IHR provisions and improve the functions of WHO, the world can be better prepared for the next public health emergency through advance commitment by Member States acting individually and collectively with WHO.

The Review Committee offers the following recommendations:

Recommendation 12

Establish a more extensive global, public health reserve corps. Member States, in concert with WHO, should establish a more extensive global reserve corps of experts and public health professionals to be mobilized as part of a sustained response to a global health emergency and deployed for service in countries that request such assistance. The size, composition and governing rules for activating and deploying the Global Health Emergency Corps should be developed through consultation and mutual agreement among the Member States and WHO. The number and particular skills of the experts deployed will depend on specific characteristics of the emergency to which the corps is responding. This corps would significantly expand the current Global Outbreak and Alert Response Network by strengthening its composition, resources and capacity, with a view towards better support for sustained responses to public health emergencies.

At present, WHO's capacity to prepare and respond in a sustained way to any public health emergency is severely limited by chronic funding shortfalls, compounded by restrictions on the use of funds from Member States, partners and other donors. Mindful of concerns about efficiency and accountability that motivate some of the restrictions, the Committee concludes that the establishment of a contingency fund outside of WHO, but available for deployment by WHO at the time of a public health emergency, will be a prudent step to assure an immediate and effective global response.

Recommendation 13

Create a contingency fund for public health emergencies. Member States should establish a public health emergency fund of at least US$ 100 million, to be held in trust at an institution such as the World Bank. The fund, which would support surge capacity, not the purchase of materials, would be released in part or whole during a declared Public Health Emergency of International Concern, based on approval of a plan for expenditures and accountability submitted by WHO. The precise conditions for use of the fund should be negotiated among the Member States in consultation with WHO.

The Review Committee commends the effort by Member States to reach agreement on virus sharing and vaccine distribution. The Review Committee believes that success will depend on a mutual expectation of proportionate, balanced benefit and contribution by all stakeholders. An agreement that is one-sided or that expects contribution without benefit, or vice versa, will be neither acceptable nor sustainable. The Review Committee also believes that obligations and benefits not linked to a legal framework are unlikely to last.

Recommendation 14

Reach agreement on sharing of viruses and access to vaccines. The Review Committee urges Member States and WHO to conclude negotiations under the Open-ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. A successful conclusion to this negotiation will lead to wider availability of vaccines and greater equity in the face of the next pandemic, as well as continued timely sharing of influenza viruses.

The Review Committee offers the following elements for consideration as part of an acceptable agreement.

Measures to expand global influenza vaccine production capacity:

- WHO should continue its practice of working with public health laboratories to make seed vaccine strains widely available to all vaccine manufacturers.

- In so far as it is consistent with national priorities, risk assessments and resources, the Review Committee urges countries to immunize their populations yearly against seasonal influenza. This can reduce the burden of disease, add to widespread local production, distribution and delivery experience, and support increased global capacity for vaccine production. More generally, experience with comprehensive programmes during seasonal influenza (in such areas as surveillance, communication, professional and public education, health protection measures and pharmaceuticals) provides valuable preparation in advance of a major pandemic.

- The Committee urges countries to strengthen their capacity to receive, store, distribute and administer vaccines. Technological advances that reduce reliance on a cold chain and otherwise simplify administration will streamline these processes.

- The Committee urges countries to aid the transfer of technologies for vaccine and adjuvant production in parts of the world currently lacking this capacity through established programmes such as the Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP).

Measures to increase access, affordability and deployment of pandemic vaccine:

- All vaccine manufacturers should commit to a contribution of 10% of pandemic influenza vaccine from each production run to a global redistribution pool. WHO

should be responsible for managing allocations from this pool based on advice from a consultative committee.

- Increased access to vaccines and antiviral drugs can be achieved through advance agreements between industry, WHO and countries. These agreements should be negotiated without regard to virus subtype, for a specified period of time (e.g. three to five years), and should be regularly reviewed and renewed.

- Other measures that may promote greater and more equitable access to vaccine include differential pricing, direct economic aid to low-resource countries and additional donations of vaccine from purchasing countries or manufacturers.

- Countries that receive donated vaccine should adhere to the same practices of releasing and indemnifying manufacturers from certain legal liabilities as any purchaser of the vaccine.

Measures to detect and promptly indentify potential pandemic influenza viruses:

- Every Member State should commit to share promptly with WHO collaborating laboratories any biological specimens and viral isolates that may be related to a new or emerging influenza virus in human or animal populations.

The world's capacity to prevent and limit a severe pandemic is constrained by many factors: predominant reliance on vaccine production technology that is little changed in 60 years; the need to match vaccine to particular viral strains; the inability to predict which influenza viruses will be dangerous to human health; uncertainty about the effectiveness of many pharmaceutical and public health measures; the lack of field-based, rapid, affordable, highly sensitive and specific diagnostic tests; and limitations of infrastructure, resources and capacities in many countries. Also needed are

improved knowledge of and practical strategies for implementing public health and personal protective measures, such as hand washing, respiratory etiquette, isolation and social distancing.

Some of these limitations can be reduced over time through national and international research. Further, the results of research on personal and public health protective measures may apply to any emerging public health threat, especially when few or no drugs or vaccines exist. Because assessment of public health measures typically must occur in real time in the midst of an outbreak, it is crucial to design and prepare research protocols and plans in advance. Beyond research advances, global resilience depends on host and environmental factors, so that improving health status, promoting economic development and strengthening health systems can mitigate the impact of a future pandemic virus.

Recommendation 15

Pursue a comprehensive influenza research programme. Member States, individually and in cooperation with one another, and WHO should pursue a comprehensive influenza research programme. Key research goals include: strengthen surveillance technology and epidemiological and laboratory capacity to improve detection, characterization and monitoring of new viruses; identify viral and host determinants of transmissibility and virulence; develop rapid, accurate, inexpensive point-of-care diagnostic tests; enhance the accuracy and timeliness of modelling projections; create broader spectrum, highly effective, safe and longer-lasting vaccines; hasten vaccine production and increase throughput; devise more effective antiviral drugs and antimicrobials to treat bacterial complications; evaluate the effectiveness of drug, vaccine, personal protective equipment and social interventions; and enhance risk communication.

Despite everything that was done in the pandemic, the major determinant of the consequences was the virus that caused it. In the face of a virulent influenza pandemic, or any similarly global,

584 sustained and threatening public health emergency, the world remains at risk of massive disruption,
585 suffering and loss of life. The Committee hopes that these recommendations will help WHO and its
586 Member States be better prepared to avert, mitigate and cope with future threats to health.

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