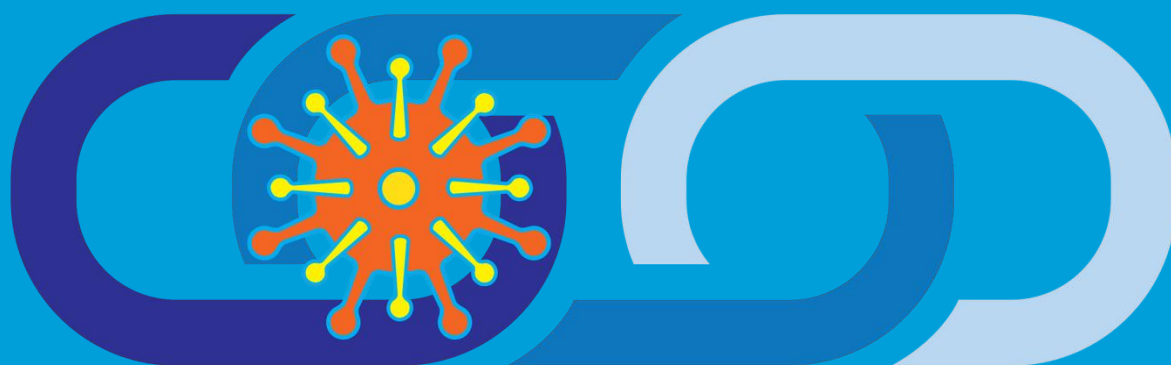


GLOBAL
INFLUENZA
PROGRAMME

PANDEMIC INFLUENZA RISK MANAGEMENT



A WHO guide to inform & harmonize national & international
pandemic preparedness and response

Pandemic Influenza Risk Management

WHO Guidance

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ABBREVIATIONS

| | |
|---------------|--|
| CAR | Clinical attack rate |
| CFR | Case-fatality ratio |
| ERMH | Emergency Risk Management for Health |
| GAP | Global Action Plan for Influenza Vaccines |
| GISRS | Global Influenza Surveillance and Response System |
| GOARN | Global Outbreak Alert and Response Network |
| IHR (2005) | International Health Regulations (2005) |
| PHEIC | Public Health Emergency of International Concern |
| PIP Framework | Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits |
| SAGE | Strategic Advisory Group of Experts on Immunization |
| UN | United Nations |

EXECUTIVE SUMMARY

Influenza pandemics are unpredictable but recurring events that can have consequences on human health and economic well-being worldwide. Advance planning and preparedness are critical to help mitigate the impact of a pandemic. This WHO guidance document, *Pandemic Influenza Risk Management*, updates and replaces *Pandemic influenza preparedness and response: a WHO guidance document*, which was published in 2009. This revision of the guidance takes account of lessons learnt from the influenza A(H1N1) 2009 pandemic and of other relevant developments.

The influenza A(H1N1) 2009 pandemic was both the first of the 21st century and the first since the adoption of the IHR 2005. The experience of Member States during the pandemic varied, yet several common factors emerged. Member States had prepared for a pandemic of high severity and faced difficulties to adapt their national and subnational responses adequately to a more moderate event. Communications were also demonstrated to be of immense importance: the need to provide clear risk assessments to decision-makers placed significant strain on ministries of health; and effective communication with the public was challenging. These, and other areas with improvement potential, were identified by the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009.

The influenza A(H1N1) 2009 pandemic provided a wealth of additional information to the established and growing body of knowledge on influenza viruses at the human–animal ecosystem interface. Other notable developments since the publication of the 2009 guidance include the adoption by the Sixty-fourth World Health Assembly of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. In addition, risk management of acute public health events that have the potential to cross borders and threaten people worldwide continues to improve as a result of the International Health Regulations (2005) and States Parties' obligations on capacity strengthening.

This guidance can be used to inform and harmonize national and international pandemic preparedness and response. Countries should consider reviewing and/or updating national influenza preparedness and response plans to reflect the approach taken in this guidance. The roles and responsibilities of WHO relevant to pandemic preparedness, in terms of global leadership and support to Member States in line with other United Nations policies of crisis and emergency management, are also articulated. This document is not intended to replace national plans, which should be developed by each country.

New in the 2013 guidance

Emergency Risk Management for Health

The approach taken in this 2013 guidance applies the principles of all-hazards emergency risk management for health (ERMH) to pandemic influenza risk management. The objectives of emergency risk management for health are to: strengthen capacities to manage the health risks from all hazards; embed comprehensive emergency risk management in the health sector; and enable and promote multisectoral linkage and integration across the whole-of-government and the whole-of-society. This guidance therefore aligns more closely with the disaster risk management structures already in place in many countries and underscores the need for appropriate and timely risk assessment for evidence-based decision-making at national, subnational and local levels.

Risk-based approach

This guidance introduces a risk-based approach to pandemic influenza risk management and encourages Member States to develop flexible plans, based on national risk assessment, taking account of the global risk assessment conducted by WHO. To support implementation, content on the application of assessments of risk and severity have been strengthened.

Approach to global phases and uncoupling global phases from national actions

In response to lessons learnt from the influenza A(H1N1) 2009 pandemic, a revised approach to global phases is introduced in this guidance. The phases, which are based on virological, epidemiological and clinical data, are to be used for describing the spread of a new influenza subtype, taking account of the disease it causes, around the world. The global phases have been clearly uncoupled from risk management decisions and actions at the country level. Thus, Member States are encouraged as far as possible to use national risk assessments to inform management decisions for the benefit of their country's specific situation and needs.

PIP Framework

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, commonly known as the PIP Framework, brings together Member States, industry, other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. Its key goals include:

- to improve and strengthen the sharing of influenza viruses with human pandemic potential; and
- to achieve, *inter alia*, more predictable, efficient and equitable access for countries in need of life-saving vaccines and medicines during future pandemics.

The Framework was developed by Member States and became effective on 24 May 2011, when it was adopted by the Sixty-fourth World Health Assembly.

1. INTRODUCTION

The influenza A(H1N1) 2009 pandemic was the first to occur since WHO had produced preparedness guidance. Guidance had been published in 1999, revised in 2005 and again in 2009 following advances in the development of antivirals and experiences with influenza A(H5N1) infections in poultry and humans. The emergence of the influenza A(H1N1)pdm09 virus provided further understanding of influenza pandemics and requirements for pandemic preparedness and response. The report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 concluded: “The world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained and threatening public-health emergency” (1).

The Review Committee recommended that WHO should revise its pandemic preparedness guidance to support further efforts at the national and subnational level. Revisions recommended included: simplification of the pandemic phases structure; emphasis on a risk-based approach to enable a more flexible response to different scenarios; reliance on multisectoral participation; utilization of lessons learnt at the country, regional and global level; and further guidance on risk assessment. The Review Committee’s report reflected the broad experiences of Member States during the influenza A(H1N1) 2009 pandemic – and the key point that previous pandemic planning guidance was overly rigid. Member States had prepared for a pandemic of high severity and appeared unable to adapt their responses adequately to a more moderate event. Communications also proved to be of immense importance during the influenza A(H1N1) 2009 pandemic, within the health and non-health sectors and to the public. Provision of clear risk assessments to decision-makers placed significant strain on ministries of health, and effective communication with the public was challenging.

This 2013 guidance is based on the principles of all-hazards emergency risk management for health (ERMH), thereby aligning pandemic risk management with the strategic approach adopted by WHO, in accordance with World Health Assembly resolution 64.10 (2). Commensurate with this approach, this guidance promotes building on existing capacities — in particular those under the International Health Regulations (2005) (3) (IHR [2005]) core capacities, in order to manage risks from pandemic influenza. Certain aspects of implementation of ERMH for national pandemic preparedness may therefore be linked with the core capacity strengthening activities required by the IHR (2005). This guidance can therefore be used as a model to illustrate how the mechanisms required for response to and recovery from pandemic influenza can be applied, as appropriate, to the management of all relevant health emergencies.

A risk-based approach to pandemic influenza management is emphasized and Member States are encouraged to develop flexible plans, based on national risk assessments. This guidance also places pandemic planning in the whole-of-society context. This 2013 revision therefore (1) reflects the approach taken at national level where pandemic influenza planning often rests with national disaster management authorities and (2) introduces or promotes all-hazards ERMH at Ministry of Health level, including mechanisms for wider national engagement.

This guidance also summarizes the roles and responsibilities of WHO relevant to pandemic preparedness, in terms of global leadership and support to Member States in line with other United Nations (UN) policies for crisis and emergency management.

2. WHO GLOBAL LEADERSHIP

WHO is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to Member States and monitoring and assessing health trends. WHO promotes health as a shared responsibility, involving equitable access to essential care and collective defence against transnational threats.

As the directing and coordinating authority for health within the UN system, WHO has a mandate for global pandemic influenza risk management (4, 5), which is reflected at all levels of the Organization and which aligns with other related UN policies for crisis management, e.g., the Inter-Agency Standing Committee (IASC) System-wide Level 3 (L3) Activation Procedures for Infectious Disease Events (6). Key mechanisms by which WHO fulfils this obligation are summarized below.

2.1 Coordination under the International Health Regulations (2005)

The IHR (2005) are binding upon 196 States Parties including all 194 Member States, and provide a global legal framework to prevent, control and respond to public health risks that may spread between countries. While important for all serious international public health risks, the IHR (2005) are particularly relevant for pandemic influenza preparedness and operational response, should such an event occur, in three main areas:

1. The core capacity development requirements for all countries under the IHR (2005) establish a binding framework for developing capacities to be able to detect and contain potential or actual outbreaks locally to the benefit of the country and the global community of nations;
2. The IHR (2005) obligations include the precise tasks that all States will have to be able to implement in any pandemic in order to apply health measures to international public health events; and
3. The central role for WHO in any international influenza event, including any which may become a pandemic and/or Public Health Emergency of International Concern (PHEIC).

Convening of an Emergency Committee, declaration of a Public Health Emergency of International Concern and issuance of IHR (2005) temporary recommendations

The IHR (2005) provide the legal framework for the timely and effective management of a broad range of serious and potentially international public health risks and events. In addition, the Regulations provide a specialized mechanism for collective global action for certain rare events of particular importance. Such serious events that endanger global public health are specified by the Regulations as public health emergencies of international concern. The term Public Health Emergency of International Concern (PHEIC) is defined in the IHR (2005) as “an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response”. This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State’s national border; and may require coordinated international action

The responsibility of determining whether an event is within this category lies with the WHO Director-General and requires the convening of a committee of health experts – the IHR Emergency Committee. This committee advises the Director-General on recommended measures to be implemented on an emergency basis, known as temporary recommendations. Temporary recommendations may include health measures to be implemented by the State Party experiencing the PHEIC, or by other States Parties, to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

The Emergency Committee also gives advice to the Director-General on the determination whether an event is a PHEIC in circumstances where there has not been agreement within 48 hours of the assessment of the event between the Director-General and the affected country/countries. The Emergency Committee continues to provide advice to the Director-General throughout the duration of the PHEIC, including any necessary changes to the temporary recommendation and on the termination of the PHEIC. WHO maintains an IHR Roster of Experts and the members of an IHR Emergency Committee are selected from this roster and/or WHO expert advisory panels. At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises, and such States Parties are invited to present their views to the Emergency Committee.

Provision of information and support to affected States Parties

The IHR (2005) also provide a mandate to WHO to perform public health surveillance, risk assessment, support States Parties and coordinate the international response to significant international public health risks and events. After preliminary assessment, WHO is obliged by the IHR (2005) to obtain verification from States Parties of unofficial reports of events that may constitute a PHEIC. If verification is sought, including in the context of potential pandemic influenza, States Parties are required to respond to WHO within a prescribed time period and include available relevant public health information. The legal requirement to respond to requests for verification by WHO aims to provide early identification and assessment of, and response to, any public health event with international implications. WHO is also obligated to provide public health information to all States Parties as soon as possible regarding public health risks, to enable them to respond and protect their populations. When WHO intends to make information available to other States Parties, it has an obligation to consult with the country experiencing the event.

Under the IHR (2005), WHO must offer assistance to States Parties in assessing or controlling public health events occurring within their territories. This support can be in the form of technical advice and guidelines, specialized materials, deployment of international teams to affected areas, and coordination of international support from various sources.

Measures adopted by States Parties in relation to travel or trade

The IHR (2005) seek to limit the public health measures taken in response to disease spread to those “that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade”. To achieve this objective, WHO regularly issues advice on trade and travel measures related to public health events where such measures are likely or relevant. While the IHR (2005) do not prevent States Parties from implementing specific trade and travel related measures, they do require States Parties to inform WHO of these measures and the justification for their introduction when they will result in significant interference, defined in the IHR (2005) as resulting in delays to movement of international travellers, baggage, cargo, containers, conveyances, goods, and the like, of greater than 24 hours. In addition to providing other States Parties with information on these measures, WHO can request the implementing State Party to reconsider their application.

2.2 Pandemic phases

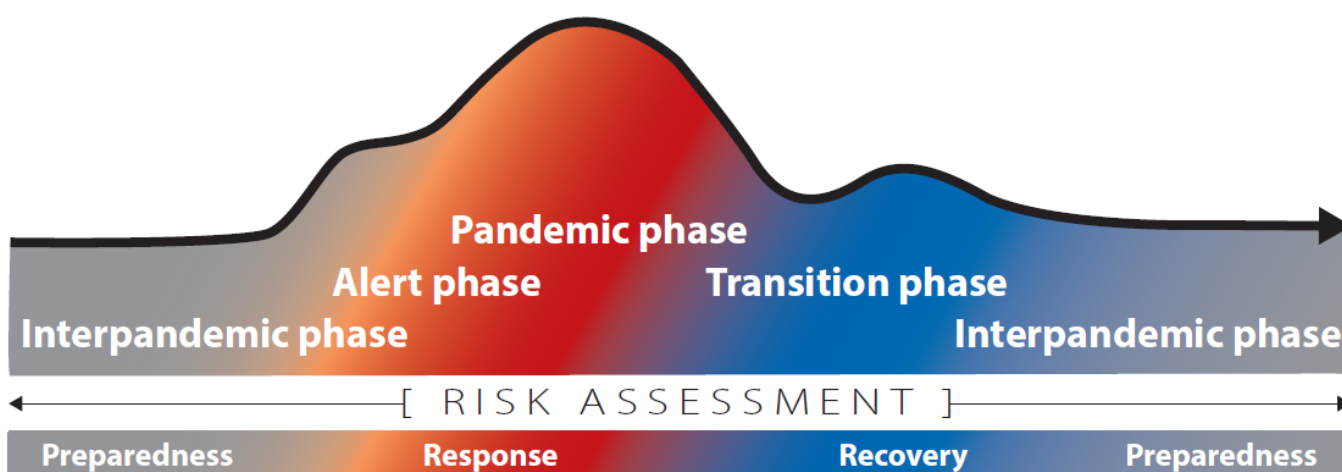
The pandemic influenza phases reflect WHO’s risk assessment of the global situation regarding each influenza virus with pandemic potential infecting humans. These assessments are made initially when such viruses are identified and are updated based on evolving virological, epidemiological and clinical data. The phases provide a high-level, global view of the evolving picture.

The global phases – interpandemic, alert, pandemic and transition – describe the spread of the new influenza subtype, taking account of the disease it causes, around the world. As pandemic viruses emerge, countries and regions face different risks at different times. For that reason, countries are strongly advised to develop their own national risk assessments based on local circumstances, taking into consideration the information provided by the global assessments produced by WHO. Risk management decisions by countries are therefore expected to be informed by global risk assessments, but based on local risk assessments.

The risk-based approach to pandemic influenza phases is represented in **Figure 1** as a continuum, which also shows the phases in the context of preparedness, response and recovery, as part of an all-hazards approach to emergency risk management. Both WHO guidance and international standards exist that describe formats and conduct of such risk assessments (see **Section 4.2**). One of the underlying principles of this guidance is to acknowledge that emergency risk management at country level needs to be sufficiently flexible to accommodate different consequences within individual countries, for example, different severities and different numbers of waves of illness.

The global phases will be used by WHO to communicate the global situation. They will be incorporated into IHR (2005) related communications to National IHR Focal Points, in Disease Outbreak News releases and various other public and media interactions, including through social media channels.

Figure 1: The continuum of pandemic phases*



*This continuum is according to a “global average” of cases, over time, based on continued risk assessment and consistent with the broader emergency risk management continuum.

Interpandemic phase: This is the period between influenza pandemics.

Alert phase: This is the phase when influenza caused by a new subtype has been identified in humans. Increased vigilance and careful risk assessment, at local, national and global levels, are

characteristic of this phase. If the risk assessments indicate that the new virus is not developing into a pandemic strain, a de-escalation of activities towards those in the interpandemic phase may occur.

Pandemic phase: This is the period of global spread of human influenza caused by a new subtype based on global surveillance. Movement between the interpandemic, alert and pandemic phases may occur quickly or gradually as indicated by the global risk assessment, principally based on virological, epidemiological and clinical data.

Transition phase: As the assessed global risk reduces, de-escalation of global actions may occur, and reduction in response activities or movement towards recovery actions by countries may be appropriate, according to their own risk assessments.

The global phases and their application in risk management are distinct from (1) the determination of a PHEIC under the IHR (2005) and (2) the declaration of a pandemic based on assessment of the risk associated with the emerging influenza virus. These are based upon specific assessments and can be used for communication of the need for collective global action, or by regulatory bodies and/or for legal or contractual agreements, should they be based on a determination of a PHEIC or on a pandemic declaration.

Determination of a PHEIC: The responsibility of determining a PHEIC lies with the WHO Director-General under Article 12 of the IHR (2005). The determination of a PHEIC leads to the communication of temporary recommendations, **see Section 2.1**.

Declaration of a pandemic: During the period of spread of human influenza caused by a new subtype, based on risk assessment and appropriate to the situation, the WHO Director-General may make a declaration of a pandemic.

While the determination of a PHEIC and/or declaration of a pandemic may trigger certain regulatory actions by WHO and Member States, as well as UN agencies under related policies of crisis and emergency management, actions at national level should be based on national/local risk assessments and be commensurate with risk.

Actions by WHO occur throughout the phases continuum; their nature and scale at any point in time will be in line with the global risk assessment. For further examples of WHO actions, see **Section 3.2**.

The nature and scale of national actions at any point in time will be in line with the current national risk assessments, taking into consideration the global risk assessment. The uncoupling of national actions from global phases is necessary since the global risk assessment, by definition, will not represent the situation in individual Member States. For further information on suggested national actions, see **Section 5**.

2.3 Pandemic Influenza Preparedness Framework

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits – widely known as the PIP Framework – brings together Member States, industry, other key stakeholders and WHO to implement a global, Member State-developed approach to pandemic influenza preparedness and response (7). The Framework aims to improve the sharing of influenza viruses with pandemic potential and to achieve, *inter alia*, more predictable, efficient and equitable access for countries in need of life-saving vaccines and medicines during future pandemics. The PIP Framework became

effective on 24 May 2011, when it was adopted by the Sixty-fourth World Health Assembly. The Framework has three core components, described below.

Virus sharing

Member States share PIP biological materials¹ to ensure on-going global monitoring and risk assessment and the development of safe and effective influenza vaccines. Standard Material Transfer Agreement 1 establishes the rights and obligations of Global Influenza Surveillance and Response System (GISRS)² laboratories when transferring PIP biological materials within GISRS and to parties outside GISRS.

Benefit sharing

Member States and WHO aim to ensure that benefits arising from the sharing of PIP biological materials are made more accessible and available to countries based on public health risk and need. Various key components are as follows:

- Standard Material Transfer Agreement 2 are binding contracts between WHO and all recipients of PIP biological materials outside of GISRS. These recipients include: influenza vaccine, diagnostic and pharmaceutical manufacturers; biotechnology firms; and research and academic institutions. Non-GISRS recipients must assess benefits they can commit, or consider committing, to the PIP benefit-sharing system based on their nature and capacity.
- Partnership contribution: An annual contribution to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers who use WHO GISRS. The Framework specifies that the contribution will be used to improve global pandemic influenza preparedness and response (8).
- Other benefits: As listed under Section 6 of the PIP Framework, other benefits include laboratory and surveillance capacity building; regulatory capacity building; and the establishment of antiviral and interpandemic vaccine stockpiles.

Governance and review

The Framework puts in place an oversight mechanism with three pillars.

1 For the purposes of the PIP Framework and its annexed Standard Material Transfer Agreements and terms of reference and the Influenza Virus Tracking Mechanism, "PIP biological materials" include human clinical specimens; virus isolates of wild-type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth reassortment. Also included in "PIP biological materials" are RNA extracted from wild-type H5N1 and other human influenza viruses with human pandemic potential and cDNA that encompass the entire coding region of one or more viral genes.

2 GISRS monitors which influenza viruses are circulating in humans around the world throughout the year. GISRS comprises WHO Collaborating Centres; National Influenza Centres; H5 Reference Laboratories; and Essential Regulatory Laboratories. The major technical roles of GISRS are to: monitor human influenza disease burden; monitor antigenic drift and other changes (such as antiviral drug resistance) in seasonal influenza viruses; obtain suitable virus isolates for updating of influenza vaccines; and detect and obtain isolates of new influenza viruses infecting humans, especially those with pandemic potential. WHO also develops logistics management capacity to ensure that public health laboratories have access to protocols, tests and diagnostic reagents necessary to identify non-seasonal influenza virus infections. (See http://www.who.int/influenza/gisrs_laboratory/en/index.html, accessed April 2013.)

- The World Health Assembly to oversee implementation of the PIP Framework.
- The WHO Director-General to promote implementation.
- The Advisory Group to provide guidance to the Director-General, monitor PIP Framework implementation and report thereon annually to the Director-General.

WHO acts as the secretariat for implementing the PIP Framework and works with private and public partners to facilitate achieving results as efficiently as possible.

Member States' responsibilities

Under the Framework, Member States are responsible for (1) ensuring the timely sharing of influenza viruses with human pandemic potential with GISRS; (2) contributing to the pandemic influenza benefit-sharing system, including by working with relevant public and private institutions, organizations and entities so they make appropriate contributions to this system; and (3) continuing the support of GISRS.

2.4 Pandemic vaccine production

WHO issues biannual recommendations on the composition of seasonal influenza vaccines. Since 2004, WHO has also been reviewing vaccine candidate viruses for A(H5N1) and other influenza subtypes with pandemic potential. This process is undertaken in consultation with WHO Collaborating Centres for Influenza, National Influenza Centres, WHO H5 Reference Laboratories and key national regulatory reference laboratories. It is based on surveillance conducted by GISRS. The recommendations and availability of vaccine viruses are announced in a public meeting and simultaneously on the WHO web site (9). They are also communicated to influenza vaccine manufacturers via the International Federation of Pharmaceutical Manufacturers and Associations and the Developing Country Vaccine Manufacturers Network.

A critical action of WHO during an emerging pandemic is the selection of the pandemic vaccine strain and of the timing for movement from seasonal to pandemic vaccine production. As soon as there is credible evidence to suggest that an influenza virus with pandemic potential has acquired the ability to sustain human-to-human transmission, WHO will expedite the process of review, selection, development and distribution of vaccine viruses for pandemic vaccine production, as well as vaccine potency testing reagents and preparations, involving all stakeholders as necessary. The efficiency of this process depends on the timely sharing of viruses and clinical specimens with WHO via GISRS and the WHO Collaborating Centres for Influenza.

Consideration of whether and when to move to pandemic vaccine production will be done in collaboration and consultation with relevant technical advisory bodies including the Strategic Advisory Group of Experts on Immunization (SAGE) and GISRS, with due consideration to applicable requirements under the IHR (2005), including any applicable advice from an IHR Emergency Committee, should one be convened. WHO may, at any stage of the process based on risk assessment, recommend that production of pandemic vaccine commence as well as virus strain that should be used in the vaccine. This may entail critical steps including switching from production of seasonal vaccine to pandemic vaccine (10, 11).

The decision to revert to seasonal vaccine production will be based on the formal recommendation for the composition of influenza vaccines, which is based on the virological and epidemiological information provided by GISRS and on the advice of relevant technical advisory bodies.

3. EMERGENCY RISK MANAGEMENT FOR HEALTH

3.1 Principles of Emergency Risk Management for Health

Health and the systems that support it are vulnerable to loss and disruption from a variety of acute hazards including: (1) health events, such as pandemic influenza, chemical spills and nuclear contamination; (2) hazards secondary to emergencies and disasters, such as cholera outbreaks following floods; as well as (3) system destabilizers, such as earthquakes or acute energy shortages. Management of the risk associated with such hazards is central to the protection and promotion of public health.

To a varying extent, risk is managed within existing health systems and via programmes focused on specific hazards. However, some functional components of hazard-specific preparedness and response systems are common to all hazards and can therefore be consolidated into a comprehensive system of emergency risk management for health (ERMH). The objectives of ERMH are to:

- strengthen country and community capacities to manage the health risks from all types of hazards (12).
- ensure that the essential components required in a comprehensive emergency risk management programme are in place in the health sector.
- link and integrate these components into (1) health systems, (2) multisectoral disaster management systems, and (3) other mechanisms across the whole of society, including relevant risk management within non-health sectors.
- enable the health sector to advocate for and strengthen the health aspects of national and international policies and frameworks related to emergency and disaster risk management, particularly in the reduction of risk and health impact from all hazards.

The emergency risk management for health continuum describes the range of measures to manage risks through prevention and mitigation, and preparing for, responding to and recovering from emergencies³. Risk management measures for any health emergency, including pandemic influenza, should be made on the basis of national and local risk assessment, taking account of the global assessment produced by WHO as appropriate.

Emergency risk management for health is based on the principles listed below.

Comprehensive risk management: A focus on assessment and management of risks of emergencies rather than events.

All-hazards approach: Use, development and strengthening of elements and systems that are common to the management of risks of emergencies from all sources.

Multisectoral approach: Recognition that all elements of government, business and civil society have capacities relevant to ERMH.

Multidisciplinary approach: Recognition of the roles of many disciplines in health are required to manage the health risks of emergencies through risk assessment, mitigation, prevention, preparedness, response, recovery and capacity strengthening.

³ For the purposes of risk management for pandemic influenza, three main groups of measures are used - preparedness, response and recovery. Prevention and mitigation are important in the context of comprehensive ERMH. They are reflected in both preparedness and response activities to be considered in national Pandemic Influenza Risk Management, Section 5.

Community resilience: Utilization of capacities at community level for risk assessment, reporting, providing basic services, risk communication for disease prevention and long-term community care and rehabilitation.

Sustainable development: Recognition that development of country and community capacities in health and other sectors requires a long-term approach to protect health and build resilience.

Ethical basis: Consideration of ethical principles throughout health emergency risk management activities.

3.1.1 Ensuring ethical Emergency Risk Management for Health

Management of an influenza pandemic, as with any urgent public health situation, requires certain decisions that balance potentially conflicting individual and community interests. For example, during the influenza A(H1N1) 2009 pandemic, countries experienced pressures on critical services that required prioritization (13) which impacted at the individual level. In addition, questions about social distancing measures, forced isolation and quarantine arose, together with debates on mandatory vaccination of health-care workers.

Ethics do not provide a prescribed set of policies; rather, ethical considerations will be shaped by the local context and cultural values. Nevertheless, it is important that any emergency measures that limit individual rights and civil liberties are necessary, reasonable, proportional, equitable, non-discriminatory and in full compliance with national and international laws (**Annex 3**) (14).

3.1.2 Emergency Risk Management for Health throughout the whole-of-society

A pandemic will affect the whole of society. No single agency or organization can effectively prepare for a pandemic in isolation, and uncoordinated preparedness of interdependent public and private organizations will reduce the ability of the health sector to respond. A comprehensive, coordinated, whole-of-government, whole-of-society approach to pandemic preparedness is required (**Annex 4**).

In the absence of effective planning, the effects of a pandemic at country level could possibly lead to social and economic disruption, threats to the continuity of essential services, lower productivity, distribution difficulties and shortages of supplies and human resources. It is therefore essential that all organizations – private and public – plan for the potential disruptions that a pandemic may cause. Business continuity planning should be considered for all essential service providers (**Annex 5**).

3.2 Emergency Risk Management for Health: essential components

The six categories of ERMH essential components are: policies and resource management; planning and coordination; information and knowledge management; health infrastructure and logistics; health and related services; and community emergency risk management capacities. A summary of the essential components in each of the categories is provided in **Table 1**.

Table 1: Essential components in each category.

| Categories | Essential components |
|---|--|
| Policies and Resource Management | <ul style="list-style-type: none"> • Policies and legislation • Capacity development strategies • Monitoring, evaluation and reporting • Financing • Human resources |
| Planning and Coordination | <ul style="list-style-type: none"> • Coordination mechanisms • ERMH units in Ministry of Health • Prevention and mitigation planning and coordination • Preparedness and response planning and coordination • Recovery planning and coordination • Business continuity management • Exercise management |
| Information and Knowledge Management | <ul style="list-style-type: none"> • Risk assessments • Early warning and surveillance • Research for ERMH • Knowledge management • Information management • Public communications |
| Health infrastructure and logistics | <ul style="list-style-type: none"> • Logistics and supplies • Safer, prepared, and resilient health facilities |
| Health and related services | <ul style="list-style-type: none"> • Health-care services • Public health measures • Specialized services for specific hazards |
| Community ERMH capacities | <ul style="list-style-type: none"> • Local health workforce capacities and community-centred planning and action |

WHO has been mandated by a series of World Health Assembly resolutions to provide Member States with guidance and technical support regarding pandemic influenza (4, 5). Some of these obligations are specific to pandemic influenza and others overlap with the Organization’s responsibilities in all health emergencies. Examples of the various functions, which are fulfilled at all levels of WHO, are provided for each category of essential component.

3.2.1 Policies and resource management

Appropriate policies, plans, strategies and legislation form the basis of effective governance of ERMH. Policies and legislation should use an all-hazards approach, i.e. one that recognizes that risk management measures for hazard-specific emergencies have common elements and should cover the ERMH continuum through prevention and mitigation, preparedness, response and recovery.

Legislation should clearly articulate procedures for declaring and terminating a national public health emergency, based on national risk assessment. It should also define emergency management structures across the government national emergency/disaster management authority and should articulate the precise roles, rights and obligations of different organizations during a health emergency, based on an ethical framework to govern policy development and implementation. National legislation should be consistent with legally binding international agreements and conventions. Policies specific to the health sector should be compatible with legislation and should include defined roles and responsibilities,

procedures and standards of implementation of ERMH. Policies and mechanisms to finance all ERMH activities need to be considered.

This category of essential components also includes the management of human and material resources. A human resource plan should be developed and should contain the staffing requirements for the management of health emergencies and define the competencies needed. These plans should also specify the roles, responsibilities and authorities of the responders with written terms of reference for each specific function.

Capacity development is central to ensure that the health workforce is well equipped to implement ERMH. These efforts should be systematic and start with a thorough capacity assessment and analysis of training available for different target groups (15). Based on these analyses, training programmes that are appropriate, effective and efficient should be developed and instigated within educational institutions and as continuing professional development for the workforce.

Role of WHO in supporting policies and resource management

- Provide support to assess, strengthen and maintain core capacities in order to meet IHR (2005) obligations (16).
- Provide technical support to document the disease burden and economic impact of seasonal influenza and develop a national vaccine policy, if indicated.
- Advise on ethical frameworks to govern policies.
- Provide support and guidance to strengthen workforce capacities, e.g. health-care worker training.
- Strengthen GISRS and other laboratories to increase influenza diagnostic and surveillance capabilities and provide technical support, capacity building and technology transfer for influenza vaccines and diagnostics.
- Promote the increase of global production capacity for pandemic vaccines in developing countries, though the Global Action Plan for Influenza Vaccines (GAP) (17).

3.2.2 Planning and coordination

The health sector should be properly represented at all levels of government in any emergency/disaster risk management coordination forum to ensure that health needs are identified and technical advice is provided to other sectors. One of the roles of these fora will be to develop and strengthen appropriate command and control systems across the national disaster management authority, within each government ministry and at subnational levels. Another important role of these fora is to ensure that the most current evidence is available to inform policy decisions.

In addition, an operational entity within the Ministry of Health or related institution should be responsible for coordinating and supervising emergency risk management implementation throughout the health sector, with stakeholder involvement. Similar entities should be in place at all subnational and local administrative levels.

Prevention and mitigation actions for any risk should be determined following a detailed risk assessment and be included in ERMH programmes at the national and subnational levels. The implementation of prevention, mitigation and preparedness measures should be coordinated with relevant technical departments inside the Ministry of Health and with the whole of government, business and civil society (**Annex 4**).

Effective coordination should be integral to all aspects of the response, starting with the initial risk assessment and including: the development of short- and long-term action plans; the assignment of resources to priority needs; and the provision of urgent community care and support. Incident management systems may be considered to facilitate the coordination under a common management structure. ERMH processes should be well documented in contingency plans and should include standard operating procedures that are appropriately disseminated, regularly exercised and updated .

Recovery needs to be an integral part of response planning and should be done in parallel with other risk management actions, i.e. well in advance of an emergency. Sufficient attention should be given to recovery planning for the health sector.

Role of WHO in planning and coordination

- Consistent with the whole-of-society, whole-of-government approach required for robust risk management for pandemic influenza, advocate collaboration and coordinate prioritized activities with organizations of the UN system, bilateral development agencies, nongovernmental organizations, the private sector and stakeholders in non-health sectors.
- Establish joint initiatives for closer collaboration with national and international partners in (1) early detection, reporting and investigation of influenza outbreaks of pandemic potential and (2) coordination of research on the human–animal ecosystem interface.
- Collaborate with the animal health sector, e.g. the Food and Agriculture Organization of the United Nations and the World Organisation for Animal Health, on preparedness, prevention, risk assessment and risk reduction mechanisms to decrease exposure of humans to influenza viruses at the human–animal ecosystem interface.
- Promote agreements for international technical assistance, resource mobilization and fair sharing of influenza products such as through the UN prequalification programme, Essential Medicines List and the PIP Framework (7, 18, 19).
- Provide guidance and/or technical support to Member States in the preparation of pandemic influenza risk management plans and in identifying priority needs and response strategies and assessing preparedness.
- Facilitate regional/cross-border collaborations.

3.2.3 Information and knowledge management

Information and knowledge management encompasses technical guidance for risk management, communications and early warning and surveillance, which are highlighted below, as well as risk assessment (see **Section 4.1**), research for emergency risk management and information management.

3.2.3.1 Technical guidance

Practitioners should be provided with practical technical guidance on all aspects of ERMH. This guidance should include clinical and operational management of the event.. Continuity of health-care provision strategies should be periodically updated, as well, to reflect new research findings and lessons learnt from past health emergency events.

3.2.3.2 Communication

Effective and efficient communication is critical throughout the ERMH continuum and includes information dissemination within the health sector, between health and other sectors and, crucially, with the public.

In risk communication, national and local government authorities provide information to the public in an understandable, timely, transparent and coordinated manner before, during and after a health emergency. The objectives are to develop and maintain public trust in local and national health systems and to convey realistic expectations about capacities for health emergency risk management. Risk communication also promotes the effective exchange of information and opinion among science, public health and veterinary experts, which facilitates the assessment, implementation and coordination of risk management activities.

A communications strategy involves processes to collect, develop and distribute information in a timely manner and procedures to ensure that formats are appropriate to the target audiences. The strategy should take into account behavioural aspects of how people react to, and act on, advice and information they receive, not only from authorities but also from sources such as mass and social media. Public understanding of hazards and risks is complex, context-dependent and culturally mediated, thus communications strategy development may benefit from community participation (20).

ERMH plans and activities across all hazards should use the principles of risk communication to build the capacity to understand and anticipate public concerns and develop effective and responsive dialogue mechanisms. This can be achieved through an emergency communications committee that has developed and tested standard operating procedures to ensure streamlined, expedited dissemination of information for decision-making and public communication.

3.2.3.3 Early warning and surveillance

Accurate timely information is one of the most valuable commodities during a health emergency or disaster. This information serves as the evidence base for critical decisions at all levels of administration and defines the messaging for public communication and education. An effective system, with minimal data sets of information required throughout the management of an emergency, should be developed and tested in preparation for a response.

The systems required for early warning and surveillance should be robust and enable the capture of data required for assessment of severity, the implementation of protocols for operational research, including efficacy studies on interventions applied, and assessments of national impact based on criteria such as workplace and school absenteeism, regions affected, groups most affected and essential worker availability.

Role of WHO in information and knowledge management

- Provide guidance and/or technical support to Member States on identifying priority needs, prevention, mitigation and response strategies to support preparedness planning.
- Facilitate development of national guidelines for relevant activities such as targeted vaccination campaigns, laboratory biosafety and safe specimen handling/shipping.
- Promote public health research priorities relevant to all resource settings for pandemic, non-seasonal and seasonal epidemic influenza over the medium- to long-term period via the WHO Public Health Research Agenda for Influenza (21).
- Provide support and guidance on capacity building for health systems (22), infection prevention and control in health-care settings (23), surge capacity and national vaccine deployment (24).
- Assess and monitor the type and pathogenicity of circulating influenza viruses through information provided through GISRS.

[21]

- Provide technical guidance and advice to support Member States to develop effective and responsive pandemic communications, including risk communication and behavioural interventions messaging (25).
- Provide guidance, technical support and tools for detection, investigation, rapid risk assessment and reporting (26).
- Provide technical support and information to national authorities:
 - to enhance surveillance and collection of clinical, virological and epidemiological data to facilitate assessment of the extent of human-to human transmission and the epidemiological situation;
 - on risk assessment of clusters of influenza-like illness; and
 - on interventions to reduce the spread of influenza disease.
- Define standards for initial case investigations and for routine sentinel surveillance.
- Establish and refine global case definitions for reporting by countries of human cases of influenza caused by viruses with pandemic potential.
- Coordinate and disseminate relevant public health messages through channels such as the WHO web site, published materials, press conferences and social media.
- Provide regular and timely feedback on the results of the analysis of data reported by Member States to WHO.
- Periodically reassess and modify recommended interventions in consultation with appropriate partners, including those outside the health-care sector, on the acceptability, effectiveness and feasibility of interventions.
- Provide principles and update guidance for appropriate: infection prevention and control; laboratory biosafety (27); clinical management in health-care facilities and home-based care (28); use of antivirals; and use of seasonal and pandemic vaccines.

3.2.4 Logistics and infrastructure

Effective management of health emergencies requires access to and management of adequate infrastructure and logistics, the most important of which involve transportation, telecommunications, stockpiling and distribution of medicines and supplies, and establishment of temporary health facilities. To ensure that logistic support will be available during health emergencies, the Ministry of Health should consider making advance arrangements with government departments responsible for transport, communications, public works and the armed forces together with external agencies, such as nongovernmental organizations, UN agencies and private companies. The type and quantity of supplies and medicines will be determined by the nature of the hazard. The most critical supplies for pandemic influenza are those needed to prevent and treat the disease and its complications while maintaining critical non-influenza health services.

The Ministry of Health or the central coordinating body could also consider identifying, supporting, training and deploying operational and logistics response teams.

Role of WHO in supporting health infrastructure and logistics

- Manage the WHO strategic global stockpile of antivirals, and access to pandemic vaccines under the Standard Material Transfer Agreement 2 under the PIP Framework. Relevant standard operating procedures will be developed to ensure rapid deployment of these strategic public health supplies. As appropriate, reference will be made to the **“Guiding Principles for use of PIP Partnership Contribution “Response” Funds”** dated 23 October 2014
http://www.who.int/influenza/pip/guiding_principles_pc_response_funds.pdf?ua=1.

- Develop logistics management capacity to ensure that public health laboratories have access to protocols, tests and diagnostic reagents to be able to identify non-seasonal influenza virus infections (29).

3.2.5 Health and related services

Regardless of the nature of a health emergency challenge faced, health and related services will need to be provided to the affected population to save lives, manage public health, prevent secondary effects and maintain essential non-hazard-related emergency services. While many of these health services do not differ from services provided in non-emergency situations, their organization and delivery may change significantly during a health emergency. This will require thoughtful planning beforehand. Health services related to triage, emergency care and maintenance of non-influenza acute care are among the many specified services requiring effective planning for implementation during a pandemic. Examples include activating contingency plans for health and laboratory facilities to deal with potential staff shortages, adjust triage systems as required and implementing mortuary management procedures as necessary.

In addition to service provision and public health measures, this essential component also includes identifying priorities and response strategies for public and private health-care systems triage and surge capacity. Surge capacity should be planned in advance for different scenarios with predetermined procedures for mobilizing staff on short notice. Mechanisms for ensuring adequate human resources for long-term events, such as an influenza pandemic should be considered, including planning for staffing of alternative care facilities for cohorting influenza patients, based on national plans. It is also important to consider ensuring that health-care workers have the opportunity for rest and recuperation.

Role of WHO in supporting health and related services

- Provide advice and technical guidance on organization and delivery of health and related services, e.g. laboratory services, blood services, non-pharmaceutical measures and mass casualty management systems.
- Utilize existing clinical networks to review clinical information and effectiveness and safety of clinical interventions.
- Provide advice on measures for controlling international disease spread through temporary recommendations issued under IHR (2005).
- Support health system capacity assessments for emergency risk management (15).

3.2.6 Community capacities

Community capacities are a vital component of ERMH. The community-based health workforce is a crucial front line for ERMH activities and has the language and cultural skills to implement effective local ERMH activities, including social mobilization. This workforce may include appropriately trained and accredited community health workers, trained volunteers, community-based organizations that promote health, health education and social mobilization, and those from key sectors (water, sanitation, hygiene, agriculture, food security, shelter and education) that contribute to promoting health. Developing local action plans based on national plans for any hazard is also an important consideration for strengthening community capacities.

Role of WHO in supporting community capacities

- Promote the role played by the community-based health workforce in emergency risk management and advocate for the scale-up of this vital resource (30).
- Advise on strengthening community-based health workforce programmes, including recruitment, training, supervision, evaluation, deployment and retention (31).
- Provide guidance on training community health workers (32).
- Provide advice and guidance on community community-level response activities during an influenza pandemic. (22).

4. NATIONAL PANDEMIC INFLUENZA RISK ASSESSMENT

4.1 Influenza viruses and pandemics

Influenza, a viral respiratory disease, can cause high morbidity and mortality in humans and is known to affect some animal species. Clinical disease can range from mild to severe and in some cases result in death. While influenza B remains a human disease, influenza A viruses are found in human, avian and some mammalian species. An influenza pandemic occurs when an influenza A virus to which most humans have little or no existing immunity acquires the ability to cause sustained human-to-human transmission leading to community-wide outbreaks. Such a virus has the potential to spread rapidly worldwide, causing a pandemic.

Past pandemic influenza viruses have been reported to arise through either (1) genetic reassortment: a process in which genes from different influenza viruses combine to create a strain with a new complement of genes, (2) genetic mutation: a process in which genes in an animal influenza virus change allowing the virus to infect and transmit easily in humans, or (3) some combination of both. Gaps in the virological record have meant that it has not been possible to determine exactly which of these processes have occurred nor their order. As influenza viruses are unpredictable, it is uncertain what combination of changes will allow the next pandemic influenza virus to emerge. Influenza pandemics are unpredictable but recurring events that can have significant global consequences. Since the 16th century, influenza pandemics have been described at intervals ranging between 10 and 50 years with varying severity and impact. Characteristics of the past four pandemics are summarized in **Table 2**.

Table 2: Characteristics of the past four influenza pandemics (33)

| Pandemic year of emergence and common name | Area of origin | Influenza A virus subtype (type of animal genetic introduction/recombination event) | Estimated reproductive number (34, 35) | Estimated case fatality | Estimated attributable excess mortality worldwide | Age groups most affected (36) |
|--|----------------|---|--|-------------------------|---|-------------------------------|
| 1918 "Spanish flu" | Unclear | H1N1 (unknown) | 1.2–3.0 | 2–3% (37) | 20–50 million | Young adults |
| 1957–1958 "Asian flu" | Southern China | H2N2 (avian) | 1.5 | <0.2% | 1–4 million | All age groups |
| 1968–1969 "Hong Kong flu" | Southern China | H3N2 (avian) | 1.3–1.6 | <0.2% | 1–4 million | All age groups |
| 2009 -2010 "influenza A(H1N1) 2009" | North America | H1N1 (swine) | 1.1–1.8 (38) | 0.02% (39) | 100 000–400 000 (40) | Children and young adults |

In June 2009, WHO declared the first influenza pandemic of the 21st century after the emergence of the new A(H1N1)pdm09 virus subtype. This virus was first isolated from humans in Mexico and the United States of America in April 2009. Within a few weeks, the virus had spread rapidly, and there was sustained human-to-human transmission worldwide. The triple-reassortant virus contained a unique combination of gene segments from avian, swine and human influenza viruses. Risk factors for severe influenza A(H1N1)pdm09

disease were similar to those for seasonal influenza, e.g. pregnancy and many chronic medical illnesses, although younger age groups were more affected than usual.

Prior to 2009, much of the focus on influenza viruses with pandemic potential was on the avian influenza subtype A(H5N1). A human outbreak of avian influenza A(H5N1) was detected in 1997 in Hong Kong SAR, China. This was the first recognized instance in which a highly pathogenic avian influenza virus had been transmitted to humans and resulted in serious illness. Since its widespread re-emergence in 2003–2004, this avian virus has resulted in millions of poultry infections and over 800 human cases. On rare occasions, limited human-to-human transmission of influenza A(H5N1) has occurred – most often to a family or other household member acting as a caregiver. However, none of these events has so far resulted in sustained community-level transmission.

Most animal influenza viruses do not cause disease in humans. However, viruses circulating in animals or derived from viruses circulating in animals have caused infections in humans, including avian and swine viruses and reassortants, notably of the H1, H3, H5, H7, H9 and H10 subtypes. Most of these human infections have been sporadic and the viruses have not spread further among people.

Humans generally acquire these infections through direct contact or close exposure to infected animals or contaminated environments. Control of influenza among animals is therefore essential to reduce the risk of human infection, to reduce the potential for pandemic strains to evolve and to prevent or reduce the economic consequences to the animal industry. Successfully meeting this challenge requires long-term commitment from countries and strong coordination between animal and human health authorities and practitioners.

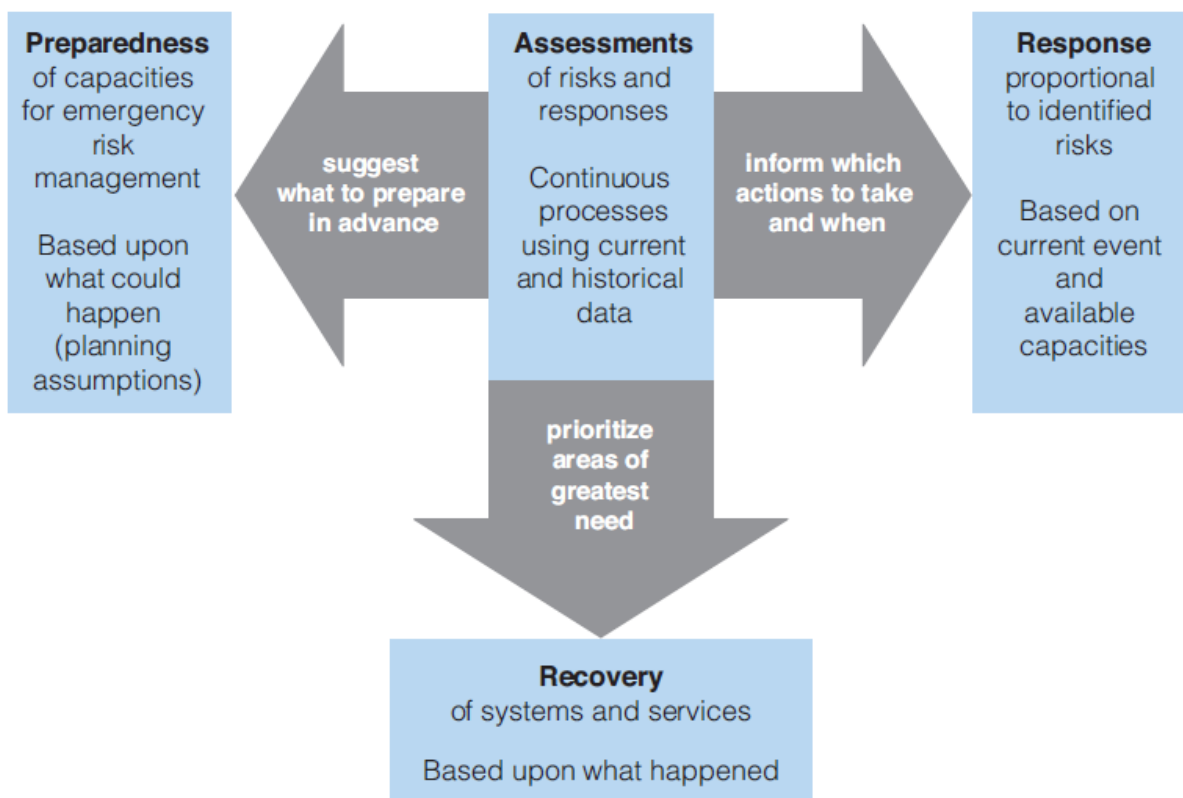
Experience with the emergence of such a variety of different influenza strains that transmit from animals to humans illustrates the highly unpredictable nature of influenza viruses such that assumptions about where the next influenza virus with pandemic potential will emerge, or what its characteristics will be, cannot easily be made. This uncertainty underscores that planning should not focus only on avian influenza but should be based on broad and robust surveillance and evidence-based risk assessment.

4.2 National risk assessments

Risk assessment is a systematic process for gathering, assessing and documenting information to assign a level of risk (26). Risk assessment aims to determine the likelihood and consequences of events that impact on public health at global, national, subnational and local levels. It provides the basis for taking action to manage and reduce the negative consequences of risks to public health.

Risk assessment is a systematic process for gathering, assessing and documenting information to assign a level of risk (26). Risk assessment aims to determine the likelihood and consequences of events that impact on public health and development objectives at global, national, subnational and local levels. It provides evidence-based information for decision-making to manage and reduce the negative consequences of risks to public health and it facilitates the communication of risks and uncertainties to the public. In an all-hazards approach, risk assessments can be performed to identify and prioritize preparedness, including mitigation and prevention, activities and response and recovery programmes, as illustrated in **Figure 2**.

Figure 2: Pivotal role of risk assessment in preparedness, response and recovery actions



For each influenza virus with pandemic potential, WHO will conduct global risk assessments in collaboration with the affected Member State(s), to inform decision-making for risk management (41). While WHO will communicate these global assessments and the uncertainties that surrounds them throughout the event, each Member State is strongly advised to assess national risk related to pandemic influenza in the context of their local experience, resources and vulnerabilities. Member States are also encouraged to share their risk assessments through networks or multilateral arrangements and to utilize regional resources for risk assessment.

At any point in a pandemic, one or many Member States may be responding to a national-level epidemic, while other Member States may not be affected for some months to come. Consequently, each Member State is encouraged to conduct its own risk assessments, which will determine the timing, scale, emphasis, intensity and urgency of the actions required at their national and local levels. More information on suggested national actions is provided in **Section 5**.

National pandemic influenza risk assessment should involve a multidisciplinary team representative of the whole of government, together with stakeholders, and linked to relevant decision-makers. Since pandemic risk assessment has similar components across the whole of society, it should be conducted collaboratively with stakeholders at national, subnational and local levels.

A risk assessment considers hazard, exposure and context coupled with risk characterization. A hazard assessment relevant to pandemic influenza includes: identifying influenza viruses of concern; reviewing key

virological and clinical information about each influenza virus; and ranking them by pandemic potential and possible consequences.

An exposure assessment seeks to define the groups of individuals known to have been, or likely to be, exposed to an influenza virus of concern and to delineate the susceptibility of these groups in terms of immunity and disease severity. This process incorporates epidemiological and susceptibility factors such as travel history, incubation period and estimation of potential for transmission.

These two assessments are then complemented by a context assessment. A context assessment is an evaluation of the environment in which the event takes place. It examines factors that affect risk, including: social; technological and scientific; economic; ethical; and policy and political factors, see **Table 3**.

Table 3: Factors to consider in context assessments

| Factor | Examples |
|---------------------------------|---|
| Social | <ul style="list-style-type: none"> • population size and characteristics such as distribution of high-risk groups • behaviours • impact of seasonal influenza • impact on lifestyle, e.g. acceptability and applicability of any social distancing recommendations |
| Technical and scientific | <ul style="list-style-type: none"> • ability to implement surveillance and mitigation activities • the likelihood that all suspect cases can be identified • the availability of mechanisms to reach specific high risk groups • the availability and acceptability of effective preventive measures and of treatment or supportive therapies |
| Economic | <ul style="list-style-type: none"> • direct and indirect financial costs including: <ul style="list-style-type: none"> ○ household income ○ hospitalization costs • potential impacts on tourism and trade • impact on business continuity of essential services |
| Ethical | <ul style="list-style-type: none"> • privacy issues • use of unlicensed products • transparency • unequal risk burden • potential requirements for the protection of critical infrastructure |
| Policy and political | <ul style="list-style-type: none"> • likely response of key stakeholders and media • government capacity to participate in risk management efforts • the country's recent experience with influenza • past and ongoing emergencies with implications for future hazards, vulnerabilities and capacities. |

Once the hazard, exposure and context assessments are conducted, the risk can be characterized. Risk characterization seeks to organize the assessments into a determination of likelihood and impact of each risk. In the context of pandemic influenza, risk characterization employs these assessments to evaluate whether a particular influenza virus has pandemic potential and the degree to which such an event will impact on society, and, consequently, the urgency and scale of risk management actions to be implemented.

Throughout the risk assessment process, the uncertainty for each part of the assessment should be recorded and shared by the evaluating team. This documentation should include an overview of the basis for each assessment to ensure ongoing consistency in risk assessment processes.

Risk assessment is a continuous process throughout the risk management continuum. Member States are encouraged to conduct risk assessments at the national, subnational and local levels, in order to prioritize the development of risk management programmes tailored to the hazards present.

4.3 Assessment of pandemic severity

Gauging the severity of an influenza pandemic – a critical component of overall pandemic risk assessment – is an important consideration for WHO and Member States in planning for and responding to a pandemic. Early information about severity can help support decision-making at global and country levels. As a pandemic spreads from country to country, data derived from existing influenza disease and virological surveillance, coupled with field investigations and other data sources, can be used to adjust global and national responses. Some of these data-collection processes are provided through existing WHO guidance and related resources (42).

Early assessments in countries first affected by human infection with a new influenza subtype will inform the global community. However, each country's context and pandemic-influenza-related severity will differ, requiring careful evaluation not only of the data reported but the capacities, demographics and other features of the country in which the observations are made. In addition, continual severity assessments will be necessary over the course of a pandemic since the accuracy and precision of severity-related information will change.

Severity assessments should be conducted at the community, national and global level. Each of these assessments will enable refinement of risk assessments at the other levels. As when conducting other components of risk assessments, a country may measure a severity parameter directly, do so with the assistance of an external partner or rely on applicable information from others. For example, during the influenza A(H1N1) 2009 pandemic, informal networks of experts in epidemiology, clinical medicine, virology and mathematical modelling shared preliminary information with WHO to enable a global assessment of severity.

To be useful, the severity assessments should be done when public health decisions are needed. To that end, a risk assessment, incorporating severity, should provide as much information as possible to answer the following key questions about an emerging pandemic.

- How rapidly are new cases accruing?
- What types of illnesses and complications are being seen?
- What groups of people (e.g. age groups or groups at risk of severe outcomes) will become severely ill and die?
- Is the virus sensitive to antiviral agents?
- How many people will become ill?
- What will be the impact on the health-care sector, including such factors as health-care utilization and impact on the health-care work force?

Operationally, these questions will help guide decisions regarding vaccine production and strategy for usage, antiviral use, mobilization of health-care resources, school closures and other social distancing strategies.

The data that answer each of these key questions will be considered in the context of three indicators. Each of these indicators will contain information derived from a variety of different types of data, including virological, epidemiological, and clinical. The data will be grouped into the following indicators to help make them more accessible and understandable to the public and policy makers.

Transmissibility: Reflects the ease of movement of the virus between individuals, communities, and countries. The factors that will go into describing transmissibility include both virological factors and epidemiological observations. As with all of the indicators, the values of each of the observations or

measurements that are used to reflect transmissibility will be interpreted in the context where they are made as they will be influenced by social and climatic factors.

Seriousness of Disease: A pandemic virus that has a high level of clinical severity can result in a disproportionate number of persons with serious or grave illness, some of whom will die in the absence of effective treatment or adequate clinical management. However, the severity or virulence of a virus will also depend on the presence of underlying medical conditions that predispose individuals to severe illness, as well as age. An infection is likely to be much more severe for some segments of a population than others and descriptions of the groups at risk will be part of this indicator.

Impact: If the health-care sector and other critical essential services are impacted at a high level it may not be able to accommodate the stress on its resources. The impact on the health sector will also be influenced by public concern and health-care policies put in place in response to the event. As such, assessing impact will aid in understanding how these issues interact with inherent characteristics of the virus and the way it behaves.

Examples of representative parameters for each indicator are provided in **Annex 6**. As appropriate, some of these data may also be communicated directly to policy-makers and planners. WHO will communicate with its geographically and technically diverse group of staff, networks and external experts to help interpret the available qualitative and quantitative data provided through national severity assessments. The severity assessments must be flexible in order to accommodate unforeseen characteristics of the pandemic as it evolves (e.g. a new indicator could be included or a known one excluded).

Any severity assessment plan has inherent limitations. Assessments are dependent upon the data available. Data first must be sought, then found, collected, shared, analyzed and communicated. Resource availability and competing interests may impede any of these steps and the ways in which these steps proceed will affect the validity of the data. Even under the best operational circumstances, data must accumulate over time before accuracy can be achieved. The case-fatality ratio, a commonly sought and communicated severity-related parameter, is well reported to have significant variability over the course of a pandemic and is not useful in the very early stages of an event because it is likely to be inaccurate and misleading (43, 44). In these very early stages, the proportion of known cases requiring mechanical ventilation, for example, might be used instead of the case-fatality ratio.

Severity varies within a population owing to a variety of risk factors (45). Population risk factors in terms of community resilience have not been carefully studied. However, general health status, availability of resources, including health-care services and medications, and cultural dynamics that affect transmission and care-seeking are likely to be relevant and will complicate comparisons between populations. As such, WHO will attempt to interpret the observations described above in the context in which they are made and project how they might affect subsequently affected Member States whose context is different. To do this, it will be necessary to communicate a wide variety of data to describe the full profile of the event. These considerations further increase the need for severity assessments to occur in the context of robust risk assessments. Further information on the representative parameters for core severity indicators is provided in **Annex 6**.

5. NATIONAL PANDEMIC INFLUENZA RISK MANAGEMENT

Individual countries may be exposed to the pandemic influenza virus at different times, have different case and case fatality rates, surveillance and response capacities, and vulnerabilities. They may experience different numbers and severities of waves of illness arising from the pandemic virus. Therefore, flexibility must be embedded in planning such that movement between the groups of activities below can be done with agility to reflect the national situation and meet local needs. For example, activities in the recovery period may need to be supplemented, as necessary, by response actions, should there be a subsequent pandemic wave. Mechanisms must be in place to enable this flexibility and for national emergency response procedures to be implemented – as guided by national risk assessment – irrespective of the global phase.

The following national actions are grouped by the six categories of essential components of ERMH (**Table 1**) and are indicative of actions to be considered following risk assessments. The degree of implementation should be commensurate with the degree of risk, national priorities and needs. These suggested national actions are intended to build on the progress made in developing and strengthening existing systems. Programmes to develop and implement activities at local level based on local risk assessments, resources and needs should be coordinated and consistent with national plans, policies and legislation.

5.1 Policy and Resource Management

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Review or develop national pandemic risk management programmes, including preparedness activities and response plans, and establish, as needed, the full legal authority and legislation required to sustain and optimize pandemic preparedness, capacity development and response efforts across all sectors.
- Perform forecasts of the national economic impact of a pandemic and cost-effectiveness of preparedness to advocate for funding and to aid risk management planning.
- Integrate pandemic risk management plans into existing national emergency risk management programmes.
- Establish goals and priorities for the stockpiling and use of pandemic influenza vaccines and antiviral drugs.
- Explore ways to provide drugs and medical care free of charge (or cover by insurance) to encourage prompt reporting and treatment of human cases caused by a non-seasonal influenza virus or virus with pandemic potential.
- Strengthen and maintain capacities to detect, assess, notify and report events, the capacity to respond promptly and effectively and the capacities at designated points of entry relating to the identification and management of pandemic risks in accordance with IHR (2005) Annex 1A and 1B.2.
- Advise subnational and local governments on best practices in pandemic planning and implement a quality control system to regularly monitor and evaluate the operability and quality of local and regional plans.
- Develop procedures for access to and timely allocation of resources for preparedness, capacity development and intervention implementation at national and subnational levels, including activities to be fulfilled by humanitarian, community-based or nongovernmental organizations.
- Create a national roster of experts to provide high-level technical advice in areas such as ethics, risk assessment, infection prevention and control, respiratory diseases and emergency management.
- Assess existing capacities and identify priorities for pandemic risk management at national and subnational levels.

- Develop strategies, plans and training to enable all health-care workers, including community-level workers, to respond during influenza outbreaks and throughout a pandemic (31).
- Develop occupational health policies for essential services workers and develop guidance and policies to enable workers to stay home when ill.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Prioritize and guide the allocation and targeting of additional human and material resources to achieve the goals of pandemic risk management plans.
- Assess whether international assistance is required to meet humanitarian needs. Alternatively, consider providing resources and technical assistance to countries experiencing outbreaks of influenza with pandemic potential (46).

Consider activation or deactivation of specific legislation or procedures, based on pre-determined national-level triggers.

Recovery activities to be considered

Review the lessons learnt about policies and resource management and revise national and subnational pandemic risk management plans; encourage stakeholders across all public and private sectors to do likewise. Implement mechanisms for restocking of resources.

5.2 Planning and coordination

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- If not already in place, consider appointing a cross-governmental, multi-agency national pandemic risk management committee. Suggested activities of this committee could include the following:
 - Develop, exercise (47) and periodically revise national and subnational pandemic risk management plans in close collaboration with all relevant public and private partners. Review subnational pandemic plans against the national plan and involve subnational and local representatives in testing interoperability.
 - Provide the key assumptions, guidance and relevant information to promote development of pandemic business continuity plans and strategies for public and private sector workplaces (**Annex 5**).
 - Lead and coordinate multisectoral resources to mitigate the societal and economic impact of a pandemic (**Annex 4**).
 - Consider planning for containment measures (**Annex 7**).
- Planning and coordination activities of the Ministry of Health entity responsible for ERMH could include the following activities:
 - Identify, brief regularly and train key personnel to be mobilized as part of a multisectoral expert response team for influenza outbreaks of pandemic potential.
 - Encourage collaboration with neighbouring countries on aspects of pandemic preparedness planning that may have regional or cross-border implications through information sharing, participation in

regional and international initiatives, exercises and coordination of responses to address trans-border issues including interoperability of plans.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Update leadership and other relevant sectors on global and national pandemic influenza risk assessments.
- Provide the key assumptions, guidance and relevant information to public and private sectors to facilitate implementation of their pandemic business continuity plans.
- Finalize preparations for an imminent pandemic by activating national and subnational command and control systems.
- Activate pandemic contingency planning arrangements for the health sector and all sectors deemed critical for the provision of essential services.
- Switch to pandemic working arrangements.
- Respond, if possible, to requests for international assistance by offering resources and technical assistance to countries with ongoing pandemic activity.
- Collaborate with neighbouring countries on information sharing.
- Provide regular updates on the evolving situation to WHO and other partners to facilitate response coordination.
- Review and, if necessary, revise pandemic risk management plans to manage possible future pandemic wave(s).
- Evaluate the resources and capacities needed to monitor and respond to subsequent waves.

Recovery activities to be considered

Review the lessons learnt about planning and coordination across all sectors and share experiences with the international community. Review and, if necessary, revise pandemic risk management plans to manage a possible future pandemic.

5.3 Information and knowledge management

5.3.1 Technical guidance

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop and disseminate guidance on all aspects of pandemic response including: clinical management; prevention and control of health-care associated infections; surveillance throughout the pandemic; public health measures; surge capacity; and management of non-influenza acute care patients.
- Establish linkages with, and consider developing rosters of experts, for example, academics, health professional groups, who could be engaged in developing technical guidance. Similarly, develop and maintain lists of stakeholders to facilitate the dissemination of technical guidance.
- Anticipate the need for rapid revision and dissemination of guidance, e.g. new laboratory protocols as the diagnostics for the new strain become available.

- Develop and maintain lists of stakeholders to facilitate the dissemination of technical guidance and test guideline dissemination mechanisms. Develop case-finding, treatment and management protocols/algorithms.
- Provide guidance to health-care workers to test and report cases of suspected pandemic influenza infection in patients with respiratory illness, especially those who have travelled to an affected country/countries or their close contacts.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Update, if necessary, national guidance and recommendations on the use of planned interventions taking into account information from affected countries.
- Update, if necessary, laboratory protocols for virus detection, identification, shipping and sharing with WHO Collaborating Centres for Influenza.
- To the extent possible, use standardized protocols to monitor safety, efficacy and supply of pharmaceutical interventions.
- Revise case definitions and diagnostic and treatment protocols/algorithms, as required.

Recovery activities to be considered

Communicate to the public and other stakeholders the lessons learnt about the effectiveness of policy and technical guidance during the pandemic and how the gaps discovered will be addressed. Evaluate guidance dissemination mechanisms and work with professional associations towards improvement. In addition, analyse data collected during the event for dissemination and consider revising the national risk assessment algorithms.

5.3.2 Communications

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop effective strategies to inform, educate and communicate with individuals and families to improve their ability to take appropriate actions before, during and after a pandemic.
- Identify appropriate spokespeople.
- Identify communications channels and assess their ability to reach all target population groups. Develop protocols and provide training to spokespeople for each communication channel.
- Pre-test messages through each medium, including social media, and test communications procedures through exercises.
- Build effective relations with key journalists and familiarize them with influenza and pandemic related issues.
- Develop communication strategies to support the implementation of non-pharmaceutical interventions including restrictions on mass gatherings and school closures.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Provide regular briefing updates to all spokespeople to ensure that the information conveyed is consistent and up-to-date.
- Conduct frequent and pre-announced public briefings through popular media outlets such as the web, television, social media and radio to counter panic and dispel rumours.
- Activate mechanisms to ensure the widest possible dissemination of information. Topics likely to require regular communication include :
 - What is known and not known about the virus, the state of the outbreak, use and effectiveness of measures and likely next steps.
 - What is known and not known about the pandemic disease, including transmission patterns, clinical severity, treatment and prophylaxis options.
 - The importance of compliance with recommended measures to stop further spread of the disease.
 - Societal concerns, such as the disruption to travel, border closures, school closures and the impact on the economy or society in general.
 - Sources of emergency medical care, resources for dealing with urgent non-pandemic health-care needs, and resources for self-care of medical conditions.
 - Any changes to the status of the pandemic.
 - The ongoing need for vigilance and disease-prevention efforts to prevent any upswing in disease levels.
 - Advice for travellers.
- Ensure effective communication of public health measures to reduce the spread of pandemic influenza, e.g. hand and respiratory hygiene, reduction of unnecessary travel and overcrowding of mass transport systems, self-isolation for sick individuals, except their nominated caregiver, and minimization of contact with others.
- Gather feedback from the general public, vulnerable populations and at-risk groups on attitudes towards the recommended measures and barriers affecting their willingness or ability to comply.
- Update communications strategies as feedback from the general public and stakeholder organizations is collected and analysed.

Recovery activities to be considered

Publicly acknowledge the contributions of all communities and sectors to the pandemic effort. Review the lessons learnt about communications and revise in readiness for the next major public health event. Communicate that the event may be over but that a second (or subsequent) wave(s) is/are possible and that the pandemic virus will revert to a seasonal pattern and be present as one of the circulating viruses for some time to come.

5.3.3 EARLY WARNING AND SURVEILLANCE

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Ensure that mechanisms are in place for meeting obligations under IHR (2005) to detect, assess, notify and report events. Such mechanisms include the capacities to respond promptly and effectively and

requisite capacities at designated points of entry relating to the identification and management of pandemic risks in accordance with IHR (2005) Annex 1A and 1B.2.

- Develop or strengthen national surveillance to collect up-to-date virological, epidemiological and clinical information on trends in human seasonal influenza infections to aid estimates of additional capacities needed to detect increases in pandemic activity.
- Enhance virological and epidemiological surveillance to detect and investigate unusual cases/clusters of influenza-like respiratory illness or deaths associated with non-seasonal influenza viruses, identify potential animal sources of human infection; and assess the risk of human-to-human transmission.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Undertake a comprehensive assessment of the earliest national cases of pandemic influenza.
- Ensure that, as required under the IHR (2005), any notification is followed by ongoing communication to WHO of timely, accurate and sufficiently detailed public health information on the event, including, where possible, case definitions, laboratory results, source and type of risk, number of cases and deaths, conditions affecting the spread of the disease and the public health interventions employed.
- Collect and analyse available data to evaluate the virological, epidemiological and clinical characteristics of the national epidemic.
- Modify national case definitions and update clinical and laboratory algorithms for diagnosis, as necessary.
- Collect specimens for testing and virological characterization using protocols and procedures developed in collaboration with WHO.
- Document the evolving national epidemic including population susceptibility, changes in epidemiological and clinical features, geographical spread, trends and impact.
- Collect more detailed epidemiological and clinical data as time and resources permit.
- Maintain adequate virological surveillance to detect antigenic and genetic changes and changes in antiviral susceptibility and pathogenicity (48, 49).
- Continue to update the health sector and other relevant ministries and decision-makers on new information or other changes that affect disease status, signs and symptoms, case definitions, protocols and algorithms.
- Activate the surveillance activities required to detect subsequent pandemic waves.
- Monitor and assess national impact using criteria such as workplace and school absenteeism, regions affected, groups most affected and essential worker availability.

Recovery activities to be considered

Review and revise situation monitoring and assessment tools for subsequent waves of disease, the next pandemic and other public health emergencies. In addition, resume seasonal influenza surveillance programmes incorporating the pandemic virus subtype as part of routine surveillance.

5.4 Health infrastructure and logistics

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop pandemic risk management plans throughout the health sector, including for health facilities, laboratories and other allied health services (50).
- Plan for the increased need for antibiotics, antipyretics, hydration, oxygen and ventilation support within the context of national clinical management strategies.
- Develop mechanisms and procedures to select, procure, stockpile, distribute and deliver antivirals, essential pharmaceuticals, personal protective equipment, diagnostics tests and vaccines, when available and based on national goals and resources. Consider whether these mechanisms are adequate to conduct containment measures (**Annex 7**).
- Develop a deployment plan to deliver pandemic influenza vaccines to national and subnational distribution points within 7 days from when the vaccine is available to the national government and develop a mass vaccination campaign strategy (23).

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Implement vaccine procurement plans.
- Implement distribution and deployment plans for antivirals, vaccines and other pharmaceuticals, other medical supplies and personal protective equipment, according to national plans.
- Monitor essential health-related resources such as: medical supplies; antivirals, vaccines and other pharmaceuticals; health-care worker availability; hospital occupancy/availability; use of alternative health facilities; laboratory material stocks; and mortuary capacity.
- Deploy pandemic vaccine when available in accordance with national plans, priorities and vaccine availability.

Recovery activities to be considered

Restock medications and supplies and service and renew essential equipment in preparation for possible subsequent waves of pandemic virus-induced disease or other health emergencies. In addition, review the status of, and replenish, national and local stockpiles.

5.5 Health and related services

5.5.1 Health services

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Consider policy and needs of an in-country approach to antivirals and vaccination, including mechanisms for evaluating effectiveness and monitoring for adverse events.
- Estimate and prioritize requirements for antiviral treatment or prophylaxis and vaccination during a pandemic.
- Consider capacity and resources for stockpiling essential medicines and equipment (51).
- Consider mechanisms for identifying, and measures to protect, vulnerable populations.

- Assess health system capacity to detect and contain outbreaks of pandemic influenza disease in hospital settings.
- Develop mechanisms to monitor uptake, compliance, safety and effectiveness of mitigation measures and share findings with the international community and WHO.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Implement national plans for antivirals and/or vaccination campaigns according to priority status and availability, in accordance with the evidence or modify/adapt antiviral and vaccine strategies based on monitoring and surveillance information.
- Enhance infection prevention and control practices in health-care and laboratory settings and issue personal protective equipment as needed in accordance with national plans.
- Activate alternative strategies for case isolation and management as needed.
- Address the psychological impacts of the pandemic, especially on the health workforce, and provide social and psychological support for health-care workers, patients and communities.
- Reassess the capacity to implement mitigation measures to reduce the spread of pandemic influenza.
- Consider vaccination of health-care workers, when available and based on national goals and policies.
- Conduct ongoing evaluations of antiviral effectiveness, safety and resistance, and vaccine coverage, effectiveness and safety, throughout their deployment, according to national plans, mechanisms and procedures.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Conduct a thorough evaluation of all the specific responses and interventions used, including: (1) antiviral effectiveness, safety and resistance; (2) vaccine coverage, effectiveness and safety, and share findings with the international community.
- Begin rebuilding essential services in preparation for subsequent waves of disease and/or other health emergencies.
- Work to increase seasonal influenza vaccination coverage of all groups at high risk, in accordance with national policy.

5.5.2 Public health-related measures

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Identify the range of non-pharmaceutical interventions that might be recommended and develop protocols and communications to support their implementation (52, 53).
- Develop a framework to facilitate decision-making for activation and de-escalation of specific measures, such as school closures or cancellation or restriction of mass gatherings based on appropriate risk assessment criteria.
- Plan for actions relating to temporary recommendations issued under IHR (2005), especially measures to slow the spread of disease.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Assess and determine whether cancellation, restriction or modification of mass gatherings is indicated.
- Implement social distancing measures, as indicated in national plans, such as school closures and other societal-level disease control measures including adjusted working patterns.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

Conduct a thorough evaluation of the effectiveness of the individual, household and societal measures implemented and update guidelines, protocols and algorithms accordingly.

5.6 Community capacities

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop guidance and plans to provide necessary support for prevention, treatment and infection prevention and control for ill persons isolated at home and their household contacts.
- Develop plans and mechanisms to enable increased access to treatment and care for community members, including the involvement of civil-society organizations and other partners providing community services.
- Develop public health education campaigns, including creating messages and feedback mechanisms targeted towards hard-to-reach, disadvantaged or minority groups.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Initiate public health education campaigns in coordination with other relevant authorities on individual-level infection control measures.
- Implement appropriate individual/household medical and non-medical disease control measures for suspect cases and their contacts in households.
- Advise household contacts to minimize their level of interaction outside the home and to isolate themselves at the first symptoms of influenza.
- Advise individuals to stay home when ill.
- Provide infection control guidance for household caregivers taking into account relevant WHO guidance.

Recovery activities to be considered

As needed, provide psychosocial services to facilitate individual and community-level recovery.

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ANNEXES

Annex 1 Guidance revision process

The content of this WHO guidance document, *Pandemic influenza risk management*, has been largely based on *Pandemic influenza preparedness and response: a WHO guidance document*, which was published in 2009. The draft content was reviewed by a WHO Internal Steering Committee, comprising technical experts in influenza, multisectoral collaboration for influenza, risk management, event management, communications, influenza at the human–animal ecosystem interface, antivirals, vaccine research and emergency risk management for health, and assessed for relevance and continued applicability to the risk management of pandemic influenza.

Throughout the revision process, the Internal Steering Committee met four times, with significant e-mail correspondence between meetings. Members of the Internal Steering Committee were invited to provide inputs and updates to relevant sections of the document, according to their expertise.

During 11–12 April 2013, an external Peer Review Group meeting was convened to: (1) consider the revised guidance in relation to emergency risk management for health as well as recommendations from the report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009; and (2) provide feedback, comment and input on the draft guidance.

The peer reviewers' comments were noted, and taken into account in a revised draft of the document. The revised draft was sent to the peer reviewers for acknowledgement of the changes requested and inclusion of additional comments, then finalized for Member State engagement.

Commenting Process

All 194 Member States were informed in writing of the publication of the interim guidance and invited to contribute comments to the document. The commenting period was open from 10 June 2013 – 30 September 2013. A reminder was sent in writing to the Focal Points of the Permanent Missions to the United Nations in Geneva on 9 September 2013.

Over 65 comments were received from 18 Member States. These comments were analysed to ensure they did not duplicate other comments, categorized according to subject matter, and reviewed by the Internal Steering. Comments received were examined against, and analysed for, their added value and feasibility.

Declaration of interests

All external peer reviewers acknowledged herein completed and submitted a WHO Declaration of Interest for WHO Experts form. These declarations of interest were assessed and presented to the Peer Review Group meeting. The Chair of the Peer Review Group formally declared no interests. Of the 16 other external peer reviewers who participated in the review of this guidance document, three declared interests. The peer reviewers with declared interests are listed below, together with a short description of the interests concerned.

Peer reviewers with declared interests

Dr Nick Phin

At the time of the Peer Review Group meeting, Dr Nick Phin was about to undertake a retrospective review of clinical and safety data on patients given aqueous zanamivir during the influenza A(H1N1) 2009 pandemic and the 2010–2011 influenza season as part of the compassionate use programme. The research is being led by Public Health England with some sponsorship from GlaxoSmithKline. This sponsorship consists of £25 000 for a short-term researcher post and £25 000 to reimburse the resources used by hospitals to identify and provide the data. As the review is retrospective and there is no specific information on the use of medicines included in this project, no conflict of interest was determined.

Professor Lone Simonsen

In 2011, Professor Simonsen provided consulting services in the area of influenza and respiratory syncytial virus disease burden modelling and methodological issues with observational study designs to GlaxoSmithKline and BioCryst for US\$ 10 000 and in 2012 received less than US\$ 5000 to participate in expert panels for GlaxoSmithKline, Merck, AstraZeneca and Novartis. As no specific information on burden modelling is included in this guidance, no conflict of interest was determined.

Dr Benjamin Cowling

Dr Benjamin Cowling was paid US\$ 2000 for consultation work on influenza treatment and prevention strategies for Crucell NV in 2012. He was also the principal investigator and account-holder for an investigator-initiated trial of influenza vaccine supported by significant funding from MedImmune in 2009–2010. This was vaccine-specific research. As there are some references to vaccines and vaccine policy throughout this guidance, it was felt this research could constitute a conflict of interest and therefore Dr Cowling was excluded from discussions on vaccine-related issues.

Annex 2 Planning assumptions

Planning for a future influenza pandemic is challenging in part because important features of the next pandemic are not known. In this situation, assumptions relating to the epidemiology of influenza are needed in order to make decisions in public health planning, as well as estimating required resources.

This Annex provides some planning assumptions to be considered by national authorities in developing a pandemic influenza risk management strategy. These assumptions are based on information known at the time of publication about seasonal influenza, avian influenza and past influenza pandemics. These data should not be taken as predictive of features of the next pandemic. The characteristics and impacts of past pandemics have varied between and within countries. These differences are most likely attributable to both the characteristics of the pandemic virus and the local vulnerabilities to the disease.

It is not the intention of this Annex to provide a comprehensive review of the epidemiology of influenza. However, it will be updated as new scientific data become available that significantly change these assumptions. Key references are provided for readers to review the existing literature.

A2.1 Modes of transmission

Assumptions

- Modes of virus transmission of pandemic influenza are expected to be similar to those of seasonal influenza: via the large droplet or contact (either direct or indirect) route, with a contribution by particle airborne route, or a combination of both.
- The relative contribution and clinical importance of potentially different modes of transmission of influenza are unknown. However, epidemiological patterns suggest that the spread of the virus is mostly through close contact via the droplet or contact route.

Implications

- To decrease viral transmission, good hand hygiene, isolation of ill people and the use of personal protective equipment are important measures when caring for people with influenza.
- An airborne precaution room is not indicated for routine care. However, health-care workers should wear eye protection, a gown, clean non-sterile gloves and particulate respirators during aerosol-generating procedures.

Scientific basis

- Droplet and contact transmission appear to be major routes of transmission for seasonal influenza (Brankston G et al, 2007; Bridges CB et al, 2003).
- However, data are insufficient to determine the relative importance of the different modes of transmission. In addition, there is lack of standardization and consensus about the technical definition (i.e. particle size) of an aerosol versus a droplet (Tellier R, 2006; Lemieux C et al, 2007, Lindsley W, 2012).
- Relative heat and humidity affect the efficiency of transmission of influenza via aerosol. (Hanley BP, 2010). Some have reported the lack of aerosol transmission at 30°C, while transmission via the contact route was equally efficient at 30°C and 20°C. (Lowen AC et al, 2007; Lowen AC et al, 2008).
- Certain procedures performed in health-care settings can create aerosols. Some of these procedures have been associated with a significant increase in the risk of disease transmission and have been termed “aerosol-generating procedures associated with pathogen transmission” (WHO, 2007). These procedures include intubation, cardiopulmonary resuscitation, bronchoscopy, autopsy and surgery where high-speed devices are used (WHO, 2007).

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A2.2 Incubation period and infectivity of pandemic influenza

Assumptions

- Incubation period: 1–3 days.
- Latent period: 0.5–2 days.
- Duration of infectiousness: about 5 days in adults and possibly longer in children.
- Basic reproduction number (R_0): 1.1–2.0.

Implications

- The incubation period and the duration of infectiousness are useful for planning purposes with regard to: length of isolation for cases; development of a definition for contacts of cases; and the length of quarantine for contacts.
- A relatively short incubation period would make it difficult to stop the spread of pandemic influenza by contact tracing and quarantine.
- Viral shedding before symptoms develop would make it difficult to stop the spread of pandemic influenza solely by screening and isolating clinically ill persons.
- Once the pandemic begins, it will be important for countries to undertake surveillance and special studies to assess the incubation period and the duration of infectiousness of the pandemic virus.

Scientific basis

- An early study using Australian maritime statistics suggested that the mean incubation period of the 1918 pandemic influenza was 32.71 hours (1.4 days). (McKendrick and Morison as reviewed by Nishiura, 2007).
- A meta-analysis of 56 volunteer studies (Carrat et al, 2008) found that:
 - an increase in the average total symptoms score was noted by day 1 after inoculation, total scores peaked by day 2 and returned to baseline values by day 8;
 - viral shedding increased sharply between 0.5 and 1 day after challenge and consistently peaked on day 2 (mean generation time 2.5 days) and the average duration of viral shedding was 4.8 days;
 - viral shedding curves and total symptom score curves showed similar shapes, although viral shedding preceded illness by 1 day.
- Longer durations of viral shedding are not rare. As reviewed by Carrat et al, in one study subgroup, five participants (20%) shed influenza B virus 8 days after inoculation, while another study also reported 9 days of shedding for influenza A(H3N2).
- Reasonable estimates of the basic reproduction number (R_0): for past pandemic viruses as well as seasonal influenza viruses converge between 1.5 and 2.0 (Ferguson NM et al, 2005; Ferguson NM et al, 2006; Colliza V et al, 2007; Vynnycky E et al, 2007) and for A(H1N1) 2009 ranged from 1.1-1.8 (Fraser et al, 2009; Lessler et al, 2010; Opatowski, et al 2011).
- The incubation period of influenza A(H5N1) human cases (7 days or fewer; mostly 2–5 days) appears to be longer than that of seasonal influenza. In clusters in which limited human-to-human transmission has probably occurred, the incubation period appears to be approximately 3–5 days, although in one cluster it was estimated to be 8–9 days (WHO writing committee, 2008).
- Patients with influenza A(H5N1) disease may have detectable viral RNA in the respiratory tract for up to three weeks; data, however, are limited. (Reviewed by WHO writing committee, 2008; and Gambotto et al, 2007).

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A2.3 Symptom development and clinical attack rate

Assumptions

- About two-thirds of people with pandemic influenza are expected to develop clinical symptoms.
- Uncomplicated clinical symptoms of pandemic influenza are expected to be similar to those of seasonal influenza: respiratory symptoms; fever and abrupt onset of muscle ache and headache or backache.
- Averaged overall (across all age groups), population clinical attack rates are expected to be 25% to 45%.

Implications

- Existing clinical criteria for influenza-like illness can serve as the basis for pandemic disease surveillance. However, countries are encouraged to monitor closely the evolution of clinical characteristics of pandemic influenza to facilitate refinement of a clinical case definition.
- Since clinical presentations of influenza are usually nonspecific, pandemic surveillance should be supported by laboratory diagnosis. This step is critical to confirm and describe comprehensively the first cases in each country.
- Because the number of ill persons may overwhelm existing health-care capacities, countries should plan for rapid scale up of health-care capacity and prioritization of limited resources.
- Wide variations in clinical attack rates among different age groups and localities have been observed with previous pandemics. Countries are encouraged to estimate clinical attack rates based on their own data and experiences.

Scientific basis

- A pooled analysis of 522 persons who were voluntarily infected with influenza reported the proportion of symptomatic infection (any symptoms) as 66.9% (95% CI: 58.3, 74.5). No significant differences were noted according to the virus type or the initial infectious dose (Carrat et al, 2008).
- A modelling study using 1957 pandemic data from the United Kingdom estimated that 60–65% of infected individuals experienced clinical symptoms (Vynnycky E et al, 2008).
- An analysis of an influenza outbreak experience in an isolated island, Tristin da Cunha, in 1971 suggested that almost all susceptible persons developed symptomatic illness (Mathews JD et al, 2007).
- During the 1918 pandemic in the United States of America, influenza-like illness rates averaged 28%, with a low of 15% and a high of 50% (Frost WH, 1919). These data were derived from house-to-house surveys.
- In one report, age-specific serological attack rates for the 1957 pandemic averaged 40%, with a low of 5% and a high of 70%. In contrast, a 20% serological attack rate was reported for the 1968 pandemic (Stuart-Harris CH, 1970).
- A retrospective questionnaire survey from one USA city revealed the overall clinical attack rate during the 1968 pandemic was 39%; and it was similar among all age groups (Davis LE et al, 1970). Another serological survey found that about 25% (range of 21% to 27%) of children tested positive for antibodies to the influenza strain that circulated in 1968 (Chin J et al, 1974).
- Clinical attack rates calculated from an estimated basic reproduction number (R_0): between 1.5 and 2.0; range from approximately 25% to 45% (Ferguson NM et al, 2005; Ferguson NM et al, 2006; Germann TC et al, 2006; Colliza V et al, 2007; Halloran ME et al, 2008).
- Clinical attack rates from A(H1N1)pdm 2009 were estimated to be 7% to 15% (Fraser C et al, 2009) with a secondary attack rate from 7-13% (Cauchemez S et al, 2009, WHO writing group 2009).
- Gastrointestinal symptoms have been observed among patients with influenza A(H5N1) but have varied by clades (WHO writing committee, 2008).

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A2.4 Dynamics and impact of a pandemic

Assumptions

- An influenza pandemic can begin at any time of the year and in any place in the world; it is expected to spread to the rest of the world within several weeks or months.
- The duration of a pandemic wave is expected to be from several weeks to a few months but will likely vary from country to country; within a single country, variations may be seen by community.
- Most communities are expected to experience multiple waves of different magnitudes of a pandemic.
- Increased hospitalizations, excess mortality and secondary complications are expected to vary widely among countries and communities. Vulnerable populations are expected to be affected more severely.
- Workplace absenteeism is expected to be higher than the estimated clinical attack rate.

Implications

- Each country should develop and strengthen its capacity to detect the early emergence of a potential pandemic event and to respond rapidly.
- Countries should guide their local governments and communities to develop their own pandemic influenza risk management plans.
- Actions during the post-peak periods between pandemic waves should be considered in overall pandemic risk management plans.
- Countries are encouraged to further estimate and prepare health-care needs based on their own resources and experiences, with particular concern to vulnerable populations.

- In a series of waves as experienced with 20th century pandemics, an early wave may lead to depletion of stocks of consumables, such as personal protective equipment and pharmaceuticals, before later waves.
- Countries are encouraged to further estimate excess workplace absenteeism during a pandemic based on their own contexts and to guide all sectors to develop business continuity plans for high and possibly fluctuating levels of absenteeism throughout the pandemic.

Scientific basis

- Early reports and later analysis of epidemiological evidence suggest that milder epidemic waves (in Europe in April and May, 1918 and in the USA in the (Northern Hemisphere) Spring of 1918 preceded the most severe pandemic wave in (Northern Hemisphere) Autumn 1918 (Frost WH, 1919; Olson SR et al, 2005).
- A review of data from the North Denmark region for the A(H1N1) 2009 pandemic indicated three waves with the third in December 2010-January 2011 being the most severe (Orsted et al, 2013)
- An influenza virus A(H1N1) resistant to oseltamivir was first reported from Norway in January 2008 and then spread throughout much of the Northern Hemisphere during the next two months (WHO, 2008). It was subsequently detected in the Southern Hemisphere during the influenza season of 2008.
- Excess mortality data from 1918–1920 show that population mortality varied more than 30-fold across countries (Murray CL et al, 2006).
- Excess mortality estimates among countries during the 1918 pandemic ranged from a low of 0.20% (Denmark) to a high of 4.39% (India) (Murray CL et al, 2006).
- Variation of excess mortality within countries for the 1918 pandemic ranged from
- 46 2.12% to 7.82% in India and from 0.25% to 1.00% in the USA. During the 1918 pandemic in the United States of America, there were marked and consistent differences in morbidity and mortality among persons of different economic status: the lower the economic level, the higher the attack rate. This relationship persisted even after adjustments were made for factors such as race, sex, age and other conditions (Sydenstricker E, 1931).
- A multinational analysis of the 1968 pandemic showed very different epidemic patterns in the six countries studied (Viboud C et al, 2005).
 - In the USA, a large epidemic was observed in 1968–1969, followed by a milder wave in 1969–1970, late in the winter season.
 - In Canada, the two epidemic patterns were similar in amplitude and timing.
 - In other countries (Australia, France, the United Kingdom and Japan), the first epidemic was mild, followed by a much more intense epidemic in the next season.
- A simulation study in the United Kingdom estimated that, overall, about 16% of the workforce is likely to be absent due to school closures during a pandemic. This estimate rises for sectors with a high proportion of female employees, such as health and social care (Sadique MZ et al, 2008).

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Annex 3 Ethical considerations

Preparedness planning for an influenza pandemic involves balancing potentially conflicting individual and community interests (12). In emergency situations, the enjoyment of individual human rights and civil liberties may have to be limited in the public interest. However, efforts to protect individual rights should be part of any policy. Measures that limit individual rights and civil liberties must be necessary, reasonable, proportional, equitable, non-discriminatory and in full compliance with national and international laws.

Ethics do not provide a prescribed set of policies; rather, ethical considerations will be shaped by the local context and cultural values. The principles of equity, utility/efficiency, liberty, reciprocity and solidarity are especially helpful in the context of influenza pandemic preparedness planning.

For example, the principle of utility suggests that resources should be used to provide the maximum possible health benefits, often understood as “saving most lives”. Utility considerations include the following:

For individual benefit:

- the likelihood that an individual with pandemic influenza disease will experience a medical benefit if provided antiviral or adjuvant treatment;
- the likelihood that an individual at risk of infection will become infected/ill if influenza-specific antiviral prophylaxis is not provided.

For community benefit:

- the likelihood that an infected individual will infect other persons if not given access to antivirals (for treatment or prophylaxis) and infection control measures;
- the overall reduction in disease burden expected to result from the intervention;
- the potential value of giving priority to:
 - essential health-care workers,
 - other workers who provide life-saving services,
 - workers who provide critical services necessary for society to function as normally as possible; such policies should be developed with great care, given the danger that decisions favouring certain categories of workers may be perceived as unfair and undermine public trust.

Another important principle, which may sometimes conflict with utility considerations, is equity.

Considerations of equity in use of antivirals may lead to giving priority to:

- the worst-off (in terms of severity of illness);
- vulnerable and disabled populations;
- uninfected persons who are at high risk of developing severe complications and death if they become infected.

Regardless of the criteria selected to govern the allocation of therapeutic and preventive measures, certain basic elements will be important in all plans; for example, those which:

- Facilitate access to the highest level of treatment possible given available resources, with careful attention to the needs of all populations.
- Provide health-care workers with clear and transparent screening and treatment protocols in line with the latest guidance from WHO or relevant national health authorities.
- Incorporate mechanisms that:
 - ensure that the guidelines and protocols are followed;
 - enable health-care workers to inform health authorities when clinical experience suggests the need for revisions of protocols;

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- enable health-care workers to (1) take part in the process of updating guidelines and protocols as the pandemic progresses, and (2) propose prioritization criteria for maintenance of a functioning health-care system in a crisis situation;
- ensure a fair balance of treatment for pandemic influenza patients and patients with other serious conditions;
- enable prioritization protocols for non-influenza patients and their access to the general health-care infrastructure;
- identify the pandemic influenza patients who will receive hospital-based versus home-based care and criteria for early discharge (potentially even if still infectious).

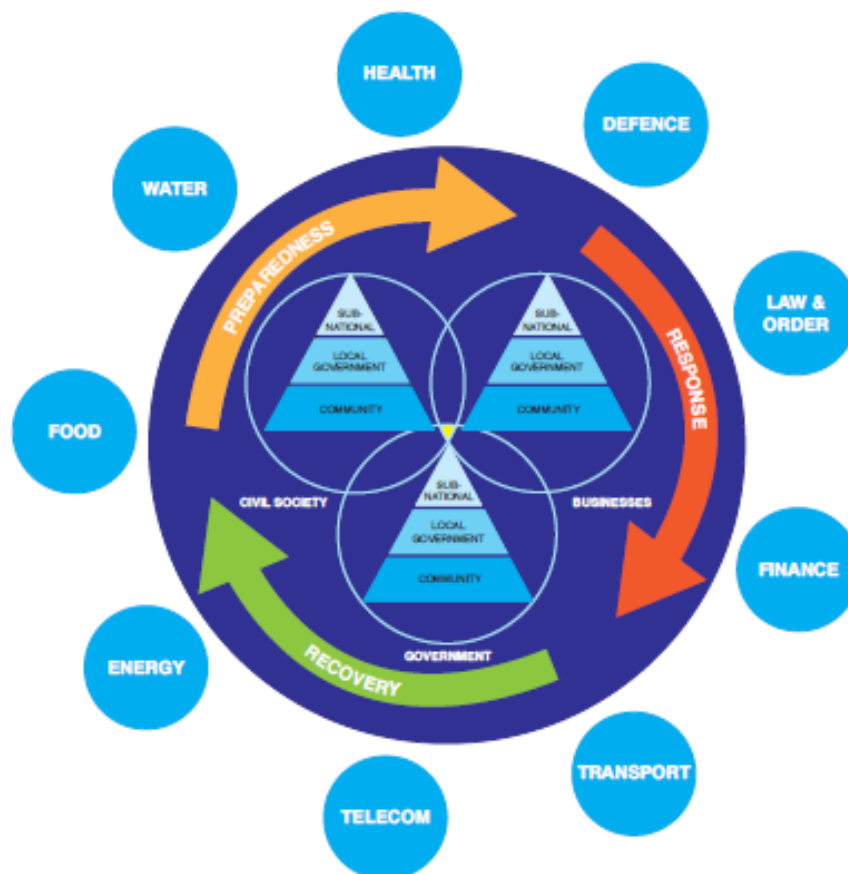
As part of pandemic influenza planning, policy-makers are encouraged to establish a fair process for setting priorities and promoting equitable access to services and supplies that: (1) involves civil society and other major stakeholders in the decision-making process so that decisions about the criteria to be used in allocating scarce resources are made in an open, transparent and inclusive manner and (2) incorporates clear, pre-established mechanisms for revising decisions based on new evidence when appropriate. An open, trusted process will strengthen solidarity and enhance the whole-of-society approach to pandemic risk management.

Annex 4 Whole-of-society approach

An influenza pandemic will test the resilience of nations, businesses, and communities, depending on their capacity to respond. No single agency or organization can prepare for a pandemic on its own. Inadequate or uncoordinated preparedness of interdependent public and private organizations will reduce the ability of the health sector to respond during a pandemic. A comprehensive approach to pandemic risk management is required.

As illustrated in **Figure 3**, the whole-of-society approach encompasses three major groups in society – governments, business and civil society – at the global, national, subnational, local and community levels. The nine circles around the disaster management continuum of mitigation, prevention, preparedness, response, and recovery represent nine key essential areas: health, defence, law and order, finance, transport, telecommunications, energy, food and water.

Figure 3: Whole-of-society approach (53)



All sectors of society should be involved in pandemic risk management. A concerted and collaborative effort is required by government ministries, businesses and civil society to sustain essential infrastructure and mitigate impacts of pandemic influenza on health, the economy and the functioning of society.

All levels – global, national, subnational, local and community – should prepare for a pandemic. The global and national levels should provide leadership and strategic planning while the local level should prepare to take specific actions. All organizations should incorporate pandemic preparedness into existing crisis and

continuity management systems. As the impact and duration of pandemic waves are unpredictable, and may continue for multiple seasons, local communities should develop flexible plans to support the full spectrum of their potential needs.

A4.1 Role of government

In national pandemic influenza risk management, the government is the natural leader for overall pandemic coordination and communication efforts. The national government should help other public and private agencies and organizations by providing guidance, planning assumptions and making appropriate modifications to the laws or regulations at all levels and sectors to enable appropriate pandemic response. These efforts are supported by WHO and other United Nations Organizations under the IHR (2005) (4). As part of their capacity building activities under the IHR (2005), governments globally have been assessing and revising their national legislation and regulations to ensure they can fully comply with their obligations. These activities include intersectoral collaboration and ERMH at all governmental levels.

Leadership should be based on strong political will and engagement with all stakeholders and sectors with good coordination and command and control mechanisms between the Ministry of Health, national public health authorities and non-health sectors. Emergency management roles, responsibilities and mechanisms also need to be clarified, communicated and tested, with particular attention to sustainability of response capacity and decision-making roles (55).

Pandemic risk management is a whole-of-government responsibility. All ministries should work with the Ministry of Health within the national coordination system to ensure a consistent approach to preparedness and business continuity planning. Plans that encompass a variety of scenarios should be developed from risk-based assumptions generated by the Ministry of Health and should be tested for compatibility. In addition, pandemic risk management processes need to take place at the national, subnational, local and community levels; central government should stipulate which level is responsible for specified activities. The central government should also provide guidance to local authorities on preparedness planning; conduct training to ensure effective dissemination at all levels; and design and implement exercises to test plans and encourage community mobilization. Throughout the whole of government, roles, responsibilities, designated leads and chains of command should be clearly mapped. Standard operating procedures can help generate common understanding and coordinated implementation (54).

All ministries are responsible for ensuring their respective sectors are well prepared to respond to and recover from pandemic influenza; examples of ministry-specific activities are provided below.

- **Ministries of Transportation** should plan to minimize infection risks and staff absences in vital transportation, airports and sea ports, and loading and unloading facilities, to enable continued supply of medicines and food. Mechanisms for communication and education of public transport users should be considered well in advance.
- **Ministries of Finance** should plan to maintain essential cash, credit, banking, payment, international funds transfers, salary, pension and regulation services in the face of significant absenteeism; systemic resilience to pandemic risk should be tested. National-level financial planning for pandemic risk management is also a task for the national emergency committee and the Ministry of Finance and the mechanisms to draw down emergency funding for interventions should be tested prior to a pandemic.
- **Ministries of Justice** should consider how to maintain all essential legal and administrative operations during a pandemic. Measures should also be considered to minimize the spread of infection in prisons and other institutions under their authority. Plans for infection control and risk reduction in facilities

should be tested in conjunction with the Ministry of Health plans to ensure that messaging is consistent and that public health principles are upheld.

- **Ministries of Defence** should consider which military assets could be released and mobilized in the event of a pandemic, based on Ministry of Health planning assumptions and risk assessment.
- **Ministries of Education** should have a key role in the surveillance and reduction of influenza risk to communities. Surveillance of absenteeism in schools can be used as a proxy indicator of community transmission. Linking of school surveillance systems with the Ministry of Health is therefore vital to ensure that school-based interventions, including closures, are guided by public health principles.
- **Ministries of Energy** should ensure that key providers within the energy sector have well-developed and well-exercised preparedness plans. Alternative plans for energy supplies, in case of major disruptions, should be evaluated.
- **Ministries of Communication** should have the responsibility to ensure that communications channels remain open at times of crises. As the formal partner to the Ministry of Health in disseminating information, the Ministry of Communication should be closely involved in the development of a national communications plan across the government.
- **Ministries of Agriculture** and Animal Health should have a key role in the surveillance and monitoring of non-seasonal influenza viruses and on preparedness, prevention, risk assessment and risk reduction mechanisms to decrease exposure of humans to influenza viruses at the human–animal ecosystem interface.
- In addition to leading the health sector response, **Ministries of Health** should provide planning assumptions and technical input for the development of plans by other sectors, provide public education and other communication messages and provide advice on reducing risk of infection in essential workers.

A4.2 Role of business

In many countries, essential services are provided by a mix of public and private providers. It is therefore vital that, along with public agencies, private essential goods and service providers undertake pandemic risk management activities. At a national level, the business sector should be represented in the national planning committee, to ensure a consistent planning approach and establish formal communication channels.

The continuity of activities by businesses involved in medical supplies and services, e.g. manufacturers, distributors and providers, is critical to pandemic risk management. Other business sectors also have important roles. For example, human resource surveillance systems in larger businesses to monitor absenteeism can provide valuable information for national risk assessment and the retail sector can use strategies to reduce population density in shopping areas. Businesses have an obligation to protect their employees during any health emergency; the provision of accurate and timely communication messages developed on the national communication plan, personal protective equipment and training is encouraged.

A4.3 Role of civil society

In many countries, national and international civil society and community-based organizations will have a key role in providing community-based services to meet the needs of vulnerable populations. It is therefore critical that these organizations have planned how to maintain or expand their essential services during a pandemic. In addition, community-based organizations can translate scientific and government messages and recommendations, which otherwise may be met with mistrust or scepticism by parts of society.

Community leaders can build public confidence, disseminate information and identify people at risk. Governments should therefore involve civil society and local communities in developing pandemic risk management plans. Governments should also work with local and international humanitarian agencies and organizations to identify how the basic needs of vulnerable populations will be met in a pandemic. The adoption of this whole-of-society approach will clarify responsibilities, identify gaps and avoid duplication in planning and implementation.

Throughout the UN system, agencies, funds, programmes and partners support pandemic risk management efforts, in particular assisting countries and promoting multisectoral and whole-of-society approaches, facilitating and enhancing regional and global synergies and establishing norms for effective work (56). The overarching objectives through which this work has been pursued are captured in the UN System and Partners Consolidated Action Plan for Animal and Human Influenza, which identifies specific outputs and activities of the UN system and partners under seven strategic objectives, namely: animal health and biosecurity; sustaining livelihoods; human health; coordination of national, regional and international stakeholders; communication: public information and supporting behaviour change; continuity under pandemic conditions; and humanitarian common services support (57). The UN system also works to ensure continuity of its essential operations during pandemics and to maintain staff health and safety to ensure a timely, consistent and coordinated response across the UN system to a possible global threat (58).

A4.4 Critical interdependencies among essential services

Although there are variations between countries, key essential services are: health, defence, law and order, finance, transport, telecommunications, energy, food and water (**Figure 4**). Public and private providers of these essential services are interdependent and rely on the goods and services of other sectors in order to sustain their operations. Pandemic plans should take into account potential failures generated by interdependencies. These include failures of individual businesses or small numbers of businesses representing the sole providers of an essential good or service. Interdependencies need to be identified by each individual essential service provider. Issues that need to be clarified in the process of identifying interdependencies include:

- critical goods and services necessary for the organization to provide its essential service/s;
- key interdependencies for each critical good or service;
- the impact of the loss or reduction of any of the critical goods or services to the customers/beneficiaries;
- critical employee groups;
- the impact of the loss or reduced availability of critical employee groups; and
- likely points of failure.

The health-care sector always faces especially severe challenges during a pandemic. Health-care institutions depend on goods and services that are delivered by the following sectors:

- transport for the movement of supplies, personnel and patients;
- telecommunications to support patient care, provide teletriage and maintain business processing;
- energy to power facility, clinical and security systems;
- water for health-care facilities, pharmaceutical operations and sanitation services;
- pharmaceuticals, including consumables, for treatment of patients; and
- finance to ensure the supply chain.

Flexible business continuity plans should be developed for multiple scenarios ranging from some delays/interruptions to significant interruptions to essential services, with corresponding action plans.

Annex 5 Business continuity planning

Business continuity plans, which document business continuity management processes, are at the heart of preparing all levels and groups of society for an emergency; pandemic risk management should be an integral part of any establishment's business continuity management. Business continuity plans should be based on risk assessment of the potential effects of a pandemic on the ability to maintain or expand operations. The risk assessment should include consideration of vital components outside the specific organization, such as the resilience of supply chains for essential goods and services. The plans can be used to manage business interruptions, including significant absences of staff or disruption of supplies.

Business continuity plans should be based on explicit assumptions that characterize the parameters of a pandemic and its potential impacts. Public health authorities should communicate planning assumptions and guidance to other sectors of society.

Regardless of the type of the organization, business continuity plans should include the following actions:

- Identify the critical functions that need to be sustained.
- Identify the personnel, supplies and equipment vital to maintain critical functions.
- Consider how to deal with staff absenteeism to minimize its impact on critical functions.
- Provide clear command structures, delegations of authority and orders of succession.
- Assess the need to stockpile strategic reserves of supplies, material and equipment.
- Identify units, departments or services that could be downsized or closed.
- Assign and train alternative staff for critical posts.
- Establish guidelines for priority of access to essential services.
- Train staff in workplace infection prevention and control and communicate essential safety messages.
- Consider and test ways of reducing social mixing (e.g. telecommuting or working from home and reducing the number of physical meetings and travel).
- Consider the need for family and childcare support for essential workers.
- Consider the need for psychosocial support services to help workers to remain effective.
- Consider and plan for the recovery phase.

Annex 6 Representative parameters for core severity indicators

| Indicator | Representative parameters |
|------------------------|---|
| Transmissibility | <p>From initial investigations</p> <ul style="list-style-type: none"> • Number of symptomatic cases of influenza/influenza-like illness per week • Basic reproduction number (R_0): the average number of secondary cases generated from one case at the start of the epidemic • Generation time: the mean delay between the time of infection of an index case and the times of infection of secondary cases infected by the index case • Serial interval: the average length of time between symptom onset of individual cases and the persons they infect • Secondary attack rate: the proportion of individuals exposed to a known case who become infected, e.g. in a household where a case is discovered • Clinical attack rate (CAR): the proportion of the population that is symptomatically infected in a given time period. CAR is relatively simple to measure since it does not rely on detection of asymptomatic individuals. CARs can be calculated for different age groups, different settings (e.g. school, workplace) and different risk groups (e.g. pregnant women) • Spatial distribution of cases: mapping of countries/regions in which the virus has been detected in a given time period <p>From later investigations</p> <ul style="list-style-type: none"> • Attack rate: the proportion of the population that become infected in a given time period (e.g. as obtained from population serologic studies) • Incidence proportion: the proportion of people who develop new disease during a specified time period • Prevalence: the proportion of people who have disease at a specific time • Mode of transmission, particularly if new modes or previously uncommon modes of transmission (e.g. faecal–oral) are important <p>From influenza (sentinel) surveillance systems</p> <ul style="list-style-type: none"> • Weekly ILI or MAARI (medically attended acute respiratory illness) cases as a proportion of total visits, or incidence rates. • Weekly percentage of respiratory pathogen samples testing positive for influenza. • Combination of weekly ILI or MAARI weekly percentage positivity rates for influenza. |
| Seriousness of Disease | <p>From initial investigations: molecular</p> <ul style="list-style-type: none"> • Sensitivity to available antiviral medicines • Presence of genetic markers that have been associated with increased risk of severe disease • Pre-existing immunity in the population, as measured by the level of cross-reactive antibodies <p>From investigations: clinical</p> <ul style="list-style-type: none"> • Case-fatality ratio (CFR): the proportion of symptomatic cases that die. Estimations of CFR are particularly difficult at the early stages of a pandemic. Since reliable case-fatality ratios will only be available in later stages of a pandemic, other parameters that may be of use are: <ul style="list-style-type: none"> ○ the proportion of hospital admissions attributed to respiratory causes that require mechanical ventilation or die ○ the proportion of influenza admissions, intensive-care admissions and deaths with pre-existing medical conditions |

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|----------------------|---|
| | <p>From later investigations</p> <ul style="list-style-type: none"> The proportional distribution of cases by clinical illness (i.e. the proportions of cases that are asymptomatic/have mild illness/severe illness/die – the “clinical severity pyramid”) <p>From influenza (sentinel) surveillance systems</p> <ul style="list-style-type: none"> Cumulative death: hospitalization ratio (ideally for confirmed influenza) Cumulative ICU: hospitalization ratio (ideally for confirmed influenza) SARI /ARI or ILI ratio |
| <p>Impact</p> | <p>From initial investigations</p> <ul style="list-style-type: none"> Daily hospitalization rate: the number of persons in a given population who are hospitalized each day, expressed in terms of confirmed or suspected cases The proportion of emergency department visits attributed to pandemic influenza The proportion of emergency department visits that require hospitalization The proportion of hospitalized cases that require admission to an intensive-care unit or require mechanical ventilation The proportion of all hospital beds occupied by patients with pandemic influenza The percentage of overall laboratory capacity directed to influenza testing <p>From later investigations</p> <ul style="list-style-type: none"> Number of deaths attributed to influenza Crude disease-associated mortality rate: the number of persons in a given population who die of the illness, expressed in terms of confirmed or suspected cases <p>From influenza (sentinel) surveillance systems</p> <ul style="list-style-type: none"> weekly or monthly number or proportion of SARI cases with percentage flu-positive among SARI cases weekly excess Pneumonia &Influenza (P&I) or all-cause mortality stratified by age. weekly number of confirmed influenza cases admitted to ICU; weekly number of confirmed influenza cases admitted to hospital. <p>Potential societal impact parameters from other sectors</p> <ul style="list-style-type: none"> Interruption of critical infrastructure and services Work and school absenteeism School closures Tourist visitor numbers and expenditure Gross Domestic Product Border, travel and trade actions by countries Nature of public perception |

Annex 7 Containment measures

Before the presence of human infection with a new influenza subtype is identified, the clinical syndrome associated with a new influenza subtype is likely to be similar to that caused by currently circulating seasonal viruses. It will therefore be very difficult to recognize an emerging pandemic sufficiently early to achieve containment at source, given current capacities for detection and intervention (59). Evidence supporting containment at source is extremely limited, with theoretical evidence only. Modelling studies suggest that containment may be possible in certain near-ideal scenarios characterized by low to moderate transmissibility (basic reproduction number, $R_0 \leq 1.7$); very early detection of initial cluster/outbreak (within 15–21 days); a non-urban pandemic epicentre with limited size (60), density and mobility; access to well-trained response workers within a highly organized response infrastructure; a short period of communicability and low rate of asymptomatic illness; and antiviral drug susceptibility.

However, even in these near-ideal situations, it is unlikely that this approach would be feasible given the large amount of resources (antiviral drugs, geographical cordon, health-care personnel) that would need to be mobilized (61). The data from theoretical modelling studies are based on mass use of neuraminidase inhibitors within a defined “containment zone” coupled with movement restrictions (geographical cordon) and targeted at a population of 500 000 people. Moreover, the experience in 2009 was that obtaining initial data on the R_0 , communicability and rate of asymptomatic illness associated with influenza A(H1N1)pdm09 was challenging, thus data in a future pandemic would be unlikely to be available within the timescale that would make this approach feasible.

Nevertheless, measures that have been associated with containment such as social distancing, hand/respiratory hygiene and judicious use of antiviral drugs may be effective in mitigating the impact of outbreaks of a new influenza subtype in individual countries. These measures are most likely to be successful and are better supported by data demonstrating effectiveness when implemented in specific local (smaller scale) circumstances, e.g. households and closed or semi-closed institutions. Although there is no evidence of any wider population-level containment effect, these measures may reduce the spread and overall impact of the pandemic and could be considered as part of a country’s national preparedness plan, depending on available resources.