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BACKGROUND

In the context of finalizing the "Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits", the World Health Assembly requested the Director-General to continue to work with Member States and to undertake technical consultations and studies as necessary in order to support the work of the Open-Ended Working Group (OEWG) in reaching final agreement (see resolution WHA63.1 subparagraph 1(2)). The OEWG defined the following studies, which should draw on lessons learnt from the pandemic (H1N1) 2009 and the ongoing outbreaks of influenza H5N1 (see document A63/48, paragraph 7):

- Current activity, financing and unmet financial and other needs in relation to:

  (a) laboratory and surveillance capacity building, including that required under the International Health Regulations (2005)

  (b) expanding global influenza vaccine production capacity including under the Global Action Plan to Increase Supply of Pandemic Influenza Vaccines (GAP)

  (c) increasing access, affordability and effective deployment of vaccines, antiviral agents, diagnostics and other materials for pandemic preparedness and response.

- Possible sustainable financing and solidarity mechanisms and other approaches to address the needs identified in subparagraph (a) above.

METHOD OF WORK

Given the breadth of the technical areas under scrutiny, the approximate duration of the studies will be August 2010 until the end of March 2011 using a phased approach. Generous support has been provided by the Bill & Melinda Gates Foundation until the end of December 2010.

The starting point for these studies is the guidance and information contained in the following documents: A62/5 Add.1; A63/48; and A/PIP/IGM/13 Annex 4. A fact-based approach is being used, based on data contained in WHO reports and other publicly available documents. Consistent with the request from the Health Assembly under resolution WHA63.1, and other relevant resolutions, the Director-General has undertaken consultations with stakeholders to ensure the appropriateness and feasibility of the proposed targets and options. All sources will be acknowledged in the final report.

This document is a working outline of the final report, which is expected to be available prior to the Sixty-fourth World Health Assembly. The purpose of this document, which presents a five-year plan to the end of 2015, is to define the scope of each area of study and provide illustrative targets and options. As analysis is ongoing in each technical area, however, the final targets and options may differ from those presented in this document.

Using this outline, preliminary findings will be made available to the OEWG on 1 December 2010 in English, as requested by the co-Chairs, with the understanding that all efforts will be made to provide translations as soon as possible after that date. These preliminary findings will include several possible targets and options for each technical area, as well as possible funding scenarios. Some preliminary findings will be limited by constraints of time and/or resources. Moreover, in the technical area of access, affordability and effective deployment of pandemic supplies, work will be limited to vaccines until the end of December. Other commodities will be addressed in the final document which will be made available prior to the Sixty-fourth World Health Assembly.

Prior to the Sixty-fourth World Health Assembly, the full study will be completed, drawing on guidance obtained during the OEWG held in December and further stakeholder consultations as necessary.

APPROACH TO THE TECHNICAL STUDIES

Studies in each technical area will systematically address the following issues:

- *Current state:* description of current capacity and capacity gaps at country level in that technical area;
- *Targets*: description of potential targets to improve pandemic preparedness in the next five years. All targets must be scientifically sound, technically feasible, and quantified and measurable;
- *Strategic options*: description of activities that could achieve each of the potential targets;
- *Costing*: estimation of costs for each option identified.

The financing section will address current state of influenza funding, scenarios of future funding needs and potential funding sources and mechanisms to meet those needs.

Assumptions used

No two influenza pandemics are alike. Where appropriate, assumptions used to develop a potential target, option or model will be clearly articulated.

LABORATORY & SURVEILLANCE CAPACITY BUILDING

Goal

- Enable Member States and the global community appropriately to detect, isolate, and characterize influenza viruses to prevent and respond to a pandemic event including production of vaccine.[1]

Current state

- Review and estimate country and regional capacities in the following areas, using established frameworks such as the IHR Monitoring Framework where appropriate:

  (a) Surveillance: capacity to conduct influenza-related routine surveillance through the health care system, using sentinel surveillance and other mechanisms including lab-based surveillance; event-based surveillance (early detection) through different information channels, e.g. media, animal health, and schools[2]

  (b) Laboratory: country capacity to analyse clinical samples to assess virus subtype, genetic sequence, immune response[3]

  (c) Shipping: country capacity to ship clinical specimens and/or virus isolates from local to regional and global levels.[4]

Illustrative targets

- Using the findings above, potential targets may include:

  (a) [x%] of countries have laboratory and/or surveillance capacity level of [x] by 2012[5]

  (b) [x%] of countries without influenza surveillance systems have influenza-like illness (ILI) surveillance or similar systems by 2015[6]

  (c) [x%] of laboratories in each region achieve laboratory capacity level [Y] by 2015[7]

  (d) [x%] countries in each region achieve shipping capacity level [Z] by 2012

  (e) [x%] countries achieve laboratory capacity level [Y] by 2015

  (f) [x%] countries achieve shipping capacity level [Z] by 2012.

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[1] Document A62/5 Add.1 6.6.1.

[2] Document A62/5 Add.1 6.6.1 (i).

[3] Document A62/5 Add.1 6.6.1 (iv).

[4] Document A/PIP/IGM/13 Annex 4 at 6.6.1.

[5] Document A62/5 Add.1 6.2.4.

[6] Idem.

[7] Idem.

Illustrative strategic options and cost of each

- Each target will have one or more strategic options to achieve the targets. These could include:

  (a) Provide technical assistance and support to establish [#] surveillance sentinel site(s) in [X] [regions][countries]

  (b) Provide technical support and/or assistance to train [Y] staff in [polymerase chain reaction (PCR)][other laboratory techniques] [to achieve certification in international shipping and packaging of infectious substances].[1]

  (c) Provide funds to equip [#] laboratories with [PCR machines].[2]

- Cost estimates for each option will be developed.

[1] Idem.

[2] Idem.

EXPANDING GLOBAL INFLUENZA Vaccine production capacity

Goal

- Increase the global capacity to produce pandemic influenza vaccine to meet global needs during a pandemic.[1]

Current state

- Using lessons learnt from the pandemic (H1N1) 2009 and ongoing outbreaks of H5N1, as appropriate:

  (a) Update estimates of current and forecast global influenza vaccine production capacity, including use of adjuvants,[2] drawing on recent data[3]

  (b) Update of regulatory capacity in vaccine-producing countries to test and release influenza vaccines[4]

  (c) Provide overview of new influenza vaccine manufacturing technologies with an estimate of their potential impact on global supply, probability of success, timeline to market, as well as factors related to potential barriers to transfer to developing countries such as regulatory matters and intellectual property[5]

Illustrative targets

- Influenza vaccine manufacturers have the capacity to produce enough vaccine to immunize [X%] of the global population within [Z] months of the declaration of an influenza pandemic.[6] Existing data and information will be used to develop target percentages and timeframes for immunization

- Develop influenza vaccine manufacturing capacity across regions to achieve geographically balanced representation and diversified vaccine manufacturing capacities

Illustrative strategic options and cost of each

- Develop regional and national plans to increase seasonal influenza vaccination programs[7]

- Complete the current GAP grant programme to 11 developing country influenza vaccine manufacturers and possibly provide grants to additional developing countries[8]

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[1] Document WHO/IVB 06.13 “Global pandemic influenza action plan to increase vaccine supply”.

[2] Document A62/5 Add.1 6.13.1.

[3] Document A62/5 Add.1 6.11.1.

[4] Document A62/5 Add.1 6.7.

[5] DocumentA62/5 Add.1 6.13.

[6] Document A62/5 Add.1 6.13.1.

[7] Document A62/5 Add.1 6.13.5.

[8] Document A62/5 Add.1 6.13.1.

- Establish the capacity to convert from inactivated influenza vaccine production to live attenuated influenza vaccine at the onset of a pandemic[1]

- Facilitate access to, and transfer of, influenza manufacturing technologies, including adjuvants, from developed to developing countries[2]

- Cost estimates for each option will include capital expenditures and ongoing operating expenditures

[1] Business Plan for the Global Pandemic Influenza Action Plan to increase vaccine supply, February 2008.

[2] Document A62/5 Add.1 6.13.2.

ACCESS, AFFORDABILITY AND EFFECTIVE DEPLOYMENT

Goal

- Develop mechanisms to ensure real-time access, based on public health need, to affordable pandemic vaccine by Member States without such access.[1]

Current state

- Drawing on analysis of the pandemic (H1N1) 2009:

  (a) Summarize timing and volume of vaccines deployed to Member States without access, including review of relevant Strategic Advisory Group of Experts on immunization (SAGE) recommendations[2]

  (b) Identify obstacles faced by Member States to gain access to vaccine:

  (i) Lack of available supply

  (ii) Lack of national deployment plan or funds to operationalize plan[3]

  (iii) Limited in-country regulatory, contracting and local licensure capacity[4]

  (iii) Lack of relevant preexisting agreements.

Illustrative targets

- During an influenza pandemic, countries without access to pandemic vaccine will have access to [X%] of vaccine production on a real-time basis. The value of the [X%] will be determined by the targets set in the Vaccine Production Capacity component[5]

Illustrative strategic options and cost of each

- Manufacturers commit to reserve [Y%] of their capacity for [purchase at tiered prices][donation] [by][to] WHO on behalf of countries without access for deployment based on public health need, including outbreak response.[6]

- Manufacturers put in place tiered-pricing to improve the affordability of vaccines[7]

- Cost estimates for each option will include capital expenditures and ongoing operating expenditures

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[1] Document A62/5 Add.1 6.6.1.

[2] Document A62/5 Add.1 6.11.1.

[3] Document A62/5 Add.1 6.11.2.

[4] Document A62/5 Add.1 6.7.1.

[5] Document A62/5 Add.1 6.13.1.

[6] Document A62/5 Add.1 6.9.3.

[7] Document A62/5 Add.1 6.12.1.

SUSTAINABLE FINANCING, SOLIDARITY MECHANISMS AND OTHER APPROACHES

Goal

- Establish sustainable financing mechanisms for pandemic influenza preparedness and response.[1]

Current state

- Describe influenza financing for pandemic influenza preparedness performed in the years before pandemic (H1N1) 2009 as well as funding for the response to pandemic (H1N1) 2009.

Projected resource requirements for pandemic preparedness

- Summary of estimated costs to implement options in each technical area and funding gap (estimated funds available vs. costs).[2]

Potential funding sources and mechanisms

- Propose potential mechanisms to sustainably fund pandemic influenza preparedness using examples of unique mechanisms used in other diseases and industries[3]

- This may include:[4]

  (a) Pandemic Influenza Preparedness Fund

  (i) Solidarity Contributions (e.g. [$x] / [seasonal] [pandemic] influenza vaccine dose; charge [$x] for candidate vaccine viruses)[5]

  (ii) Other contributions (cash, in-kind)[6]

  (b) Advance Market or Purchase Commitments

  (c) Insurance Mechanisms.

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[1] Document A62/5 Add.1 6.14.

[2] Idem.

[3] Document A62/5 Add.1 6.14.3.

[4] Document A/PIP/IGM/13 Annex 4, Appendices 1 and 3.

[5] Document A63/48 White Paper 4.

[6] Idem.