OPEN-ENDED WORKING GROUP OF MEMBER STATES ON PANDEMIC INFLUENZA PREPAREDNESS:
SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS

TECHNICAL STUDIES UNDER RESOLUTION WHA63.1

Final document

CONTENTS

Executive summary

I. Background ............................................................................................................................................. 5

II. Method of work, approach to the technical studies and assumptions .............................................. 6

III. Laboratory and surveillance capacity-building .................................................................................. 7

IV. Expanding global influenza vaccine production capacity ................................................................. 18

V. Access, affordability and effective deployment ..................................................................................... 43

VI. Sustainable financing, solidarity mechanisms and other approaches ............................................. 71

Annexes

Annex A1. Laboratory and surveillance capacity-building ................................................................. 87

Annex A2. Expanding global influenza vaccine production capacity ....................................................... 102

Annex A3. Access, affordability and effective deployment ......................................................................... 112

Annex A4. Financing mechanisms: case studies ...................................................................................... 121
EXECUTIVE SUMMARY

This document is a response to a request from the World Health Assembly in the context of the Open-Ended Working Group on Pandemic Influenza Preparedness. It provides Member States with technical information to assist them in reaching final agreement on the Framework for the sharing of influenza viruses and access to vaccines and other benefits. The study covers three technical areas of importance for increasing global preparedness for pandemic influenza: (i) laboratory and surveillance capacities of countries, (ii) global influenza vaccine production capacity and (iii) access to vaccines and other necessary pandemic supplies by countries without such access. With a common approach, the current state of global capacity is reviewed for each technical area, gaps in those capacities are identified, and targets to reduce the gaps are proposed. Options and associated costs for achieving the targets are then presented. The final section of the study addresses sustainable financing mechanisms to meet the estimated costs. By identifying gaps and assessing the costs for reducing those gaps, concrete funding needs emerge, allowing a realistic assessment of financing requirements over time.

Parts of the study, covering laboratory and surveillance capacity, vaccine production and access to vaccines, were presented to Member States in December 2010 as Preliminary Findings. The entire study has now been edited, resulting in certain editorial and typographical changes in the text and footnotes; however, no substantive changes have been made to the Preliminary Findings that were available in December 2010 or to the supporting evidence.

As indicated in the Preliminary Findings, two new sections have now been added: a discussion of antiviral medicines and diagnostic tests. Likewise the section on financing mechanisms was updated with data on antiviral medicines. Annexes for each section are presented in the last section of this document.

Summary of findings

1. Laboratory and surveillance capacity-building

Globally, influenza-specific laboratory and surveillance capacity in many developing countries needs to be strengthened. Low capacity is most frequently found in three WHO regions: the African, Eastern Mediterranean and South-East Asia regions. Over the next five years, increasing surveillance and laboratory capacity in several countries in these regions will require specific, targeted activities. Depending on the number of countries in which work is carried out, the total estimated one-time start-up cost will range from US$ 10.4 million to US$ 44.9 million, and the annual cost thereafter will be US$ 32.2–101 million per year.

2. Expanding global influenza vaccine production capacity

The global production capacity of pandemic influenza vaccine is currently approximately 876 million doses per year. It is based on demand and on the capacity to produce seasonal influenza vaccine. If there are no interventions, production is anticipated to increase to approximately 1.8 billion doses per year in 2015, due mainly to investments by multinational companies and the governments of high-income countries.

Many complementary strategies may be used to increase global production capacity and global access to pandemic vaccines. A coordinated approach could result in increased pandemic vaccine production, which would significantly increase access to such vaccines by countries that currently do not have access. The strategies that could be considered include increasing the uptake of seasonal vaccine (estimated at US$ 280 million to US$ 3700 million); shifting to higher yield technologies, such as the production of live attenuated vaccine (estimated at US$ 450 million) and use of adjuvants (estimated
at US$ 230 million to US$ 420 million); and maintaining or building new vaccine production capacity (estimated at US$ 125 million to US$ 490 million).

3. Increasing access, affordability and effective deployment of vaccines, antiviral agents, diagnostics and other materials for pandemic preparedness and response

**Vaccines**

One constraint to real-time access to pandemic influenza vaccines by countries without access is a lack of supply, because of pre-purchase agreements held by other countries. The main mechanism to address this constraint is to establish pre-purchase agreements on behalf of countries that do not have access, either by expanding existing country agreements or through new agreements. The estimated costs of this option generally include a reservation fee (estimated at US$ 0.5/dose), to be paid annually to the manufacturer, and purchase and deployment of vaccine at the time of a pandemic (estimated at US$ 4.2/dose). Both costs will vary according to the number of doses reserved. On the basis of the target groups identified by the WHO Strategic Advisory Group of Experts on immunization, three potential groups of people were identified who should be targeted for vaccination (ranging from 8 million to 334 million people); the costs were forecasted from current information on prices. The costs of pre-purchase agreements range from US$ 10 million to US$ 335 million for reserve fees and an estimated US$ 70 million to US$ 2795 million at the time of purchase.

**Antiviral medicines**

In contrast to vaccines, antiviral drugs for pandemic influenza could be made available at the start of a pandemic. Seasonal demand for influenza antiviral drugs, is, however, usually low, especially in lower income countries; therefore, stocks of antiviral medicines may not be immediately available. Both price and availability are determined by market conditions in higher-income countries. WHO has highlighted two options:

- procurement and maintenance of an antiviral agent stockpile to meet immediate needs at the time of the emergence of a pandemic and
- establishment of agreements with manufacturers and concomitant financing to purchase antiviral medicines to sustain the public health response throughout a pandemic.

As for vaccines, the cost of these options will vary with the number of countries, populations and treatment courses (estimated range of US$ 82 million to US$ 763 million).

**Diagnostic reagents and test kits**

In a pandemic, diagnostic tests are used mainly to identify and confirm outbreaks of pandemic influenza and to guide clinical decisions on treatment. The network of National Influenza Centre laboratories and Collaborating Centres in the WHO Global Influenza Surveillance Network represents the main mechanism by which countries identify outbreaks and monitor influenza activity in their countries and regions. Some laboratories in the Network provide critical reagents and set standards under their WHO terms of reference. The costs associated with this activity are included in the regular recurrent costs of WHO Collaborating Centres.

In the clinical setting, some tests are conducted with so-called “rapid point of care diagnostic kits” for influenza. These tests have the advantage that they can be performed without a laboratory; however, they must be purchased commercially, their price varies, they generally have low sensitivity, and they provide less specific information than laboratory tests.

**Sustainable financing, solidarity mechanisms and other approaches**
To the extent possible, the estimated costs were broken down into “units” to allow development of implementable “packages” and estimated yearly financial requirements. With this approach, “packages” of activities and their estimated costs were formulated, comprising elements from each of the three technical areas (laboratory and surveillance capacity, vaccine production capacity, and access). Costs were estimated for 5- and 10-year periods. Existing financing mechanisms and tools are described, and some are applied to show their potential use in financing these activities. Various types of financing will be needed to suit various implementation and funding needs. A separate document provides further details of potential financing mechanisms for concrete packages of benefits.

Full document available at:

**TECHNICAL STUDIES UNDER RESOLUTION WHA63.1**


Also available:

**PANDEMIC INFLUENZA PREPAREDNESS: OPTIONS FOR SUSTAINABLE FINANCING OF BENEFIT SHARING**