

Consultation on Health Systems Response to H1N1 Pandemic Influenza: Setting Priorities to related vaccination interventions

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Prioritization of vaccination against pandemic influenza

Preamble:

Influenza pandemic usually strikes in two or more waves, either during the same year or in successive influenza seasons. The second pandemic wave may appear within three to nine months after the first one, and be severe enough to bring about even more morbidity and mortality. Each pandemic wave may last for 3-4 months.

Since the spread of the pandemic H1N1 influenza virus is considered unstoppable, vaccination remains a priority, once the vaccine becomes available. Use of the newly developed H1N1 vaccine is expected to mitigate and slow down the spread of the pandemic. The vaccine is expected to reduce the impact of the pandemic on the population, especially on high-risk groups, diminishing complications of the disease, hospitalization rates and mortality. Epidemiologically, the impact of widespread and successful and timely H1N1 pandemic vaccination programs would result in remarkable reduction in morbidity (flattening of the epidemic curve), slowing down of the transmission of the disease and reduction in related mortality.

Countries will strive to gain access to as much vaccine as possible, at least to preserve their health systems functioning, but there will be no enough vaccine for every country in the world to vaccinate every member of the population. Implementation of other non-pharmaceutical measures, such as social distancing, school closure, avoidance of large gatherings, antibiotics and personal hygiene among others will, always, be indispensable.

Objectives of vaccination:

The WHO Strategic Advisory Group of Experts (SAGE) identified three different objectives that countries could adopt as part of their pandemic vaccination strategy:

- 1. protect the integrity of the health-care system and the country's critical infrastructure.** Examples:
 - Health-care workers as a first priority to protect the essential health infrastructure. Within the health-care workers, those who are responsible for case management in the intensive care units will receive the top priority.
 - Critical workers such as truck drivers, bakers, bakers and the like if they are critical for food delivery and or other critical services.

- Others would include those working in disciplines related to national security and political leadership.

2. reduce morbidity and mortality:

- This group includes influenza patients at increased risk for severe disease, complications and death from infection. Examples: Pregnant women; those aged above 6 months with one of several chronic medical conditions; healthy young adults of 15 to 49 years of age; healthy children; healthy adults of 50 to 64 years of age; and healthy adults of 65 years of age and above and people with morbid obesity.

3. reduce transmission of the pandemic virus within communities.

- Example: Individuals in areas where there is considerable crowding and thus risk of increased transmissibility, e.g. schools. Children before or at school entries who are in closer physical contact than adults and can amplify infection rates.

4. A fourth objective could be added: fulfillment of some international obligations; e.g. vaccination of pilgrims to Makkah (Hajjees).

Setting priorities for vaccination:

Most countries in the Eastern Mediterranean Region may not have timely and adequate procurements of newly developed vaccines against the current pandemic influenza. The H1N1 vaccines will not be available on the private market. Moreover, Governments that have already filed purchase orders will be receiving their prepaid purchase orders in batches over a relatively long period that could extend over six months. Accordingly, Governments should prepare plans for appropriate and optimal use of procured vaccines.

All countries should give highest priority of immunization to health-care workers; especially those who are responsible for case management of critically-ill influenza patients, as well as health-care workers of chest and fever hospitals. Loss of services provided by this group would result in detrimental impact on morbidity and mortality and would compromise the integrity of the health-care system and the overall country's crucial infrastructure.

Successful vaccination of school children would significantly reduce the transmission rate of the pandemic influenza virus in communities. However;

it is highly unlikely that countries with large populations would have enough vaccines to conduct mass immunization campaigns aiming at vaccination of all school children. Should enough amounts of vaccine be made available, countries may consider such a strategy during the second wave of the pandemic provided that top priority groups were vaccinated.

Vaccination strategy: Step-wise approach:

As vaccines available initially will not be sufficient, a **step-wise approach** to vaccinate particular groups may be considered. Countries need to determine their order of priority based on country-specific conditions. Given the possibility of limited vaccine quantities especially at the beginning, a vaccination policy needs to be developed beforehand with predefined and accepted priority groups to receive the vaccine. The decision on who gets vaccinated first will be largely determined by the available amounts of vaccines, the main objective of vaccination and identification of the appropriate target group.

Countries are advised to identify the prime objective for vaccination against H1N1 pandemic influenza, and develop detailed plans that prioritize, in a stepwise manner, recipients of the procured amounts of the vaccine as it is most likely that countries will receive their limited share of the vaccine in installments.

Should countries receive their share of pandemic influenza late during the decline phase of the first wave, they may consider using their procured stock for vaccinating those who are most likely be severely hit during the beginning of the second wave of the pandemic.

Deployment of vaccines:

Countries could use a variety of vaccine deployment strategies to reach these objectives but any strategy should reflect the country's epidemiological situation, resources and ability to access vaccine, to implement vaccination campaigns in the targeted groups, and to use other non-vaccine mitigation measures.

Logistic issues related to deployment and plans for implementation of vaccination program against H1N1 influenza should be well-defined and tested. Potential anticipated challenges should be identified through simulation exercises and alternative actions to overcome them be considered. Past experience in mass immunization campaigns for poliomyelitis (NIDs), measles, meningococcal meningitis among other would greatly ease logistic challenges during such a vaccination program.

Other considerations:

1. Deployment plans: Countries are expected to make use of their population census, demographic profiles of different groups, fertility rates, and statistics on and distribution of health care workers and other potential priority groups for estimating their needs and setting priorities.
2. Post-marketing surveillance: Since influenza viruses evolve constantly, it is impossible to carry out a complete clinical analysis of seasonal influenza vaccines yearly because the composition changes each year to adapt to the virus and so countries will always be a year behind. A complete clinical evaluation is not needed also because manufacturers produce seasonal influenza vaccines using the same procedure and equipment, but for a different virus each year. In the USA, vaccines for seasonal influenza are licensed without clinical trials on the basis of a "strain change". The US regulatory authorities consider the change from seasonal to pandemic H1N1 influenza vaccine production (using the same procedure) as a change in the strain and therefore will not request clinical trials before registration. Since new technologies are involved in the production of some pandemic vaccines, which have not yet been extensively evaluated for their safety in certain population groups, it is very important to implement post-marketing surveillance of the highest possible quality. In addition, rapid sharing of the results of immunogenicity and post-marketing safety and effectiveness studies among the international community will be essential for allowing countries to make necessary adjustments to their vaccination policies.
3. Seasonal influenza vaccines: As most of the production of the seasonal vaccine for the 2009-2010 influenza season in the northern hemisphere is almost complete and is therefore unlikely to affect production of pandemic vaccine, SAGE did not consider that there was a need to recommend a "switch" from seasonal to pandemic vaccine production.
4. WHO assistance to Member States: WHO has a cross-organizational operation that is in place to secure vaccines for developing countries. This is spearheaded by the Director-General's Office and the legal and vaccine departments. WHO is engaged in four types of activities:
 - i. To negotiate donations with manufacturers. Two have been announced: 100 million doses by Sanofi-Aventis and 50 million doses from GlaxoSmithKline.
 - ii. WHO is working with other manufacturers to reserve a portion of their vaccine production for WHO at a reduced price.

- iii. Who is working with governments to raise funds to purchase vaccines.
- iv. WHO is also working with 11 vaccine manufacturers based in developing countries, providing them with seed financing and technical expertise to help them produce influenza vaccine domestically. WHO have also helped them access technology and given them sub-licenses to use technology for producing live attenuated vaccine. These 11 companies will be manufacturing some of the 30 different expected vaccines.