

WHO-EM/CSR/056/E

Summary report on the

Consultation on determining the feasibility of introduction of seasonal influenza vaccines in the Eastern Mediterranean Region

Marrakesh, Morocco
30 August–1 September 2012



World Health
Organization

Regional Office for the Eastern Mediterranean

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1. Introduction

In 2005, following growing recognition of the threat posed by pandemic influenza and the need for significantly strengthen global pandemic influenza preparedness and response, the Fifty-eighth World Health Assembly in resolution WHA 58.5 requested the WHO to seek solutions with partners to reduce the global shortage of both seasonal and pandemic influenza vaccines and to establish vaccination strategies. This resolution paved the way for development of a WHO Global Pandemic Influenza Action Plan (GAP) in November 2006. The three major strategies outlined in the Plan were to a) increase the use of seasonal influenza vaccines; b) develop surge capacity before and during an influenza pandemic; and 3) promote research and development for influenza vaccine.

Since its launch in 2006, the global action plan has been the catalyst for a significant expansion in both influenza vaccine manufacturing as well as increasing the demand for use of seasonal influenza vaccines at the global level. Among the many lessons learned from the 2009–2010 influenza pandemic in the WHO Eastern Mediterranean Region was that immunization recommendations without any supportive public health policies will not stimulate vaccination uptake and drive long-term demand that supports supply sustainability. Currently, no countries in the Region are manufacturing seasonal influenza vaccines but it is also true that unless the demand for seasonal influenza vaccine increases over time in the Region, the countries will be reluctant to invest more in developing the production capacity for seasonal influenza vaccines even for their own populations. This may result in serious implications for the middle-income and low-income countries in the Region during any future influenza pandemic, as clearly demonstrated during the last influenza pandemic, where such countries did not have access to vaccines. Consequently the severity and impact of any future influenza pandemic may be felt more strongly by these countries.

The use of seasonal influenza vaccines in the countries of the Region is very low. According to a WHO survey conducted in 2012, none of the 22 countries of the Region is currently on target to meet the related resolution of the Fifty-sixth World Health Assembly (WHA56.19), which calls for 75% coverage among those aged over 65 years. As the burden of influenza on general populations and the risk factors associated with influenza are not known, countries do not value the importance of influenza vaccination nor its significance as a public health intervention that can reduce morbidity and mortality at least in those groups with severe infections from influenza.

Developing clear policies and plans for introduction and increased use of seasonal influenza vaccine must be evidence-based and reflect national priorities. This has also been endorsed by the WHO Regional Committee for the Eastern Mediterranean in resolution EM/RC53/R.3 (2006).

Against this background, the WHO Regional Office for the Eastern Mediterranean held a consultative meeting in Marrakesh, Morocco from 30 August to 1 September 2012. Its purpose was to define a road map on how seasonal influenza vaccines could be introduced and their use increased in the Region through a process of informed analysis of available scientific evidence and assessment of the needs. The meeting provided an opportunity to determine the current needs and feasibility of introduction of seasonal influenza vaccines in the Region using a systematic and evidence-based decision-making process. Specific objectives of the meeting were to:

- review national strategies/policies for vaccination against seasonal and pandemic influenza;
- develop a regional plan for increased use of seasonal influenza vaccines in the countries of the Region;
- determine the regulatory and policy issues required for introduction of seasonal influenza vaccines in the countries of the Region.

Participants comprised representatives from national governments, including those from the national immunization technical advisory groups, infectious disease experts, representatives from the influenza division of the United States Centers for Disease Control and Prevention, Atlanta (CDC) and WHO staff from the Regional Office and headquarters.

2. Conclusions

The participants considered the development of a five-year regional plan of action to support introduction of seasonal influenza vaccine (RPA-IV). They identified five mutually reinforcing strategic approaches for the regional plan of action to support introduction of seasonal influenza vaccines. It was agreed that the proposed plan would commence in January 2013.

The regional plan comprises five strategic approaches, or “pillars”, as defined by the participants during the meeting: estimating the burden of disease associated with influenza; prioritizing risk groups for vaccination; increasing the availability of seasonal influenza vaccines; improving communication and raising awareness; and strengthening strategic partnerships and collaboration.

Estimating the burden of disease associated with influenza with specific focus of the risk in different age groups

The burden of disease associated with influenza including its seasonal trend, groups at high risk of severe disease and impact on health of the general population will be determined through the activities under this strategic pillar. Specific activities already undertaken by the Regional Office to estimate the burden of disease will produce valuable information that can guide decision-making on the public health benefits of the use of seasonal influenza vaccines. Such information will be useful

to demonstrate the age groups at highest risk of severe influenza as well as the likely effect and impact of seasonal influenza vaccination in reducing the influenza associated deaths and cases in these risk groups.

Prioritizing risk groups for vaccination

The global evidence as well as the recommendations of SAGE on the prioritization of specific target groups for influenza vaccinations will be reviewed under this strategic pillar in the context of special circumstances and ground realities prevailing in the countries of the Region. As evidence will accumulate on the burden of influenza as well as groups at high risk of severe disease, specific prioritization needs will be assessed through consultative process. Criteria to be used to consider prioritization of target groups for influenza vaccination in the Region will include the following.

- Disease severity within individual risk group
- Existence of a well-defined age group in the countries
- Size of the specific age group selected for vaccination
- Vaccine efficacy and effectiveness in the selected risk group
- Feasibility of delivery of vaccines in the selected group
- Indirect health benefits of vaccination in the selected group (e.g. prevention of spread to high-risk patients from health care providers, from children to elderly, and benefits for infants in first 6 months)
- Social acceptability or political support for vaccination of selected group
- Existence of pre-existing recommendations (i.e. how much of a problem will it cause to appear to be changing recommendation)
- Feasibility of reaching expected coverage goals in the selected group
- Safety of vaccine in specific group

Informed analysis of these criteria along with the accumulated evidence on the disease burden will help in prioritization and selection of the

highest risk groups where the use of influenza vaccines can accrue the maximum public health benefits and impact of vaccination on influenza-associated morbidity and mortality are likely to be the highest.

Increasing the availability of seasonal influenza vaccines

New approaches and methods will be used under this strategic pillar to optimize the seasonal influenza vaccine production capacity in the Region. The demand for regional seasonal influenza vaccines would be determined based on anticipated needs after selecting the priority groups for vaccination and the supply would be mapped to identify the countries where the access to vaccines would be limited. Accordingly the feasibility of lowering the price of seasonal influenza vaccines through regional pooled procurement or other innovative approaches would be explored in order to make the vaccines more affordable and equitably accessible by all countries in the Region. Finally, greater emphasis would be accorded to strengthening the national regulatory agencies to promote timely and efficient assessment and approval of locally manufactured or imported influenza vaccines. A regional network of national regulatory agencies will also be promoted to share data related to safety and efficacy of vaccines manufactured using new technologies, as well as improving their capacities for post-marketing surveillance to promptly detect and manage any adverse event associated with the use of seasonal influenza vaccine.

Improving communication and raising awareness

This strategic pillar will lead to the development of national evidence-based communication strategies on influenza and the benefits of influenza vaccination as a key element for prevention and control of influenza in specific age/risk groups. This will also lead to increasing the acceptance and uptake of seasonal influenza vaccination. Communication studies will be conducted to understand insights into the various social, cultural

and contextual factors that may determine the increased uptake or barriers to increased use of seasonal influenza vaccines.

Using information from such studies, appropriate communication strategies and advocacy plans will be developed targeting decision-makers, the general population and health care workers including professional bodies to positively influence the uptake and use of seasonal influenza vaccines. It is anticipated that as success will depend largely upon addressing the broad range of attitudes, perceptions, policy, vaccine delivery systems and socio-cultural determinants that influence the decision-making of individuals and communities, this will be an important activity of the regional plan of action. Similarly, this approach will address the importance of health care workers in influencing vaccination choices of individuals and strengthen the role of professional bodies as advocates of seasonal influenza vaccination. Particular attention will also be given in the plan to appropriate risk communication between the national government, the media and the public at large.

Strengthening strategic partnerships and collaboration

This strategic pillar will look into building sustainable and strategic partnerships with different stakeholders both within and outside the Region to help create a regional initiative for resource mobilization through partnerships and collaborative efforts. The initiative will seek support for increased efforts in technology transfer for vaccine production capacity in the Region and facilitate the establishment of a “pooled” resource for vaccine procurement, production, vaccine-efficacy studies, evaluation of vaccine coverage, etc. which will promote sustained use of seasonal influenza vaccines in the Region. Partnerships will be drawn from national governments, national regulatory authorities, WHO collaborating centres, regional donors such as the Islamic Development Bank, African Development Bank, Arab League, etc. as well as from the private sector.

The participants also stressed the need to embed operational research as an important element in all of the five strategic pillars of the plan. Operational research, among other activities, will support the development of evidence needed to strengthen public health guidance and actions essential for limiting the impact of influenza on populations, monitoring the impact and effectiveness of vaccines, vaccine policy development, evaluating the impact of vaccination policy on usage and coverage, regulatory affairs and post-marketing surveillance for monitoring adverse events following immunization.

3. Future actions

In addition to developing a five-year regional plan of action for 2013–2017, the meeting recommended a course of action over the next five years which will support introduction and enhanced use of seasonal influenza vaccines in the Region.

Stepping up the efforts for estimating the disease burden associated with influenza

The lack of disease-burden data associated with influenza in many countries in the Region remains a barrier to evidence-based decisions on the introduction of seasonal influenza vaccines. There is now a need for better understanding of influenza burden in the Region particularly in middle-income and low-income countries.

As challenges to the development of informed policies and national plans promoting the use of seasonal influenza vaccines include the absence of any data on the epidemiology and seasonality of influenza as well as information on the groups with severe disease, the recent efforts of the Regional Office to estimate the burden associated with influenza in general population in the region needs to be stepped up. The meeting recommended that such data needs to be analysed and disease trends

estimated using standardized methods and techniques. Given the current level of progress in his initiative, the meeting expected that by the end of December 2012, at least 6 to 7 middle-income and low-income countries in the Region would be able to estimate the burden of influenza using WHO's manual.

Collecting evidence on the economic impact of introduction of seasonal influenza vaccines

The meeting agreed that absence of any cost-effectiveness data in the Region on the economic benefits of the use of seasonal influenza vaccines in reducing mortality and morbidity is also a major barrier to development of any evidence-based policy that can support introduction of seasonal influenza vaccine. The meeting recommended that in order to circumvent this barrier, a demonstration project or an "investment case" should be planned and implemented once information are available on the burden of disease associated with influenza and the impact of this burden on health systems in the Region. Based on this information, an analysis would be carried out to demonstrate to decision-makers how much health care cost can potentially be saved if seasonal influenza vaccines are introduced targeting the groups with most severe infection from influenza.

Strengthening epidemiological and virological surveillance for influenza

Good quality epidemiological and virological data on influenza, especially on severe acute respiratory infections (SARI), remain the foundation for influenza disease burden estimation. As disease burden estimation is an ongoing process, strengthening of both epidemiological and virological surveillance for influenza and SARI was stressed and increasing the coverage and quality of surveillance was emphasized. The meeting recommended that good quality surveillance data for influenza and SARI would help countries to periodically review and update their

policies and plans on seasonal influenza vaccinations, if needed. Regular analysis of epidemiological and virological data can help to identify changing epidemiology of the disease or the emergence of any new or novel virus and to match the influenza vaccine strain selected for the country with that circulating in a particular country in a particular season. Therefore efforts to strengthen surveillance will contribute to the country's goal of optimizing benefits from the seasonal influenza vaccination programme.

Estimating number of medically-attended illnesses averted by vaccination

The model presented by CDC on estimating the number of medically-attended illnesses averted by annual influenza vaccination was thought to be a good advocacy tool to stress the public health benefits of annual influenza vaccination to the health policy-makers and decision-makers. Using this simple model, illness or outcomes that can be averted following annual influenza vaccines may be used by the Regional Office as a meaningful way to communicate the value of the seasonal influenza vaccines. Such model would be applied in the Region to support introduction of seasonal influenza vaccines.

Strengthening national regulatory authorities

The meeting recommended that as the five-year regional plan of action for introduction of seasonal influenza vaccine in the Region kicks off, the national regulatory authorities in all the countries in the Region need to be strengthened. Their capacities need to be strengthened in a phased manner in order to make the regulatory actions related to production, licensing, and post-marketing monitoring of vaccine effectiveness and safety of influenza vaccines stronger and more implementable at the country level.



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