WHO Consultation on Applying Surveillance Information for Evidence-based Decisions on Seasonal Influenza Vaccine Composition and Vaccination Timing in the Tropics and Subtropics

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Executive summary

The historical and continuing under-use of seasonal influenza vaccines in low- and middle-income countries, particularly in the tropics and subtropics, increasingly represents a missed opportunity to substantially reduce associated disease and economic burdens. Renewed efforts are now needed to greatly expand access to seasonal influenza vaccines in such settings, particularly among key groups at high risk such as pregnant women. The current consultation was the culmination of a series of meetings and related WHO activities intended to support countries in tropical and subtropical regions looking to introduce or expand national seasonal influenza vaccination programmes.

Despite differences in the timing and patterns of influenza seasonality in the tropics and subtropics, there is no evidence to suggest that the predominantly circulating viruses differ from those seen in temperate zones. As the same influenza viruses appear to circulate globally there would appear to be no need for a special seasonal vaccine to be produced for the tropics and subtropics. There is growing consensus that tropical and subtropical countries should instead use the most recent vaccine (northern or southern hemisphere) that best matches national patterns of seasonality and is available 2–3 months prior to the peak of the influenza season. However, despite significant capacity-building efforts in recent years, many countries still lack sufficient surveillance data, both epidemiological and virological, to inform decisions on which of the two biannual WHO-recommended vaccine compositions to use and when.

Following requests for strengthened WHO guidance in this area, the current consultation was held to help countries in the tropics and subtropics use influenza surveillance, burden, vaccine-effectiveness and other data to inform evidence-based decisions on seasonal influenza vaccine introduction and delivery. Through a combination of presentations, plenary discussions and working group activities, meeting participants representing a broad range of national, regional and global agencies, industry and other stakeholders worked to:

- share experiences and discuss challenges to better understand how countries gather and review information, deal with information deficits and use surveillance data to inform evidence-based decisions on seasonal influenza vaccination;
- review recent WHO guidance on influenza seasonality, vaccine composition and timing in tropical and subtropical countries, and discuss the concept of influenza vaccination zones in relation to national guidelines on seasonal influenza immunization;
- develop a stepwise guidance framework for the evidence-based introduction of national seasonal influenza vaccination, and identify how WHO could best support countries at each step.

During discussions, several country perspectives were provided on the obstacles encountered and lessons learnt when introducing and sustaining seasonal influenza vaccination programmes. Despite the significant strides made in many countries there remains a widely recognized need for more surveillance data and other information to inform national seasonal influenza vaccination policies. Significant knowledge gaps persist in many countries in relation to the real health and economic burdens of influenza, with little data also available on vaccine effectiveness, cost-effectiveness and social acceptability of vaccination in specific settings and among specific groups.
Other recurring issues included the complexity of influenza vaccine regulatory processes due to changing vaccine compositions over time and the lack of regulatory capacity in many countries. In addition, it is also clear that despite significant recent gains, global influenza vaccine production capacity remains insufficient to meet demand during any future pandemic. Sustaining national and global influenza vaccine production capacity and delivering new vaccines will require broad stakeholder support. From an industry perspective, influenza vaccine is a valuable public health tool that is currently under-utilized in most countries and regions. In many cases vaccination targets are not being met or even set, while demand is stagnating in some regions.

In order to map out a way forward in implementing a national “roadmap” for seasonal influenza vaccine introduction, meeting participants were assigned to individual working groups and asked to discuss the principal considerations and main required actions. The specific actions required at each point of a national influenza vaccine introduction process were identified, proposals made on the ways in which WHO could best support countries in undertaking such a process and key stakeholders listed (Annex 1).

Despite widespread gaps in the national evidence base in many countries there is in reality an ever-expanding and complex global evidence base on various aspects of influenza. One key ongoing WHO activity will be the work now being carried out, with financial support from the PIP Framework, to bring together various stakeholders to review the currently highly variable burden-of-disease literature and determine how best to support countries wishing to conduct influenza burden studies. It was further proposed that WHO initiate a process of condensing and packaging its ever-expanding range of detailed influenza-related guidance and other resources.

Similarly, the substantial but currently disparate WHO efforts and resources directed towards building up national capacities in individual areas such as laboratory and epidemiological surveillance, vaccine regulatory and licensing capacities, and deployment capabilities could all now be brought together under the unifying concept of a vaccine introduction roadmap. Other potentially beneficial activities include supporting countries in presenting to vaccine manufacturers their intention to introduce influenza vaccination and to receive early feedback on the commercial sector’s views on this. Related efforts could also be made to explore the role that could be played by the private sector in driving a vaccine-introduction process in order to develop an initial market for such vaccines prior to public sector take up.

As with previous meetings in this series, this consultation was regarded as part of a process of transforming evidence into action and WHO will continue to work with countries in tropical and subtropical regions in initiating and maintaining the actions now required for progress. Many countries have already shown what can be achieved when action is taken in the face of seasonal influenza outbreaks or in response to the ever-present need for pandemic preparedness. It is hoped that meeting participants and others will continue to work to emphasize to their ministry of health and other national decision-makers the increasing range of advocacy, capacity-building and other opportunities and assistance now available.

Introduction

Meeting participants were welcomed by Dr Daniel Kertesz, WHO Representative to Thailand, who highlighted the historical lack of awareness of the potentially high burden of disease associated with influenza in many countries in the WHO South-East Asia Region.
Meetings such as this serve to raise awareness of this crucial issue while stressing the importance of evidence-based decision-making. Participants were also welcomed by Dr Supamit Chunsuttiwat, Ministry of Public Health, Thailand, who highlighted recent trends in the incidence of influenza in Thailand and the improving levels of national influenza surveillance and burden awareness. However, despite broad political recognition of the importance of vigilance in relation to influenza, people living in tropical and subtropical countries continued to suffer a high burden of associated disease with little or no access to treatment. Dr Chunsuttiwat welcomed the current meeting as an important step in helping countries now looking to make progress in introducing influenza vaccination programmes. National political commitment backed up by technical support from WHO and other stakeholders would be vital in ensuring the success of such efforts. With its experience of influenza surveillance and of working towards the establishment of national vaccine production capabilities, Thailand welcomed this opportunity to exchange information and share the lessons learnt.

Influenza viruses are a constantly evolving and well-recognized public health threat that not only cause repeated seasonal and year-round epidemics but are capable at any time of causing a potentially catastrophic pandemic. Effective surveillance of the spread and evolution of both seasonal and potentially pandemic influenza viruses depends upon constant vigilance and the timely sharing of viruses, virological data and epidemiological and other information.

Influenza vaccines remain the primary public health intervention against both seasonal and potentially pandemic influenza viruses. As seasonal influenza viruses evolve unpredictably there is a need for two annual WHO vaccine composition meetings held in February and September to select and recommend viruses for inclusion in vaccines for the subsequent northern and southern hemisphere seasons, respectively. These recommendations are then used by pharmaceutical companies and national regulatory agencies to develop, produce and license influenza vaccines.

These biannual recommendations are only possible because of the extensive and complex interactions which take place within the WHO Global Influenza Surveillance and Response System (GISRS). Despite severe time constraints, GISRS and vaccine manufacturers work together each year to deliver seasonal influenza vaccines in time for vaccination campaigns. Key areas identified for improving and streamlining the vaccine virus selection and development process include surveillance and virus collection, virus antigenic and genetic characterization, production of candidate vaccine viruses, timeliness of vaccine potency assay availability, strengthened decision-making, communication and coordination, and the development of new vaccines, including more broadly protective vaccines.

Despite being a well-established public health threat, 74 countries of the tropics and subtropics currently have no national seasonal influenza vaccination policy in place – corresponding to an estimated 60% of the world’s population. Among children under five years of age it was estimated that in 2008 there were 20.5 million cases of influenza-associated acute lower respiratory infections, with 1 million severe cases and 28 000–111 000 deaths; with 99% of these deaths occurring in developing countries.¹

In addition, despite the huge scale of the human–animal interface and associated risk of the emergence of an influenza virus with pandemic potential, global pandemic influenza vaccine production capacity remains insufficient. Expanding routine seasonal influenza vaccination programmes in tropical and subtropical countries would not only help to address the current glaring shortfalls and inequalities in seasonal vaccine production and population coverage in many countries but is also a key strategic component of global pandemic preparedness.

The historical and continuing under-use of such vaccines in low- and middle-income countries, particularly in the tropics and subtropics, increasingly represents a missed opportunity to substantially reduce associated disease and economic burdens. Renewed efforts are now needed to greatly expand access to seasonal influenza vaccines, particularly among key groups at high risk such as pregnant women, and thus contribute to the attaining of the newly agreed United Nations Sustainable Development Goals (SDGs). In addition, given the fundamental linkage between demand for seasonal influenza vaccines and pandemic vaccine production capacity, current shortfalls in seasonal influenza vaccination coverage will continue to undermine national, regional and global pandemic preparedness efforts.

1. Influenza in the tropics and subtropics

Meeting participants were provided with an overview of recently circulating seasonal influenza types and subtypes based upon the results of laboratory testing by GISRS. An overview was also provided of the cumulative numbers and epidemiological characteristics of human infections with A(H5N1), A(H7N9) and other zoonotic influenza viruses. Human infections with zoonotic influenza viruses continue to be confirmed but no sustained human-to-human transmission has been observed. At present it is not possible to predict which subtype is most likely to give rise to a pandemic.

Despite differences in the timing and patterns of influenza seasonality in the tropics and subtropics, there is no evidence to suggest that the predominantly circulating viruses differ from those seen in temperate zones. Antigenic mapping and phylogenetic analysis indicate that influenza A(H3N2) viruses circulate globally with old viruses being replaced by new viruses moving in periodic sweeps through countries. All age groups appear to be susceptible to this subtype, with vaccines requiring regular updating. Influenza A(H1N1) and B viruses evolve more slowly and exhibit different circulation patterns that remain more stable. As a result it is children and young adults who are usually more susceptible to this subtype, with the corresponding vaccine components requiring less frequent updating.

As the same influenza viruses appear to circulate globally there would appear to be no need for a special seasonal vaccine to be produced for the tropics and subtropics. Currently, global vaccine production is a “just-in-time” process and in the absence of domestic production capacity there is no scope for producing designer tropical influenza vaccine formulations. There is growing consensus that tropical and subtropical countries should instead use the most recent vaccine (northern or southern hemisphere) that best matches national patterns of seasonality and is available 2–3 months prior to the peak of the influenza season. It was also highlighted that improved vaccines are required which give longer and better protection and greater coverage against drifted viruses, particularly A(H3N2) viruses.

Recent efforts have also been made to better determine the patterns of influenza seasonality and optimal timing of vaccination in tropical and subtropical countries. As discussed during a
preceding WHO Expert Group Meeting,\(^1\) seasonality in the tropics and subtropics has now been independently assessed by CDC, NIVEL, PATH, and WHO using different data sources and analytic approaches as part of the development of WHO guidance in this area.\(^2\) Potential limitations of this approach include the possible non-representativeness of selected data, the masking of subregional variations and the need in some cases to extrapolate data from neighbouring countries. Nevertheless, it appears that the optimum time of vaccination can be determined by seasonality analysis, with no evidence found to support the need for a specific vaccine composition recommendation for use in tropical and subtropical countries. Furthermore, analysis of the starting point of the primary peak and of the number of annual peaks in such countries had also allowed for the identification of up to eight provisionally proposed “vaccination zones”. In all cases, and independent of the geographical location of a country, the most recent WHO-recommended vaccine composition (northern or southern hemisphere) should be used. Further considerations for influenza vaccination programmes in tropical and subtropical countries include: (a) which main target groups to vaccinate and with which vaccine type; (b) the possible need for a staggered vaccination campaign in large countries; (c) the use and relative cost benefits of trivalent versus quadrivalent vaccines (particularly in children); and (d) ensuring the availability and regulatory approval of specific vaccine products.

Meeting participants welcomed the clear progress which had been made in this area while highlighting that complexities were likely to arise in translating such findings and insights into policy, even in smaller countries. It was also suggested that the utility of the long-established “northern and southern hemisphere” terminology itself be reconsidered given that the focus for tropical and subtropical countries would be on the availability of the most recent formulation regardless of geographical location. Other points raised included the expected duration of protection of influenza vaccination and the implications of this for vaccination programmes in countries with two annual peaks, the potential need for year-round vaccination in some settings and the effect of highly variable national immunization policies and priorities. In response it was highlighted that WHO recommends that any country introducing vaccination also conducts vaccine effectiveness and other studies to help answer these and related issues. During discussion the issue of the 2014 northern hemisphere vaccine mismatch was also raised. Under the current egg-based approach to vaccine production the possibility of such mismatches, although rare, would remain an issue. However, efforts were currently under way to improve the vaccine virus selection and development process.

2. Applying surveillance data to inform vaccination policy

Significant knowledge gaps persist in many countries in relation to the real health and economic burdens of influenza, with little data also available on vaccine effectiveness, cost-effectiveness and social acceptability of vaccination in specific settings and among specific groups. Efforts are therefore continuing in a number of WHO regions to promote and support the expanded and more systematic gathering of surveillance and related data in these and other areas. Such data are crucially important in enabling countries to make informed policy decisions, provide baselines for evaluating vaccine impact and make the case to national and international funding bodies for influenza vaccine introduction.


In the WHO South-East Asia Region and WHO Western Pacific Region, workshop training and other efforts continue to build upon recent gains in measuring the burden of influenza disease in low- and middle-income countries. Key supportive factors include the increasing generation of consistent SARI/ILI data in countries, the initiation of health-care admission surveys to better define denominators, and financial and other capacity-building support arising from the Pandemic Influenza Preparedness (PIP) initiative and other international funding mechanisms. Such efforts are being informed and guided by a three-step WHO burden-of-disease strategy in which disease burden, economic burden and cost-effectiveness analyses are performed to inform decisions on influenza vaccine introduction. Nationally relevant vaccine-impact and cost-effectiveness assessments depend upon the generation and analysis of local data, including on disease burden, vaccination costs and coverage, local transmission dynamics and vaccine effectiveness. A package of detailed WHO manuals and other resources covering these and other aspects of the three-step burden-of-disease strategy have been developed or are in preparation.

In the WHO Eastern Mediterranean Region improvements have been made in a number of countries in relation to the reporting and use of surveillance and other data to better understand national patterns of influenza seasonality and disease burden, and to contribute to the process of global vaccine virus selection. However, there remains a lack of public health policies, procedures and legislation on influenza vaccination, with inadequate vaccine supplies in the public sector. Inadequate information on the burden of influenza, limited awareness among groups at high risk and increased levels of population movements continue to present considerable challenges. Addressing this will require expanded and enhanced influenza surveillance, the timely and complete reporting of surveillance data, and improved generation of evidence on influenza seasonality, virus circulation and disease burden to support policy development and legislation.

In the WHO Region of the Americas significant strides have been made in recent years in the application of surveillance data to inform vaccination policy in several countries. The Pan American Health Organization (PAHO) Technical Advisory Group (TAG) recommendations 2004–2015 had urged all countries to strengthen their influenza surveillance systems in order to determine disease burden, vaccine introduction cost-effectiveness and optimal vaccination strategy. It was further recommended that seasonal influenza vaccination policies covered individuals with chronic illness, the elderly, pregnant women, children aged 6–23 months and health care workers. Countries were also encouraged to generate coverage data and to document the experiences and lessons learnt when targeting groups at high risk. In tropical areas it was recommended that the period of highest influenza activity was determined using various data sources and methods, with intensive high-coverage vaccination campaigns taking place prior to the primary peak backed up by health-service vaccine delivery during the influenza season. In all cases the most updated vaccine available was to be used and evaluations made of the impact of policy decisions.

Despite the significant strides made in many countries there is a widely recognized need for more surveillance data and other information to inform national seasonal influenza vaccination policies. Related issues include the potential under-reporting of influenza and associated need for improved diagnostic capabilities, and the need for improved health care worker training and sensitization, including raised awareness of influenza mortality rates

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among the elderly. Addressing the under-reporting of influenza might involve moving towards the more integrated national surveillance of all respiratory illnesses.

During discussion the central importance of clinical, epidemiological and laboratory surveillance data in informing decision-making was reiterated – supported where feasible by the results of burden, cost-effectiveness and other studies. Where national data were lacking then regional or global data could play a role in areas such as determining seasonality and adverse event monitoring but there was general consensus that such data were unlikely to be sufficient for shaping national policies. These would likely require robust country-level evaluations of incidence, burden and vaccine cost-effectiveness, including among groups at high risk. Such evidence would also be a key requirement in countering claims of non-transparency in vaccine introduction decisions. Addressing the under-reporting of influenza and making an informed case for its importance will be especially crucial in countries with clear competing public health priorities.

Meeting participants highlighted a number of key stakeholders and target audiences in efforts to translate evidence into policy. These include general practitioners and other health care workers, professional associations, vaccine manufacturers, the public and the media. Without public and professional acceptance of the need for such vaccines and their safety, efforts will not succeed. Conversely, media coverage of major influenza outbreaks causing high numbers of fatalities can be instrumental in bringing this disease to the attention of politicians, producing momentum for improved surveillance, changes in policy and in some countries for immediate public health intervention. In other settings, it is only by making a clear case that momentum for action will build. The attitude of the media in general is a crucial factor in determining the degree to which influenza is viewed as a priority both by the public and by national policy-makers.

3. Seasonal influenza vaccine introduction

An overview was provided of WHO influenza vaccine policy with an emphasis placed on maternal immunization given the pivotal role this played in the establishment of seasonal influenza vaccination in a number of PAHO countries. Attention was drawn to a number of key WHO policy documents and technical manuals in this area, including WHO guidance on introducing new vaccines in a country and upcoming WHO guidance on the implementation of maternal influenza vaccination. In the case of maternal influenza vaccination a broad range of additional policy, delivery, training and communication issues are involved in moving from policy-making to implementation and acceptance.

Despite global recommendations and current vaccine introduction guidance, many countries still lack influenza vaccination policies, including on maternal influenza vaccination. WHO will continue to support policy development and operational activities in this area. This will include the collating of relevant policy-development tools and the developing of guidance to countries on establishing decision-making processes for vaccine introduction, delivering influenza vaccines to pregnant women and developing national service delivery plans. Lessons will also be learnt from country experiences and associated research projects that

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aim to close information gaps, and further expert consultations and discussions held to better identify and prioritize key aspects of the decision-making process.

When introducing a new vaccine in a country a broad range of safety, effectiveness, delivery and target group considerations need to be taken into account as part of the vaccine regulatory pathway. This will entail comprehensive communications with the national regulatory authority and familiarity with all relevant guidelines and regulations. Nonclinical and clinical safety and efficacy assessments will be essential in informing the necessary risk–benefit evaluations. The national regulatory pathways for seasonal influenza vaccines in Thailand were presented as an example of the complex processes and timelines involved in approving new vaccines, vaccines produced following major manufacturing changes and vaccines in which a strain change had been recommended. Sufficient regulatory capacity in countries will be required along with meaningful engagement with vaccine manufacturers as a key stakeholder in advocacy and introduction efforts.

Following the 2009 (A)H1N1 pandemic and 2012 WHO SAGE recommendations there has been increased global interest and investment in influenza vaccines. Against this backdrop the Partnership for Influenza Vaccine Introduction (PIVI) initiative continues to undertake a broad range of advocacy, guidance, technical support and modelling activities intended to catalyse the introduction of influenza vaccines into country programmes. Current challenges to the global expansion of such vaccination programmes include the recurrent cost of vaccines, negative perceptions of the value of influenza prevention against competing public health priorities, concerns about vaccine safety and efficacy, and a lack of established vaccination programmes targeting groups such as pregnant women and health care workers. Significant progress in overcoming these challenges in a number of low- and middle-income PIVI partner countries has demonstrated both the feasibility and sustainability of influenza vaccine procurement and introduction. In the Asia Pacific region, a comprehensive package of support and resources is also offered by the Asia Pacific Alliance for Control of Influenza (APACI). APACI aims to reduce the burden of influenza in the region by addressing a range of epidemiological issues relating to influenza and its impact. Through approaches such as the establishment of Influenza Foundations in member countries the alliance provides a platform for raising awareness of the impact of influenza, assessing disease burden, and sharing information and national experiences of influenza-related activities.

During discussions, several country perspectives were provided on the experiences and lessons learnt in introducing and sustaining seasonal influenza vaccination programmes. Recurring issues included the complexity of influenza vaccine regulatory processes due to changing vaccine compositions over time and the lack of regulatory capacity in many countries. Discussion of regional and national experiences in establishing seasonal influenza vaccination programmes in the tropics and subtropics also revealed a range of obstacles encountered in influenza vaccine licensing, acceptance and use, including problems caused by the sometimes contradictory and confusing instructions for influenza vaccine use in pregnant women. In Thailand, efforts to increase the current coverage level of 25% among pregnant women have faced the twin challenges of promoting vaccine acceptance among mothers while overcoming the long-standing questioning of the benefits of such vaccination by some physicians and antenatal care providers. There is therefore a need to train and sensitize health care workers on the importance of maternal influenza vaccination, to reduce hesitancy among groups at high risk, and promote greater awareness of the safety and efficacy of influenza vaccines. As part of this it may be necessary to develop or strengthen data on the burden and health impact of influenza on pregnant women and infants, and on the
cost of rolling out maternal vaccination programmes. It is intended that the package of current and upcoming WHO guidance and tools on burden estimation, vaccine introduction and maternal influenza vaccination will directly address these and related issues. In all cases, strategies for ensuring programme sustainability will also be required and are likely to involve both public and private financing initiatives and innovation in rolling out vaccination services beyond traditional and potentially already crowded public health facilities such as hospitals.

Other recurring themes included the crucial need for political will and advocacy among governments, nongovernmental organizations and scientific and other professional societies backed up by supportive ministerial resolutions and other legislative support. In PAHO countries the significant gains made in recent years were linked to high-level government support backed up by targeted social communications campaigns fronted by celebrity “champions” of vaccination. There was also a need to clearly identify and reach target groups through organized campaign strategies that addressed logistical and other challenges to implementation. In some countries the vaccination of health care workers was a strategic first step and approaches ranged from a mandatory requirement to targeted advocacy campaigns.

Meeting participants were then assigned to working groups to consider one of three fictional national scenarios in which an influenza vaccination policy was to be introduced. This exercise required participants to consider various aspects of the decision-making process and to develop a checklist of priority actions to address key information needs. Despite variations between the presented scenarios the following overarching themes emerged:

- Consideration is needed on whether or not sufficient evidence and data already exist upon which to base a vaccine programme introduction or expansion decision. In many cases, the current WHO SAGE recommendations on vaccinating groups at high risk, combined with global, regional and neighbouring country data on disease incidence, vaccine effectiveness and safety could provide a starting point, particularly where national data on individual groups was lacking or incomplete.
- In all cases the size of the target group(s) selected for vaccination should be quantified to determine the likely level of demand and other logistics.
- Plans should be made to determine levels of disease and economic burden among target groups and to estimate the costs of vaccine introduction and ongoing delivery to allow for credible cost–benefit evaluations.
- Assessment will be required of the capacity of the national health system to deliver vaccines (including cold-chain capacity) and to monitor any adverse effects following administration. Associated national regulatory and other capacities will also need to be evaluated.
- Studies among target groups of levels of vaccine acceptability (or vaccine hesitancy) in the context of health-seeking behaviour may be required, particularly where levels of uptake have historically been low.
- Campaign strategies, vaccine formulation choice and timing of delivery will all need to be tailored to the national situation, informed by surveillance and other data on seasonality, levels of burden among target groups and geographical considerations.
- In some settings it may be beneficial to form a dedicated influenza vaccine introduction Task Force with broad representation of all key stakeholders to inform the national influenza TAG and to oversee and coordinate key advocacy, introduction and impact-evaluation activities.
4. Influenza vaccine supply

The WHO Global Action Plan for Influenza Vaccines (GAP) was launched in 2006 and comprehensively revised in 2011. The objectives of this initiative were to promote evidence-based increases in seasonal influenza vaccine use, to increase influenza vaccine manufacturing capacity and strengthen national regulatory competencies, and to stimulate and support research and development activities to develop better vaccines. Despite significant gains made in all these areas, global influenza vaccine production capacity remains insufficient to meet demand either during seasonal epidemics or during any future pandemic. In addition, the scheduled 2016 closure of the initiative will have a number of implications in terms of financial assistance, ongoing capacity-building efforts and the development of broadly protective and pandemic vaccines. In order to ensure that the progress made to date is brought forward, a WHO consultation process is now under way to identify key actors and determine how best to proceed. Given current vaccine shortfalls and increasing awareness of the need for both influenza epidemic and pandemic preparedness and response, it is clear that developing country influenza vaccine manufacturers will have a major role to play across a range of advocacy and vaccine introduction activities.

In Thailand, work is continuing to establish domestic influenza vaccine production facilities in line with the national plan on avian and pandemic influenza preparedness and response. Key drivers include the need to ensure the availability and timely supply of pandemic influenza vaccine for the Thai population in the face of pandemic threats, to increase the global supply of pandemic vaccine in time of need and to decrease dependence upon external sources of influenza vaccine. In recent years activities have been accelerated with GAP support in terms of both pandemic preparedness and the implementing of the national influenza vaccination plan. Planned next steps include building sufficient capacity to manufacture 2–10 million doses of seasonal inactivated influenza vaccine and developing the ability to convert production to the manufacture of live-attenuated influenza vaccine in the event of a pandemic. Government support and the continued commitment and support of international partners in the context of finalizing the GAP initiative will be key requirements of success and sustainability.

An overview was also given of the lessons learnt in PAHO countries when addressing vaccine supply issues in countries that lie outside the temperate seasonality zone. In particular, the central role of the PAHO Revolving Fund for vaccine procurement was highlighted in successfully addressing vaccine-preventable diseases including influenza. Despite a range of manufacturing, regulatory and other challenges the Revolving Fund has proved instrumental in improving the access of countries in the region to seasonal influenza vaccine. A key factor underlying the success of the initiative has been increased levels of commitment from countries to establishing and meeting national vaccine demand.

When addressing issues of supply and demand, influenza vaccine manufacturers must deal with a number of constraints and considerations unique to influenza vaccines. For example, one industry analysis of vaccine dose distribution by WHO region during 2004–2013 revealed very striking differences, with a continued negative trend observed for total dose distribution in the WHO European Region and no observed convergence in the historically divergent patterns of dose distribution in different WHO regions. Associated qualitative analysis further indicated that very few countries in the world currently achieve the WHO-recommended 75% coverage level among the elderly.
It is likely that various factors are contributing to the highly variable acceptance and implementation of seasonal influenza immunization programmes globally. In India overall adult immunization coverage has been estimated to be less than 10% with even this figure declining for vaccines against diseases such as influenza that are often perceived to have low mortality risk. In addition, despite huge potential market opportunities, influenza vaccine manufacturers in India face a wide range of financial and operational challenges including erratic patterns of demand and flexible influenza vaccine pricing.

Sustaining national and global influenza vaccine production capacity and delivering new vaccines will thus require broad stakeholder support. From an industry perspective influenza vaccine is a valuable public health tool that is currently under-utilized in most countries and regions. In many cases vaccination targets are not being met or even set, while demand is stagnating in some regions. Increased demand drives increased capacity, fuels innovation in vaccine technology and strengthens pandemic preparedness. In Thailand securing and justifying the investments needed to establish national seasonal influenza vaccine production capacity realistically depended upon the contribution that such capacity will make to national pandemic preparedness and response capabilities, backed up by annual burden data and efforts to increase seasonal influenza vaccine acceptance and uptake.

In some countries the routine delivery of influenza vaccine as part of antenatal care may provide an opportunity to both initiate and reinforce vaccine introduction efforts. Increased coverage and logistical, cost-saving and other benefits could be realized by making influenza vaccine available both prior to the peak of the influenza season and opportunistically whenever pregnant women present for antenatal care. Such year-round availability is particularly crucial for pregnant women given their vulnerability to influenza. Potential approaches identified by WHO for ensuring the year-round supply of influenza vaccine include alternating between the most recent formulations when each is available, extending product shelf-life to make vaccines usable throughout the year and continued support for local vaccine production tailored to local demand in tropical countries. Such approaches will require a range of national logistical capacities supported by a willingness among manufacturers and manufacturing country regulators to demonstrate flexibility in areas such as product expiry-date setting and release of vaccine late in the production cycle. Policymakers will also need to be aware of local seasonality and strain patterns to ensure use of the most suitable WHO-recommended vaccine formulation. Countries with varying seasonality or year-round circulation of influenza, or countries with large latitudinal spread, may require alternate vaccination supply and timing. Pilot projects will be required to understand the feasibility of different year-round vaccine supply and delivery strategies.

The incorporation of seasonal and pandemic vaccines into the WHO Prequalification Programme over the last decade also has a number of implications for vaccine production and supply. Although the granting of WHO prequalified status for seasonal vaccines would not increase vaccine production in itself, the producers of such vaccines can bid for influenza vaccine contingents in United Nations purchases which for seasonal influenza vaccine is presently 20–30 million doses per year. This has important benefits both in sustaining seasonal vaccine production and maintaining the necessary production capacities needed to produce sufficient pandemic vaccines. In addition, valuable experience gained in non-producing countries in distributing and using prequalified seasonal influenza vaccine could potentially be crucial during any future pandemic, and is thus a key aspect of pandemic preparedness.
5. The way forward

Since 2004 the uptake of seasonal influenza vaccination in many countries in Latin America and the Caribbean has markedly increased and there is wide recognition of the leading role played by countries in this region in developing and implementing a roadmap with potential applicability in tropical and subtropical countries worldwide. Among the lessons emerging from a recent WHO/PAHO regional meeting on seasonal influenza vaccination in the Americas was the need to bring together a broad range of stakeholders and to promote horizontal cooperation among countries, including through the sharing of best practices. The key issue of demonstrating vaccine effectiveness and impact in target groups is also well recognized and is the focus of the activities of the Network for Evaluation of Influenza Vaccine Effectiveness in Latin America and the Caribbean (REVELAC-i).

In order to map out a way forward in implementing a national roadmap for seasonal influenza vaccine introduction, meeting participants were again assigned to individual working groups and asked to discuss the principal considerations and main required actions. The specific actions required at each point of a national influenza vaccine introduction process were identified, proposals made on the ways in which WHO could best support countries in undertaking such a process and key stakeholders listed. The consolidated outcomes of the three working groups are presented below in Annex 1.

During discussion of the working group outcomes a number of common themes and proposed next steps were identified. Despite widespread gaps in the national evidence base in many countries there is in reality an ever-expanding and complex global evidence base on various aspects of influenza. One key ongoing WHO activity will be the work now being carried out, with financial support from the PIP Framework, to bring together various stakeholders to review the currently highly variable burden-of-disease literature and determine how best to support countries wishing to conduct influenza burden studies. It was further proposed that WHO initiate a process of condensing and packaging its ever-expanding range of detailed influenza-related guidance and other resources. A single and easily accessible WHO “toolbox” of core resources could potentially be of considerable help to countries now wishing to make progress in this area. Toolbox contents could include the WHO SAGE recommendations in easily presentable form, burden-estimation guidance, vaccine introduction guidelines and the lessons learnt in PAHO countries; with further guidance developed in currently under-researched areas such as overcoming vaccine hesitancy among pregnant women and health care workers. Similarly, the substantial but currently disparate WHO efforts and resources directed towards building up national capacities in individual areas such as laboratory and epidemiological surveillance, vaccine regulatory and licensing capacities, and deployment capabilities could all now be brought together under the unifying concept of a vaccine introduction roadmap. Other potentially beneficial activities include supporting countries in presenting to vaccine manufacturers their intention to introduce influenza vaccination and to receive early feedback on the commercial sector’s views on this. Related efforts could also be made to explore the role that could be played by the private

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2 WHO/PAHO regional meeting on seasonal influenza vaccination in the Americas. Third WHO meeting on seasonal influenza vaccine composition and Third REVELAC-i network meeting. Santiago, Chile, 15–17 March 2016.
sector in driving a vaccine-introduction process in order to develop an initial market for such vaccines prior to public sector take up.

In order to make progress in all these areas it will also be necessary to place influenza firmly on the international health agenda. Efforts should be made to ensure that seasonal influenza vaccination is recognized as a central component of international efforts to reduce levels of mother and child morbidity and mortality, and as the cornerstone of pandemic influenza preparedness and response.

As with previous meetings in this series, the current consultation was regarded as part of a process of transforming evidence into action and WHO will continue to work with countries in tropical and subtropical regions in initiating and maintaining the actions now required for progress. Many countries have already shown what can be achieved when action is taken in the face of seasonal influenza outbreaks or in response to the ever-present need for pandemic preparedness. It is hoped that meeting participants and others will continue to work to emphasize to their ministry of health and other national decision-makers the increasing range of advocacy, capacity-building and other opportunities and assistance available to countries who wish to implement the roadmap for action and related tables of actions developed during this series of meetings.
## Annex 1
### Way forward in implementing a national roadmap for seasonal influenza vaccine introduction

<table>
<thead>
<tr>
<th>Step</th>
<th>Actions by countries</th>
<th>WHO support activities</th>
<th>Stakeholders to engage</th>
</tr>
</thead>
</table>
| **Building the evidence base for policy** | EPI or NIP programmes to take the lead in creating the information dossier, with input from the NIC and health information systems.  
Review available surveillance and research evidence for the country, region or globally on influenza disease and cost burdens, and learn from the actions taken by other countries.  
Identify critical knowledge gaps, including on groups at high risk, and plan some small in-country studies and/or surveys to fill gaps depending on data availability.  
Evaluate current influenza surveillance system capabilities, determine the “must-have” requirements of surveillance and improve capacity if needed.  
Develop plans to include influenza surveillance within existing disease surveillance systems or use other national sources of data to determine burden and groups at high risk.  
Carry out cost-effectiveness and other modelling efforts to demonstrate and estimate impact.  
Prepare a concise brief on the situation and potential solutions. | Provision of technical guidance and support in the form of guidelines, protocols, templates and materials.  
Conducting of workshops and training for key stakeholders.  
Curation of the global evidence base. | Professional societies, clinicians and other health workers, relevant NGOs and medical/public health schools.  
MOH and other relevant national ministries and agencies, such as those for finance and planning.  
WHO, UNICEF and UNFPA. |
| **Making a case** | Conduct advocacy meetings.  
Build NITAG functionality  
Consider establishing a Task Force to collate and present evidence to the NITAG in the areas of: evidence gaps; vaccine safety, availability and product profiles; NRA regulatory capacity; national AEFI-monitoring capabilities; delivery and other logistics capacities; and the development of policy recommendations, including for target groups.  
Develop a strategic plan with separate elements for: public engagement and testing of public acceptance; data collection and presentation to leadership (including inputs from neighbouring countries; modelling of impact, scenarios and approaches to implementation; partnerships; budget (national and micro plans); operational aspects (such as cold chain/storage, training, production of communication materials, AEFI monitoring and immunization tracking); risk–benefit and | Provision of technical support, training manuals and guidelines.  
NITAG strengthening exercises.  
Collate and share experiences from other countries and partners.  
Linking to useful resources (NGOs, technical assistance, pilot resources).  
Support NRA strengthening. | Civil society, professional associations  
NITAG, clinicians, laboratory scientists, communications specialists, regulators, MOH, anthropologists, public health agencies in country, disaster preparedness agencies, vaccine experts and MCH, EPI, ANC and NCD programmes.  
WHO, UNICEF and UNFPA. |
| Making informed decisions | NITAG makes recommendation to the government.  
Gather cost information and budgetary implications.  
Request budgetary allocation from finance ministry or concerned authorities (Planning Commission or health security organization). | Explore UNICEF and other assistance with bulk purchases. | NITAG, MOPH, National Organisations, Professional societies, civil society. |
|--------------------------|---------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
| Addressing regulatory needs | Decide upon vaccine formulations and manufacturing/import/marketing licensing rules in accordance with national regulations.  
Determine what is required for obtaining regulatory approval.  
Identify current national regulatory capabilities and capacity.  
Share regulatory experiences/challenges with other countries to address the issues.  
Determine if country will accept WHO prequalification for vaccine.  
Obtain approval to use the vaccine.  
Carry out regulatory risk assessment regarding use of influenza vaccines in pregnant women.  
Work with MOH, regulators and manufacturers to address potential issues with package insert indications for use in pregnant women. | Promote and facilitate NRA networking, and assist in the evaluation and building up of national regulatory capacities, including through provision of technical support to NRAs.  
Prequalification process. | Regulators, MOH, clinical professional societies and vaccine manufacturers and importers. |
| Assessing logistical capacity | Follow WHO vaccine introduction guidelines.  
Identify human resources and capabilities needed and associated training needs.  
Identify physical resources needed based on the logistics plan – including cold chain, storage, transport and disposal requirements, and ancillary supplies needed for vaccine administration.  
Set up immunization information systems and administration tracking.  
Exercise the effort/simulate and revise.  
Assess delivery strategies for both pre-seasonal campaign and routine vaccination.  
Consider maternal vaccination integrated into the ANC package after 2–3 years of campaign. | WHO planning tools for implementation and associated guidance and templates.  
WHO technical advisor and technical support. | WHO, UNICEF |
| **Introducing the vaccine** | Conduct advance communication activities to prepare the community for the campaign.  
Identify appropriate administration sites such as antenatal clinics, primary care clinics, community centres and pharmacies.  
Ensure appropriate stocking of vaccines and other supplies needed for administration.  
Train health care workers.  
Put adverse-event monitoring systems in place.  
Organize launch of campaign with celebrities and WHO branding. | WHO technical advisors and guidance – including in the setting up of adverse event systems. | WHO, UNICEF |
| --- | --- | --- | --- |
| **Policy advocacy** | See Making a case above.  
Ensure decision-maker, leadership and health care worker buy-in for the initiative.  
Engage with media and other key outlets to assure transparency and correct messaging.  
Engage with community, village and religious leaders.  
Publicize previous positive experiences of vaccine introduction in other countries or with other vaccines in country to promote confidence. | SAGE recommendations and advocacy from WHO.  
Risk communication training. | WHO, UNICEF, UNFPA, relevant NGOs/civil societies and medical and public health schools. |
| **Monitoring and evaluating impact** | Set milestones and deliverables.  
Monitor the implementation of all steps to inform revision and enhancement of later roll-out.  
Monitor impact – including through assessment of disease averted, over-the-counter use and volume of clinic visits.  
Monitor coverage, vaccine efficacy and potential adverse events.  
Monitor public acceptance – and follow up with the public.  
Monitor communication – including through social media impressions, likes, forwards and web site visits.  
Qualitative assessment from leadership to identify challenges and determine likelihood of future implementation. | Impact-evaluation tools, questionnaires and technical assistance.  
Technical guidance. | Public health experts, programme officials and medical and public health schools. |
Annex 2

Meeting agenda

Day 1: Tuesday 26 April 2016

9:00–9:30 Opening and welcome D Kertesz
S Chunsuttiwat

Introduction, background and expected outcome W Zhang
Disclosure of interests
Selection of chair, co-chairs and appointment of rapporteur

Administrative announcements K Lindblade

Session 1: Influenza in the tropics and subtropics
Co-chair: S Thirapakpoomanunt

9:30–9:45 Global influenza update W Zhang

9:45–10:00 Seasonal influenza vaccine strain selection – how and why N Cox

10:00–10:15 Efforts from WHOCCs on improving vaccine virus selection D Jernigan

10:15–10:30 Discussion

11:00–11:15 Evolution of the influenza virus in the tropics – which vaccine formulation to use? I Barr

11.15–11.30 Influenza seasonality in the tropics – when to vaccinate? S Hirve

11.30–11.45 Discussion

Session 2: Applying surveillance data to inform vaccination policy
Co-chair: M Rahman

11:45–12:00 Influenza disease burden in the SEA and WP regions – plans for regional burden estimates and some results E Dueger/P Gould

12:00–12:15 Review of influenza vaccine cost-effectiveness and impact studies B Cowling

12:15–12:30 Discussion

13:30–14:00 TAG recommendations for influenza vaccination in regions and their implementation P Gould/E Dueger A Abubakar

14:00–14:20 TAG recommendations for influenza vaccination in the PAHO region and country experiences in applying surveillance information to inform vaccination policy AM Ropero
14:20–14:30 Discussion

14:30–15:30 Perspectives/experiences from countries
SEAR
- Maharashtra State, India S Salunke
- Indonesia D Samsuridjal
- Sri Lanka P Palihawadana
- Thailand M Chittaganpitch

15:50–16:35 WPR
- China Z Li
- Malaysia F Kamaludin
- Lao People’s Democratic Republic A Xeuatvongsa

16:35–17:30 Plenary discussion – steps from surveillance information to decision-making on seasonal influenza vaccines

**Day 2: Wednesday 27 April 2016**

9:00–9:10 Recap of Day 1 Chair

**Session 3: Influenza vaccine introduction**

Co-chair: S Salunke

9:10–9:25 Introducing influenza vaccine – from decision-making to planning introduction P Lambach

9:25–9:40 Regulatory considerations for vaccine introduction G Grohmann

9:40–10:10 Regulatory challenges – country experience
- Thailand P Akarapanon

10:10–10:20 Discussion

10:20–10:35 Opportunities to introduce influenza vaccine – experiences of the Partnership for Influenza Vaccine Introduction initiative J Bresee

10:55–11:10 Management of provision of vaccines – the Asia Pacific Alliance for Control of Influenza (APACI) experiences J Tam

11:10–11:25 Discussion

11:25–11:30 Introduction to group work S Hirve

11:30–12:30 Group work – how to introduce evidence-based policies?

13:30–14:30 Group reporting back and plenary discussion
Session 4: Influenza vaccine supply

Co-chair: J Tam

14:30–14:45 Global Action Plan for Influenza Vaccines – experiences and lessons learnt
  L Palkonyay

14:45–15:00 Making influenza vaccine available year round
  P Lambach

15:00–15:15 Influenza vaccine supply experiences from Thailand
  S Thirapakpoomanunt

15:15–15:30 The ever challenging influenza vaccine market dynamics
  N Vora

15:50–16:10 Global demand and supply of seasonal influenza vaccine – IFPMA perspective
  M Simmerman

16:10–16:25 Supply issues in countries outside the temperate seasonality – lessons learnt from the PAHO region
  AM Ropero

16:25–16:40 Prequalification and its implications for influenza vaccine supply
  L Palkonyay

16:40–17:30 Discussion

Day 3: Thursday 28 April 2016

9:00–9:10 Recap of Day 2
  Chair

Session 5: Way forward

Co-chair: J Bresee

9:10–9:25 Seasonal influenza vaccination and vaccine effectiveness in the PAHO region – outcome from the WHO/PAHO meeting in Santiago de Chile, March 2016
  AM Ropero

9:25–9:30 Introduction to group work
  S Hirve

9:30–10:45 Group work – introducing influenza vaccination
  • actions that countries need to take?
  • ways that WHO can support?

11:05–12:15 Group reporting back and plenary discussion

12:25–12:30 Meeting closure
  N Cox
  W Zhang

13:30 - 15:00 Closed door meeting with chair, co-chairs and rapporteur
Annex 3

List of participants

Meeting participants

**Ramesh Kant Adhikari**, Kathmandu Medical College, Kathmandu, Nepal

**Agustiningsih**, National Institute of Health Research and Development, Jakarta, Indonesia

**Pramote Akarapanon**, Thai Food and Drug Administration, Nonthaburi, Thailand

**Ian Barr**, WHO Collaborating Centre for Reference and Research on Influenza, Melbourne, Australia [participated via Webex]

**Joseph S Bresee**, Centers for Disease Control and Prevention, Atlanta, USA

**Mandeep Chadha**, National Institute of Virology, Pune, India

**Amol Chaudhari**, Serum Institute of India Pvt Ltd, Pune, India

**Malinee Chittaganpitch**, Thai National Institute of Health, Nonthaburi, Thailand

**Supamit Chunsuttiwat**, Department of Disease Control, Nonthaburi, Thailand

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**Nancy Cox**, Centers for Disease Control and Prevention, Atlanta, USA

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**Pranee Jatumanont**, The Government Pharmaceutical Organization, Bangkok, Thailand

**Jude Jayamaha**, Medical Research Institute, Colombo, Sri Lanka

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**Fadzilah binti Kamaludin**, Ministry of Health Malaysia, Putrajaya, Malaysia

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**Mahmudur Rahman**, Institute of Epidemiology, Disease Control & Research, Dhaka, Bangladesh
Ririn Ramadhany, National Institute of Health Research and Development, Jakarta, Indonesia
Siddhartha Saha, Centers for Disease Control and Prevention, New Delhi, India
Subhash Salunke, Public Health Foundation of India, Pune, India
Nayana Yasindu Samaraweera, Ministry of Health, Colombo, Sri Lanka
Djauzi Samsuridjal, University of Indonesia, Jakarta, Indonesia
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Anthony Waddell, Freelance, Stanley, United Kingdom
Sonam Wangchuk, Department of Public Health, Thimphu, Bhutan
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Ponthip Wirachwong, The Government Pharmaceutical Organization, Bangkok, Thailand
Anonh Xeuatvongsa, National Immunization Program, Vientiane, Lao People’s Democratic Republic
Thitipong Yingyong, Department of Disease Control, Nonthaburi, Thailand

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Siddhivinayak Hirve WHO/HQ/HSE/GIP
Daniel Kertesz SE/ACO/THA
Philipp Lambach HQ/FWC/IVB/IVR
Nancy Cox was selected as chair of the meeting. Sit Thirapakpoomanunt, Mahmudur Rahman, Subhash Salunke, John Tam and Joseph Bresee were appointed as co-chairs for sessions 1–5 respectively. Anthony Waddell was appointed as rapporteur.
Annex 4

Declaration of interests

In accordance with WHO policy, all participants completed the WHO form for Declaration of Interests for WHO Experts. With the exceptions of Amol Chaudhari, Benjamin Cowling, Nancy Cox, Daniel Jernigan, Wan Noraini Wan Mohamed Noor, Subhash Salunke, Djauzi Samsuridjal, Mark Simmerman, John Tam, Sit Thirapakpoomanunt, Nishant Vora and Ponthip Wirachwong, no personal current or recent (within the last 4 years) financial or other interests relevant to the subject of the meeting were declared.

All declarations made were evaluated by the WHO Secretariat prior to the meeting. It was concluded that the interests declared did not conflict with the objectives of the meeting and that the above individuals could participate in full. At the start of the meeting the interests that had been declared were disclosed to all participants.