Points for Consideration for First Introductions of Dengue Vaccines

BANGKOK, THAILAND
JUNE 18-19, 2012
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REPORT OF THE ASIA-PACIFIC DENGUE PREVENTION BOARD MEETING
BANGKOK, THAILAND, JUNE 18-19, 2012

LETTER FROM THE DIRECTOR

Dear Colleagues,

This is a very exciting time to be involved with the development and introduction of dengue vaccines. Over the last decade, very substantial progress has been made in the clinical development of several vaccines. In addition, primarily under the DVI, very important work has been completed and is still underway to create an enabling environment for the introduction and use of new dengue vaccines.

One of the key lessons of the last several decades of vaccine development and introduction is that developing countries will not receive the benefits of a new vaccine if planning does not start early. Waiting until a vaccine is licensed to begin planning for its introduction in developing countries has historically resulted in a delay of a decade or more before the vaccine reaches some of those most in need.

To make sure that developing countries have immediate access to new dengue vaccines, DVI has examined many issues of vaccine introduction and has sponsored a wide range of studies. A primary mechanism for conducting this work are the Dengue Prevention Boards (DPBs) in the Asia-Pacific and Americas Regions. Reports of previous sessions are available at the DVI website.

It now seems likely that at least one dengue vaccine will be available for use in developing countries in 2015. The DVI is therefore convening meetings of the DPBs with the goal of identifying Points for Consideration to be used by developing countries as they evaluate whether they wish to be among the first countries to introduce the vaccine.

This report concerns the Bangkok 2012 meeting of the Asia-Pacific DPB. The Americas DPB meeting in Bucaramanga, Colombia is scheduled for mid-July, 2012. The present report provides a sound initial set of Points for Consideration. Following further discussion and review in Bucaramanga, DVI will prepare a final set of Points for Consideration.

We hope these Points for Consideration will facilitate decision making by developing countries so that they can access the vaccine as soon as it is available.

Sincerely,

Luiz Jacintheo da Silva

Director, Dengue Vaccine Initiative
SUMMARY

The Asia-Pacific Dengue Prevention Board (APDPB) meeting was held in Bangkok on 18-19 June, 2012, to develop Points for Consideration that will provide a framework for countries to decide if they are interested in and capable of undertaking introduction activities for the first dengue vaccines once they are licensed.

The meeting was organized by the Dengue Vaccine Initiative (DVI), a consortium of the International Vaccine Institute (IVI), the International Vaccine Access Center (IVAC) at the Johns Hopkins School of Public Health, the Sabin Vaccine Institute, and the Immunizations, Vaccines and Biologicals Department of the World Health Organization (WHO).

Participants included representatives of Ministries of Health of seven countries in the Asia-Pacific region (Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Sri Lanka, Thailand), from research and partner institutions (AFRIMS, Bill & Melinda Gates Foundation), from the vaccines and diagnostics industries (GlaxoSmithKline, Inviragen, Merck, sanofi pasteur, and Standard Diagnostics), and from the Dengue Vaccine Initiative (DVI).

One of the candidate vaccines is in late stage clinical development and the first efficacy results are expected by the fourth quarter of 2012. If the efficacy results warrant licensure, first filings for vaccine licensure are possible as early as 2013 and first registrations as early as 2014. Countries must therefore urgently determine if they wish to be among the first to introduce this vaccine.

To assist countries in making this determination, the meeting participants developed Points for Consideration in six specific areas for countries to use to assess their ability and interest in being amongst the first-to-introduce a dengue vaccine.

Once Ministries of Health have indicated their interest in being among the first-to-introduce a dengue vaccine, and determined an introduction timeframe, upon invitation, the DVI will organize a series of discussions with country representatives and the vaccine manufacturer, to determine national needs for vaccine and other partner supports.

During 2013, first-to-introduce countries will finalize the design of introduction activities, and presumably launch the vaccine soon after it is registered and available in countries.

**Dengue incidence has increased dramatically in recent decades with the number of annual reported cases tripling since the 1980s.**

MEETING OBJECTIVES

The purpose of the APDPB meeting was to develop Points for Consideration that will:
- Provide a framework for decision-making concerning the first dengue vaccines to be licensed;
- Be useful to other countries that may decide subsequently to adopt a dengue vaccine; and,
- Ensure efficient introduction in a limited number of first-to-introduce countries/populations to demonstrate the impact of vaccination on illness.

Points for Consideration were developed in six specific areas:
- Regulatory
- Evidence for Decision-Making
- Impact Modeling
- Immunization Systems
- Demand and Financing
- Post-Licensure/Demonstration Projects

**Introduction Activities will be designed to:**
- Generate data that will be useful to other countries that will subsequently introduce dengue vaccines;
- Demonstrate a public health impact of the vaccine;
- Assess means of ensuring vaccine access for people at risk and equitable access for those living in poverty.
**UPDATE ON DEVELOPMENT OF DENGUE VACCINES**

Vector control has not been highly successful in controlling dengue transmission and there are no drugs specific for the treatment of dengue. Vaccines, therefore, are an essential tool for controlling the disease.

The Asia-Pacific Dengue Prevention Board meeting reviewed the progress being made in the development of vaccines and diagnostics.

**CLINICAL DEVELOPMENT**

**Purified Inactivated Vaccine (PIV)**
GSK Vaccines, the US Army and the Brazilian MOH (Fiocruz) are co-developing a tetravalent whole virus PIV. Two Phase I trials are planned in the US later in 2012.

**Recombinant envelope protein vaccine**
An adjuvanted recombinant protein developed at Hawaii Biotech is being further clinically developed by Merck. Merck will conduct Phase I testing of Isco-matrix adjuvanted vaccine in Australia in 2012 to supplement previous Phase I testing with an alum adjuvanted vaccine.

**PHASE II**

**Live attenuated chimeric tetravalent dengue vaccine (DENVax)**
Inviragen has entered Phase II clinical trials with a tetravalent chimeric live attenuated dengue vaccine in Puerto Rico, Colombia, Singapore and Thailand. In addition, rapid immunization strategies and needleless administration are being investigated.

**Live attenuated chimeric tetravalent dengue vaccine (TetraVax-DV)**
Phase II clinical trials with a live attenuated tetravalent vaccine developed by the US National Institutes of Health (NIH) are ongoing in the US. Phase II trials are planned in Brazil. Vaccine strains have been licensed to 4 developing country manufacturers: Vabiotech, Vietnam, Biological E, India, Panacea, India, and Butantan, Brazil, and Phase I trials from these companies are expected to start soon.

**PHASE III**

**Live attenuated chimeric tetravalent yellow fever dengue vaccine**
sanofi pasteur is conducting several Phase III trials in Australia, and in countries in Asia, and Latin America. To date, safety of the vaccine has been found to be comparable to control vaccines or NaCl placebo. The immunogenicity of the vaccine has been shown to be balanced and homogenous for all 4 serotypes. First results of efficacy are anticipated by the fourth quarter of 2012.
**Other Vaccine Studies**

The US Army has a number of other ongoing vaccine developments in pre-clinical phases.

GSK has an ongoing burden of disease study in Brazil (and will initiate new disease burden studies in 2012), and an ongoing serological survey in Thailand.

**Diagnostics**

**Dual Antigen-Antibody rapid test** - Standard Diagnostics has developed a dual antigen–antibody rapid diagnostic test. Because NS1 antigen is detected only in the first few days of dengue illness, and because IgM is only detected a few days after the onset of illness, antigen or antibody testing alone can fail to diagnose if testing is too late or early, respectively, after onset of illness. A dual antigen-antibody test can increase the sensitivity of testing.

**Preparing for Dengue Vaccine Introductions**

Historically, vaccines have taken twenty years or more to reach markets in the developing world; with a dengue vaccine the goal is to cut this time to zero and begin getting vaccines to those in need as soon as they are available. Work must begin now to prepare countries to introduce dengue vaccines, once available, so that the traditional lag time for vaccine introduction can be shortened.

By the time a new vaccine is available, countries should ideally have the capacity to conduct all necessary activities for successful vaccine introduction. These include the regulatory capacity to license and control quality and safety of the vaccine, evidence based immunization strategies, logistical and delivery capacities, and surveillance to monitor safety and the impacts of the vaccine on disease, and communications capacities.

**Points for Consideration for First-to-Introduce Countries**

**Regulatory**

First-to-introduce countries should consider:

**Whether their NRAs are WHO recognized** - It is essential that first-to-introduce countries have a WHO recognized National Regulatory Authority (NRA) because the countries will need the capabilities to:

- Oversee Phase III and IV trials.
- Make licensing decisions for innovative products including recombinant chimerics vaccines/Genetically Modified Organisms (GMOs).
- Develop and validate lot release testing for innovative vaccines.
- Recognize and assure GMP.
- Develop a process and capacity to investigate Adverse Events Following Immunization (AEFIs) from clinical trials, in routine or catch-up campaigns.

**A vaccine is seen as an important tool for controlling dengue and reducing its economic impacts, especially on the poor.**
Countries will also need to:

**Involve WHO recognized regulators to discuss needs for licensing decisions** - Ideally an expert panel would be constituted and there would be a joint review of the dossiers / application for licensure involving the national NRAs.

**Do a gap analysis of NRA** - First-to-introduce countries should conduct a gap analysis for all necessary NRA functions and indicate where they need support, where they can obtain that support, and what the time frame and budget would be. The DVI’s role can be to assure a mechanism for the requests for support.

**Assess whether they have an expedited review process** - NRAs in first-to-introduce countries should have a mechanism for prioritizing the review of dengue vaccines.

**Assess manufacturers’ risk management plans** - The regulatory process should include an assessment of the manufacturer’s risk management plans, including the design of Phase IV studies and long-term safety monitoring.

**Determine whether they are capable of assessing country specific issues (GMOs, etc)** - Some countries may have specific issues that they wish to address, and innovative vaccines may present specific challenges for NRAs, such as how to conduct an environmental impact assessment of a Genetically Modified Organism (GMO). First-to-introduce countries should ensure that they are capable of addressing these issues. This could include inter-ministerial cooperation (Health, Agriculture, etc).

**Assure there is coordination between the NITAG and NRA** - First-to-introduce countries should ensure that there is good coordination between the National Immunization Technical Advisory Groups (NITAG) and the NRA.

### Evidence for Decision-Making

First-to-introduce countries should have the ability to undertake or participate in:

**Epidemiological surveillance** - At a minimum, countries should have evidence of burden of disease including the extent of the disease (incidence and sero-prevalence), the distribution of the disease (age and area), the severity of the disease (morbidity and mortality rates), the cause of the disease (serotype prevalence), and the disease vector.

Ideally these data should be available for the past 10 years, and at minimum for 3 years.

These data are essential for establishing priorities relative to other vaccine preventable diseases, for determining priority target groups where resources and/or vaccines are limited, for accurately forecasting the demand and logistical requirements for a vaccine, and for assessing the impact of the immunization program on the disease.

**Economic studies** - At a minimum countries should have data on direct cost of illness (by severity, by type of care, by public and private sectors, by individuals and households), indirect costs of illness (absenteeism, loss of productivity), outbreak costs, willingness to pay, cost-utility (effectiveness, budget impact), cost of prevention (vector control).

These data are essential for evaluating national resources requirements, allocating government and partner funding by priority, evaluating affordability for governments and individuals, assessing program sustainability, and determining the marketability of a vaccine.
Policy studies - A number of policy assessments targeting high ranking decision-makers and politicians should be completed to build evidence for decision-making. These would include risk-benefit, programmatic (logistical and supply), and strategic assessments (scheduling, co-administration, target age groups, herd effect, duration of protection).

Social studies - A number of social dimensions should be well understood in advance of vaccine introductions. These would include evaluation of Knowledge, Attitude and Practices (KAP studies) to address public opinion and demand for a vaccine and to educate the media.

Modeling - Using epidemiological and economic data, countries should model impacts on disease and costs. Outputs of modeling will help to better inform decision-making and encourage other countries to generate county-specific data.

Impact Assessments - At some stage, countries will need to have the ability to assess public health impacts and vaccine effectiveness after vaccine introduction. First-to-introduce countries should be aware that their experiences may guide later-introducer countries.

Of note, some countries may consider building evidence iteratively and choose to first introduce a vaccine on a limited scale or area.

Impact Modeling

Impact modeling can help to answer important strategic and policy questions for new vaccine introductions. Therefore, first-to-introduce countries should consider using modeling for:

Development of optimal immunization strategies – Countries should first determine the strategic objectives of their immunization program (e.g. disease elimination, minimize disease burden, minimize hospitalizations, etc) in order to model for the best strategic options. Factors that can be integrated into modeling include age targets (stratified or not), schedules (catch-up immunization supplemental to routine immunization or not), geographically stratified targets (urban or rural), transmission dynamics (hyperendemic or endemic sporadic outbreaks), at-risk targets, and other preventive measures (integration with vector control). Furthermore, modeling can help to plan for the optimal use of limited quantities of vaccine (which is likely to be the case for first-to-introduce countries). Modeling can be used to estimate vaccine effectiveness, or cost effectiveness, under different scenarios or other set objectives.

Modeling can be used to determine required vaccine coverage rates to achieve desired program objectives at different levels of vaccine efficacy.
For first-to-introduce countries that choose to model the impacts of immunization, these components should be considered for inclusion in the model design:

- Urban vs rural vs regional (including population density, movement of people, etc).
- Critical vaccination fraction.

**Immunization Systems**

Prior to an introduction decision, first-to-introduce countries should consider:

**Capacity for surveillance** - The country should have the capacity to assess the disease burden and its distribution.

**Whether a vaccine has been licensed** - Countries cannot initiate vaccine introduction until a vaccine has been licensed. They should therefore coordinate the timing of introduction activities with the availability of a licensed vaccine.

**Whether the National Immunization Advisory Group (NITAG) has made a recommendation** - The decision to introduce a new vaccine normally follows a recommendation by the NITAG. The NITAG should therefore be prepared to review the vaccine and make a decision whether to recommend for use or not.

**Whether finance is available before introduction starts** - Additional funds will need to be raised to support the many activities of a dengue vaccination program. Countries should consider how the vaccination program will be financed. Financing and supply should be assured before introduction activities are initiated.

**Whether other requirements have been examined** - Immunization systems can be complex. The country should consider if any other requirements need to be met before introduction can be considered.

After a decision to introduce has been made, first-to-introduce countries should ensure that:

- Compliance with vaccination schedule.
- Dosing and onset of protection (after one, two and three doses, duration of protection, outbreak control).

It should be noted that modeling can be used to assess impact of immunization programs with or without vector control.

**Roles and responsibilities have been apportioned**
- The country should identify all stakeholders who will play a part in vaccine introduction and ensure that all responsibilities have been clearly apportioned.

**Intersectoral collaborations have been established** - Collaborations should be established with control initiatives, especially with vector control departments, to ensure that control activities are continued.

**A strategy has been developed for vaccine rollout** - Factors that need to be determined for a rollout include:

- Age at introduction for routine program.
- Whether the introduction will be phased / incremental in some administrative units or not.
- Identification of the areas at risk (urban or rural), and the development of a clear communication strategy to explain the rationale.
- Whether catch up campaigns are required to meet program objectives and in what age groups.

**Cold chain capacity and logistics management needs have been assessed** - The introduction of a new vaccine in the immunization system will require careful assessment of the capacity to store and deliver the vaccine. The old chain requirements for the new vaccine should be determined in advance of vaccine introduction. Where necessary, plans should be prepared to strengthen the capacity.
Health workers training needs have been assessed - Healthcare workers will need to be made aware of all of the characteristics of the new vaccine being introduced, including the immunization schedule and the appropriate target groups. The country should plan for training, including preparation of appropriate job aids, where needed.

Communication plans have been developed - Communication plans and materials should be prepared for:

- Decision-makers
- The health community
- General public
- Media

Vaccine hesitancy has been assessed - Increasingly countries are facing public reluctance to be immunized. The country should assess whether anti-vaccine activities need to be addressed.

A plan for safety surveillance has been developed - The national Adverse Events Following Immunization (AEFI) surveillance and response should be reviewed and strengthened where needed. Special surveillance for severe disease should be initiated for dengue.

Monitoring and evaluation plans have been developed - The occurrence of disease will need to be continuously monitored in unvaccinated areas. Tracking systems should be reviewed and strengthened if necessary to ensure that everyone being vaccinated receives all three doses of vaccine and that high coverage is achieved. Plans should be developed to respond to outbreaks. Diagnostic and case confirmation protocols should be developed.

Demand and Financing

First-to-introduce countries should have met the minimum requirements noted under the other considerations in order to be capable of assessing their demand and finance requirements. These countries will have determined dengue to be a priority disease, based on the health and economic burdens, and public demand.

First-to-introduce countries should consider:

Whether they have adequate epidemiological and cost data to model the health impacts of various rollout scenarios - The impacts of immunization on program objectives (i.e. reduction in cases and/or hospitalizations and/or mortality) and costs of a program should be determined for various scenarios. Policy makers/recording bodies should determine an acceptable balance between costs and impact. This will vary between countries, depending on the importance of each model output.

Whether they have historical data from the rollout of previous vaccines that can help determine accurate demand - Countries with previous experience at new vaccine rollouts may benefit from lessons learned and utilize previously collected data on demand and costs to inform a dengue vaccine introduction plan.

The potential impacts on health and budget - These assessments can inform the appropriate timing for vaccine introduction (i.e. to be first-to-introduce or not). Assessments should include the impacts on health and budgets of additional post-licensure studies that may be required.

![Figure 4. Forecasting the demand for dengue vaccine (e.g. in Thailand)](image-url)
How to mobilize resources to finance program costs - Countries are likely to utilize different mechanisms to finance dengue vaccine introductions according to income level. Low income countries are likely to utilize partner support (e.g. GAVI). Lower middle income countries are likely to mobilize some of their own government resources but require some additional support from partners or consortia. Upper middle income countries will likely finance a dengue vaccine from their own resources.

Countries may also negotiate shared costs with suppliers for some post-licensure assessments.

Reaching agreement on price/funding for a period of time - The terms of contracts may also be more favorable for countries if they are negotiated for longer terms, bundled with other purchases, or purchased by bulk procurement agencies.

Post Licensure / Demonstration Projects

Because there is no experience with any licensed dengue vaccines, and because of the potential for sensitizing for more severe disease, some Phase IV trials may be requested of NRAs. Beyond requirements for Phase IV studies, there will be questions the countries want to answer through pilot introduction studies, such as how to introduce a vaccine to have the most impact on disease as quickly as possible. Therefore, first-to-introduce countries should consider whether or not they have the capacity to conduct post-licensure demonstration projects or Phase IV trials.

All of the other Points for Consideration to introduce vaccines are critical to enabling successful demonstration projects and must be met before demonstration projects can be considered.

Additionally, first-to-introduce countries must:

Have the political will and security - Political support at the highest levels is necessary to ensure the elements needed to carry out the demonstration projects are in place.

Have national support and community acceptance - Social studies and communications plans will be key to ensuring that national and local communities are active and supportive participants as early introducers.

Have capable NRAs - As previously discussed, countries must have a WHO recognized NRA with the capability to address issues surrounding vaccine introduction. NRAs will be a key piece of ensuring that vaccine introduction is closely and consistently monitored, as well as the success of first and future dengue vaccines.

Have the technical capacity, resources and desire to evaluate safety and effectiveness - Technical capacity includes the laboratory diagnostics capacity, trained staff, communications strategies, data management capacity, analysis expertise, etc.
**Have the capacity for surveillance** – Countries should have capacity for surveillance of both the disease and AEFIs. This is especially important in order to show if the vaccine has had a public health impact in the communities with access to the vaccine. Additionally, strong surveillance will be key as other vaccines enter the market, to determine both the national baseline disease burden and the safety and efficacy of the new vaccines.

**Be willing to share outputs of studies whether successful or not** - Because first-to-introduce counties will generate many important lessons for subsequent introducers, they should be willing to share knowledge gained whether through positive or negative study results.

**Have functioning technical collaborations** - Because of the challenges associated with dengue vaccine introduction first-to-introduce countries should be willing and able to collaborate with technical agencies such as the WHO, IVI, DVI, etc.

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**IMPLEMENTATION ISSUES FOR COUNTRIES TO CONSIDER**

Many endemic countries are likely to face particular challenges for the introduction and implementation of a dengue vaccine. First-to-introduce countries should carefully consider issues specific to dengue immunization when assessing their willingness and ability to introduce a dengue vaccine.

**The sanofi pasteur dengue vaccine will not be given in the Expanded Program on Immunization (EPI) schedule** – The vaccine being tested in current efficacy trials is given in 3 doses at 6 month intervals, and will initially be indicated for 2 to 44 year-olds. This dosing schedule is different than for any other vaccine currently administered in national immunization programs and therefore will require additional visits and access to the target population.

**The immunization schedule for dengue vaccine could change** – initially, a dengue vaccine will be recommended for routine immunization at 2 years of age. As more study data becomes available, a license will be sought for immunization at 9 months of age. Once an indication for 9 months is granted, countries may choose to adapt the dengue immunization schedule so that a first dose is co-administered with measles.

**Existing immunization coverage may be an indicator of a country’s capacity to deliver a new vaccine** – delivering a dengue vaccine may be challenging for some countries, particularly since the vaccine will be given outside of the routine pediatric immunization schedule.

**Factors that drive the rise in dengue incidence:**

- The Aedes aegypti mosquito vector continues to expand into wider geographic areas;
- Growing urbanization and inadequate water, sewer, and waste management systems;
- Climate change, and the increase of insecticide-resistant mosquito populations;
- Increasing travel exposes more people to the risk of infection (an estimated 125 million travelers a year visit dengue endemic countries).
Countries should assess their current immunization coverage rates when considering introducing a dengue vaccine, as coverage rates serve as an indicator for existing capacity to deliver immunization.

*Appreciation of the complexity of delivering a dengue vaccine, especially if catch-up campaigns are required* – to achieve some program objectives, catch-up immunization strategies are likely to be required, in addition to routine immunization, to accelerate the impact on disease burden in the years following vaccine introduction. Countries wishing to introduce a dengue vaccine should be fully cognizant of the challenges associated with organizing and conducting catch-up campaigns and have the capacity to do so. Countries should also consider the impact of wide scale immunization on their ability to conduct subsequent efficacy trials with second- or third-to-market vaccines.

**THE FUTURE**

The Americas Dengue Prevention Board (AmDPB) meeting will be held in July 2012 to elaborate issues for considerations for countries in their region considering the introduction of a dengue vaccine.

A compilation of issues for consideration from both the Asia-Pacific and Americas Dengue Prevention Board meeting will then be developed and made available to dengue endemic countries. Separate meeting reports from each session will also be developed.

Once Ministries of Health have indicated their interest in being among the first to introduce a dengue vaccine, and determined an introduction timeframe, DVI is prepared to organize discussions with countries and the vaccine manufacturer to determine vaccine needs as well as needs for partner supports.

These discussions are expected to be held by the end of 2012. During 2013, the countries would complete a final design of the introduction activities and launch vaccine introduction upon licensure in countries and availability of vaccine.

*The mission of the Dengue Vaccine Initiative is to encourage the development and use of vaccines to prevent dengue. As a consortium of organizations committed to a world without dengue, DVI is working to lay the groundwork for dengue vaccine introduction in endemic areas so that, once licensed, vaccines to prevent dengue will be swiftly adopted.*
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