Planning for the Introduction of Dengue Vaccines

Brasília, Brazil
22-23 August 2011
The Americas Dengue Prevention Board met in Brasília on 22-23 August 2011 to identify practical and specific steps for the rational introduction of dengue vaccines. The 60 participants included representatives of the health ministries of 12 countries in the Latin and Central America region, intergovernmental organizations, academe, the pharmaceutical industry and civil society. The meeting was organized by the Dengue Vaccine Initiative (DVI), which is a consortium of the International Vaccine Institute (IVI), the International Vaccine Access Center (IVAC) at the Johns Hopkins University, the Sabin Vaccine Institute (Sabin), and the Initiative for Vaccine Research (IVR) at the World Health Organization (WHO). The Secretary for Health Surveillance in the Brazilian Ministry of Health welcomed participants.

The meeting aimed to support the preparation of country-specific investment cases for the introduction of dengue vaccines, in particular for Brazil and Colombia, while providing information for other countries in the region. The participation of key decision-makers from health ministries was designed to help ensure practical outcomes, while the inclusion of vaccine developers and manufacturers was intended to facilitate mutual understanding of the challenges ahead. The meeting provided a dynamic forum for the open and constructive exchange of views and information. The Brasília meeting, and the Hanoi meeting of the Asia Pacific Dengue Prevention Board in April 2011, represent for the first time that strategic planning for the introduction of a vaccine to developing countries has been planned before the conclusion of clinical trials and a vaccine’s licensure.

“It is not whether but how to introduce a dengue vaccine,” said Luiz da Silva, Director of DVI. That clear statement set the tone of the meeting. Though this is the view held by experts on dengue, it is not yet widely shared by some vital decision-makers at the global and some national levels. Unfortunately, there is little realization at many levels of the risks of dengue and severe disease, the changing clinical expression of dengue, the disease burden, and the likely impact of the disease in 10 years time if it remains unchecked. A broad sense of commitment needs to be generated.

In a wide-ranging comparative analysis of priority setting in public health and the implications for dengue, four key public health questions were posed:

- Is the problem real?
- If it is real, how big an issue is it?
- If it is a big issue, can something be done about it?
- If something can be done, how much will it cost?

The answers can never be absolute and their interpretation is subject to many biases, including the personal views of those doing the interpretation. However, without exception – regardless of number of deaths or other quantitative measures – a decision to accord high priority seemed to rest invariably on the existence of champions for the cause and an effective technology - in the case of dengue, a vaccine. The existence of an effective technology allows the attack on a disease to move from a case-by-case medical approach to a systematic public health assault; that is the prerequisite for success.
Dengue has been highly politicized in the Americas. A successful campaign to control the *Aedes aegypti* mosquito vector of dengue made the region virtually dengue free in the 1950s and 60s. But the mosquito and the disease returned with a vengeance when vector control was discontinued, creating successively more extensive outbreaks with more severe disease and deaths. Clinical and epidemiological patterns have changed since then, and continue to evolve.

PAHO has long been concerned with dengue and vector control, including the establishment of a network of PAHO/WHO collaborating centers and national reference laboratories for dengue in the Americas. Its early activities, however, were outflanked by the interruption of vector control in the 1970s, and the acceleration of uncontrolled urbanization, along with its associated waste management problems, in many Latin American countries.

On other fronts, PAHO introduced a unique procurement and financing mechanism to buy vaccines, syringes and cold-chain equipment, the Revolving Fund for Vaccine Procurement, and, more recently, the ProVac Initiative to improve capacity for evidence-based decision-making. It is also working to implement the Regional Immunization Vision and Strategy, all of which stand to influence the when and how of introduction of a dengue vaccine.
EPIDEMIOLOGICAL SITUATION

All tropical areas of Central and South America, as well as most of the Caribbean, have been badly affected by dengue in the past two decades. All four serotypes of the dengue virus are now circulating in the Americas. Countries have experienced long inter-epidemic periods, and epidemics are now being seen even in countries with no history of dengue. The massive extension of both the vector and the virus has caused serious and disruptive outbreaks, with sharp increases in the incidence of both dengue fever and severe dengue. It seems that each epidemic cycle of dengue increases its magnitude and the severity of disease. Dengue affects all age groups, and its impact varies from country to country. In some parts of the Americas, the highest incidence rates are being reported in adolescents and young adults, while in others considerable mortality is seen in the over-60 year age group. In still others, dengue remains a pediatric disease.

Because the burden of dengue is likely under-reported to a considerable extent, the true burden of disease is not fully known. Nevertheless, in 2010, 1.7 million cases of dengue were reported in the Americas (and 50,000 cases of severe disease), nearly 60% of those in Brazil. Many countries experienced their largest recorded epidemics, with reported incidence rates of more than 200/100,000 inhabitants, in 2010. Outbreaks in Bolivia, Brazil, Ecuador, Paraguay and Peru continued in early 2011 and new outbreaks have been reported in the Bahamas, Panama and Saint Lucia.

GENERATING DATA

DVI outlined its close collaboration with its partners, health ministries and key stakeholders in Brazil and Colombia. In Brazil its cooperation with the health ministry concentrates on the dengue prevention and control strategy and health economic studies. With DVI’s input, the Ministry is elaborating a strategic plan for introduction of the vaccine; an advisory group, which held its first meeting in June 2011, is looking at pre-licensing and post-licensing needs from the ministry’s perspective. In Colombia, DVI works with the Ministry of Social Protection and Antioquia University as core partners in studies (due to start in October 2011) on disease burden, seroprevalence, cost-of-illness, willingness to pay and health-care utilization in order to prepare a national dengue investment case.

VACCINE CANDIDATES

The developers and manufacturers of six candidate vaccines gave presentations on the R&D status of their products. While five are still in preclinical development or Phase I trials, the sixth, sanofi pasteur’s tetravalent vaccine with dengue virus genes on a yellow fever virus backbone, continues to show great promise in Phase III trials. It is expected to be licensed in 2015. Wide-ranging discussions covered manufacturers’ production capacity, the country in which regulatory approval would be sought, export possibilities, WHO prequalification, safety, vaccination strategies (including the difficulties of reaching adults in catch-up campaigns) as well as pre-licensing and post-licensing plans, and the numerous challenges that remain.
FORECASTING DEMAND

The price of the eventual vaccine will be a determining issue and will depend substantially on demand, the size of the market and which immunization strategy is selected. Strategic demand forecasting is being applied to assessing the likely market size in Brazil and Colombia for 2015-2019. It was recognized that there would be wide variance in demand estimates depending on the assumptions of variables, such as coverage rate in catch-up campaigns, delays in introduction, and wastage.

Although there is much enthusiasm surrounding the potential vaccine or vaccines, care will be needed to not raise expectations too high; vaccine supplies will need to be ensured in advance so as to meet expected demand. The manufacturer of the lead candidate indicated that it was listening closely to the discussions on demand and had some flexibility in its production capacity.

The power of mathematical models for assessing the effectiveness of various vaccine-introduction strategies by exploring the interplay of key determinants of transmission was demonstrated. The models offer a means of predicting the spread of disease, forecasting the impact of vaccination and enabling the estimation of, for instance, the proportions of populations that need to be vaccinated to ensure protection and the optimal proportions to minimize adverse effects. The results described for one model showed that a vaccine will block the development of epidemics when coverage reaches 70% of the population.

A specific study of strategic demand forecasting described the likely number of doses needed and costs of the introduction of a vaccine in Brazil and Colombia. The resulting forecast estimated some 250 million doses for the two countries combined for the period 2015-2019, at a cost in the public sector of US $2400 million over five years.

Cost is likely the most important barrier to vaccine introduction, and (governments) may wait for the price to decline before introducing it.

~ Brian Maskery, IVI
NATIONAL POLICY CONSIDERATIONS

A series of talks described the national epidemiological situation and preparations for introducing a dengue vaccine in Argentina, Brazil, Colombia, Cuba, Ecuador, Honduras, Nicaragua, Paraguay, and Venezuela. The experience of Puerto Rico and, more generally, the decision pathways to vaccine introduction in the USA were also presented. Issues that emerged ranged broadly from specific national policies, the need for coordination at national level, health records, health-care worker training and the role of primary health care to countries’ considerable experience in introducing new vaccines, the vital need for vector control to be integrated into prevention and control strategies, immunization schedules, reporting and outbreak control.

How Does Dengue Burden Compare to Other Priority Diseases in Colombia?

Source: Mabel Carabali

ADVOCACY

Advocacy is vital to changing perceptions, creating demand and influencing policies and budgeting decisions. The dramatic progress in recent years in introducing new and under-used vaccines - rotavirus, acellular pertussis, human papillomavirus, meningococcal, pneumococcal and typhoid vaccines - has been made thanks in large part to advocacy in raising awareness, mobilizing leaders, indentifying champions, maintaining public confidence and professional knowledge, and increasing the financial sustainability of immunization programs. The Sabin Vaccine Institute brings to the DVI its expertise in advocating prevention and control of neglected tropical diseases (with notable successes against lymphatic filariasis, onchocerciasis and schistosomiasis) and introduction of pneumococcal vaccines. It will be important to adopt a systematic approach to raising the profile and understanding of dengue by public health professionals, donors and the general public; examples cited included the running of a two-day workshop on immunization for journalists and the use of social media.
Throughout the meeting, a common theme was that good initial steps have been taken but much remains to be done ... and time is short. Work is needed in many areas, including:

- Burden of disease
- Modeling
- Cost-effectiveness analyses
- Forecasting demand
- Design of vaccination strategies
- Examining manufacturing and supply issues
- Preparing investment cases
- Harmonizing regulatory processes in the region, and
- Raising general awareness.

Many questions lack answers, and updates about the progress of clinical trials of candidate vaccines and the capacities of manufacturers will be essential. Vaccination strategies will need to be examined carefully, as planning decisions will have a major impact on local manufacturers’ decisions about production capacity and potential export, as well as on national policies. Renewed and alternative sources of funding are needed both now, in the years leading up to vaccine introduction, and thereafter.

At the regional level, countries can contribute to WHO’s Strategic Advisory Group of Experts (SAGE) on immunization to help ensure strong recommendations. A common regional forum or workshop on harmonizing regulatory processes would be useful, and more general information about approaches to vaccine introduction needs to be shared regionally. WHO prequalification would accelerate vaccine introduction.

Dengue vaccines are likely to be introduced slowly, country by country, initially in countries where clinical trials were conducted and in middle-income countries with an expected strong private-sector demand. The need for open and effective communication between regional stakeholders will increase as progress is made towards vaccine introduction.

Given the political sensitivity of dengue, health ministers will likely be the decision makers and it was observed that they will need solid data for those decisions.
<table>
<thead>
<tr>
<th>BOARD MEMBERS</th>
<th>MINISTRIES OF HEALTH GUESTS</th>
</tr>
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</table>
| **Dr. Aracely Alava Alprecht**  
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sanofi pasteur

Dr. Emmanuel Burckel  
Dengue Project Leader, Latin America  
sanofi pasteur
**AGENDA**

**DAY 1: August 22, 2011**

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<tr>
<td>8:30 – 9:00</td>
<td>Welcome Remarks</td>
<td>Officials of Brazil Ministry of Health, WHO, PAHO and DVI</td>
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<td>Introduction of participants</td>
<td>Jarbas Barbosa</td>
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<td><strong>Session II: Generating Increased Support for Introduction to Dengue Vaccines</strong></td>
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<tr>
<td>9:00 – 9:30</td>
<td>Update on DVI Introduction for the meeting: The importance of having a clear and accurate understanding of the complexity of dengue vaccine introduction</td>
<td>Luiz da Silva</td>
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<td>9:45 – 10:30</td>
<td>Comparitive historical analysis of vaccine priority setting</td>
<td>Richard Mahoney</td>
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<td>10:30 – 11:00</td>
<td>Coffee Break</td>
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<tr>
<td>11:00 – 11:30</td>
<td>The Experience of PAHO in the introduction of new vaccines</td>
<td>Cuauhtemoc Ruiz Matus</td>
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<tr>
<td>11:30 – 12:00</td>
<td>Generating support for dengue vaccines: reflections on the experience in Brazil</td>
<td>Jarbas Barbosa</td>
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<td>12:00 – 12:30</td>
<td>The importance of constructing and implementing a Road Map for dengue vaccines</td>
<td>Roberto Tapia</td>
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<td>12:30 – 1:30</td>
<td>Lunch</td>
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<tr>
<td>1:30 – 1:50</td>
<td>Overview of the global burden of disease of dengue: DALYS, dollars, poverty, and families</td>
<td>Luiz da Silva</td>
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<tr>
<td>1:50 – 2:10</td>
<td>The changing view of the priority of dengue disease as seen by WHO and its regional offices</td>
<td>Joachim Homback</td>
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<td>Jose Luis San Martin</td>
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<td>2:10 – 2:30</td>
<td>The Role of Advocacy for Immunization</td>
<td>Ciro de Quadros</td>
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<td><strong>Session III: Data and their use</strong></td>
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<tr>
<td>2:30 – 3:00</td>
<td>DVI studies to generate Data for Decision Making</td>
<td>Jacqueline Lim</td>
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<td>Mabel Carabali</td>
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<td>Joao Basco Siquera</td>
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<tr>
<td>3:00 – 3:30</td>
<td>Vaccine Investment Case: Case Study</td>
<td>Brian Maskery</td>
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<td>3:30 – 4:00</td>
<td>Coffee Break</td>
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<tr>
<td>4:00 – 4:30</td>
<td>Modeling the impact of dengue vaccines on burden of disease</td>
<td>Ira Longini</td>
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<td>4:30 – 5:00</td>
<td>Approaches to modeling the impact of dengue vaccines in the Americas</td>
<td>Eduardo Massad</td>
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## DAY 2: August 23, 2011

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<tbody>
<tr>
<td>8:30 – 10:00</td>
<td><strong>Session IV: Prospects and Issues for Availability of Dengue Vaccines</strong></td>
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<td>Short presentations (10 minutes each) followed by moderated discussion with</td>
<td>Butantan, Fiocruz, GSK, Inviragen, Merck, sanofi pasteur, Alere</td>
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<td>developers of diagnostics and vaccines</td>
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<tr>
<td>10:00 – 10:30</td>
<td>Factors affecting introduction and availability of dengue vaccines</td>
<td>Richard Mahoney</td>
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<tr>
<td>10:30 – 11:00</td>
<td>Strategic Demand Forecasting and Financing of dengue vaccines</td>
<td>Orin Levine</td>
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<td>11:00 – 11:30</td>
<td><strong>Coffee Break</strong></td>
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<tr>
<td>11:30 – 11:45</td>
<td><strong>Session V: Policy Considerations</strong></td>
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<tr>
<td>11:45 – 12:00</td>
<td>Policy Considerations for introduction of dengue vaccines: Argentina</td>
<td>Jaime Lazovski</td>
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<tr>
<td>12:00 – 12:15</td>
<td>Policy Considerations for introduction of dengue vaccines: Brazil</td>
<td>Giovanini Coehlo</td>
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<td>12:15 – 12:30</td>
<td>Policy Considerations for introduction of dengue vaccines: Colombia</td>
<td>J Mendez Rico</td>
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<tr>
<td>12:30 – 12:45</td>
<td>Policy Considerations for introduction of dengue vaccines: Costa Rica</td>
<td>M.L. Avila Aguero</td>
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<tr>
<td>12:45 – 1:00</td>
<td>Policy Considerations for introduction of dengue vaccines: Cuba</td>
<td>Maria Guzman</td>
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<tr>
<td>1:00 – 2:00</td>
<td>Policy Considerations for introduction of dengue vaccines: Ecuador</td>
<td>Jhony Joe Real Cotto</td>
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<td>2:00 – 2:15</td>
<td>Policy Considerations for introduction of dengue vaccines: Honduras</td>
<td>M. Aparicia Palma</td>
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<tr>
<td>2:15 – 2:30</td>
<td>Policy Considerations for introduction of dengue vaccines: Mexico</td>
<td>H Lopez-Gatell Ramirez</td>
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<tr>
<td>2:30 – 2:45</td>
<td>Policy Considerations for introduction of dengue vaccines: Nicaragua</td>
<td>Carlos Saenz</td>
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<tr>
<td>2:45 – 3:00</td>
<td>Policy Considerations for introduction of dengue vaccines: Paraguay</td>
<td>Carlos Daniel Torres</td>
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<tr>
<td>3:00 – 3:15</td>
<td>Policy Considerations for introduction of dengue vaccines: Puerto Rico</td>
<td>Harold Margolis</td>
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<tr>
<td>3:15 – 3:30</td>
<td>Policy Considerations for introduction of dengue vaccines: Venezuela</td>
<td>Iris Villalobos de Chacon</td>
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<tr>
<td>3:30 – 4:00</td>
<td>Moderator discussion: Likely scenarios for introduction of dengue vaccines</td>
<td>Luiz da Silva, Moderator</td>
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<tr>
<td>4:00 – 4:30</td>
<td><strong>Coffee Break</strong></td>
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<tr>
<td>4:30 – 5:15</td>
<td><strong>Session VI: Communications and Advocacy</strong></td>
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<td>5:15 – 6:00</td>
<td><strong>Session VII: Summary and Conclusions</strong></td>
<td>David FitzSimons, Luiz da Silva, Cuauhtemoc Ruiz Matus, and Jose Luis San Martin</td>
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The mission of the Dengue Vaccine Initiative (DVI) 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.