

**Stop TB Partnership Vaccine Working Group:
Task Force on Economics and Product Profiles**

Meeting Summary

December 11 - 12, 2008
London School of Hygiene and Tropical Medicine
Keppel Street, London, UK

1. Introduction & Welcome: Gerard Cunningham, Uli Fruth and Lew Barker

- Agenda, attendees and proposed follow-up working groups attached
- TF Objective- Develop and implement a strategic plan for defining the economic issues that will accelerate the development and application of better TB vaccines by determining what has been done relevant to TB vaccine economics, reviewing what has worked for vaccines targeting other infectious diseases, and clarifying what are the economic and product profile gaps and priorities for development and application of better TB vaccines.

2. Epidemiology & Socioeconomic Impact of TB and Cost-effectiveness of New TB Vaccines

- Discussion of accuracy of epidemiology numbers and importance of having reliable data for successful development and deployment of new TB vaccines. Identified opportunity to provide feedback and direction to Clinical Task Force- re info that would be useful to this TF; also involvement of target countries to understand country-specific requirements.
- Noted Decision Making Frameworks exist for other diseases, e.g., Malaria vaccine DMF: (http://www.malvacdecision.net/pdfs/DMF_Framework_8-14%20w%20Phase%203.pdf). Discussed DMF use for TB vaccines R&D and considered drafting a similar document.
- **ACTION:** Identify several areas to pursue further, e.g., quality of existing (WHO) epidemiology data; helpful data gathering by Clinical; DMF for TB vaccines
- Discussion of cost-effectiveness (C-E) of vaccines and how it is measured in conjunction with C-E of other interventions, and what drives markets
- **ACTION:** Focus on C-E of existing vaccine candidates, and working with individual countries to understand what they need
- Introducing a new vaccine includes need for a clear message on perceptions, expectations, and effects. Is it possible to transcend the divide between vaccines, treatments, and diagnostics and to move together instead of working in parallel?
- Discussion of TB immunity—protection is believed to be T-cell immunity-based, but evidence is not complete; need to consider pre-exposure, post-exposure and latent TB vaccines, and the effects of all on markets
- **ACTION:** Make sure that current and future R&D take into account the economic particulars of questions regarding vaccine indications and efficacy
- Socio-cultural limitations and health system issues: PATH, GAVI, WHO have initiatives on these issues. Need to bear these in mind during continued discussion

3. Target Product Profiles (TPPs) and Advanced Market Commitments (AMCs)

- TPP is a written summary and reference for future vaccine development agreed upon by experts, government, and stakeholders. It is a planning tool that identifies criteria or goals for product development – may be used to determine which vaccines AMC will subsidize to introduce in GAVI eligible countries.
- AMC is a financial commitment to subsidize vaccine purchase at a set price; the mechanism works by having the AMC pay a higher price so that the developing countries can pay a lower price; subsidizes purchase, not development, but gives confidence to industry that there is a market. This TF needs to be ready to work on response if there is a call for TB AMC proposal.

- Presentation of “Pneumococcal Vaccine TPP and Lessons Learned for Future TPPs”- Rada Mirzayeva
 - o TPP has to be produced at the right time and in the right way to instruct development of vaccines - helps think about what is important for a successful vaccine and make everyone involved aware of the issues
 - o Reviews: Expert Advisory Committee, governments, donors, and stakeholders
- ACTION:** Subgroup to work up materials for group to react to at the next meeting—could define how TPPs can be useful for TB vaccines/some potential criteria

4. Basic market and revenue frameworks

- Analyses have been done by Applied Strategies, Boston Consulting Group
- Discussed who should be creating these frameworks, if they are accurate and sufficient, if they are important at this time, and if the potential markets will be enough to attract industry and funding to TB vaccines
 - o Noted discrepancies in predicted market size between and within different analyses, many variables, unknowns, and necessary assumptions in models; they could be too optimistic or pessimistic and difficult to be more definitive
- TB is widely perceived as a developing country issue; is there a tipping point at which time industry will want to get involved?
 - o Even if the analyses that show large markets are correct and compelling (some are skeptical), what further analyses are needed and when?
- **ACTION:** Group to undertake a critical re-review of existing models and analyses - also look at incentives for industry and determine if additional modeling is necessary
- Discussed MDR, HIV co-infection, duration of protection, transmission dynamics, and their effects on markets.
 - o Applied Strategies model looked at effect of MDR and XDR on the market; there are two drivers of this potential market-- relative cost of preventing MDR/XDR and whether a product profile that gets at MDR/XDR affects national policy
- Discussion of pricing structures, tiered pricing, and willingness to pay
 - o Tiered pricing is not entirely new and industry is already used to the idea
 - Mark-up of \$1 or \$2 on a product, has a big impact on revenue
 - o Proposed tiered pricing for different hosts; use for human/animal vaccine sales
 - o Many innovative mechanism designs to consider
 - E.g., Meningococcal A vaccine uses unusual, very successful mechanism
- Discussion of cost issues and attrition/success probabilities
 - o In total portfolio analysis by Applied Strategies, there is 7% risk of ending up with nothing even in the most optimistic scenario.
 - o How should we evaluate and quantify portfolios for innovation of TB vaccines? TPPs? Need to determine if the existing vaccine candidates are products that are likely to be economical and important for the market and provide direction and feedback to understand what developers need to strengthen or pull back on.
 - o Important needed part of market estimates is demand forecasting
- Discussion of investment externalities: Important project is to look at vaccines, drugs, and diagnostics for their combined effect under various transmission settings, geographic restrictions, etc. to make good decisions. Need to understand the progress in the other two to see what effect, if any, it would have for the prospects of TB vaccines. Consider connecting with working group on drugs to understand economics of drug development; especially because post-exposure vaccine similar to a drug; TPPs for immunotherapy?

ACTION: Explore having Stop TB PDP working groups interact and work together on integration of new tools development for TB control.

5. New Business Models

- Presentation on “Healthcare Ethical Fund for Emerging Countries”- Jean-Francois de Lavison
 - o Need new business model to close gap between product development for developed and developing countries, e.g., Dannon Communities Investments Fund
 - o Objectives- implement a social business model for healthcare improvement in low income countries through an “ethical fund”
 - o Structure- investment fund management in which shareholders sharing vision for healthcare improvement bring financial funding or skills to create different project portfolios
- Presentation on PDP Bank concept for funding vaccine development- Edge
 - o Through the PDP Bank, guarantees would be provided by donors (mainly governments) for bonds to fund vaccine development, then a levy would be charged on the sale of products to developed markets to repay loans; governments only pay out if everything fails; approach offers large potential benefits while spreading risk over several PDPs and multiple products
 - o Still many questions to resolve regarding governance and allocation, donor support, etc.
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6. Additional Topics

- Global Pathway- common document to identify next steps to accomplish to make producing and delivering a final product as efficient as possible
 - o Malaria pathway already developed; they are farther along in the process

7. Suggestions for Next Meeting Agenda

- Reports from working groups – see attached for subjects and proposed membership
- Components of Landscape Analysis Part 2 - Lessons from other vaccines
- Discussion of AMC proposal
- Regulatory issues important for implementation
- Additional participants to consider for Future Meetings: Regulatory Affairs and more Developing Country representatives