Economics of TB Vaccine Workshop

July 18-19, 2012

Summary Report

Aeras
1405 Research Boulevard
Rockville, MD 20850

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Executive Summary

Tuberculosis (TB) is an urgent public health problem; *Mycobacterium tuberculosis*, the bacterium that causes TB, infects an estimated one-third of the world's population or more than two billion people. While only 10% of those infected will progress to active disease those who do are mostly young adults in their most productive years. TB is a disease of poverty, with 95% of TB deaths occurring in the developing world.[1] Globally, TB is estimated to cost 0.5% of GNI[2,3]

Despite the longstanding availability and wide-spread use of Bacille Calmette-Guerin (BCG) vaccine for newborns and infants in the Expanded Programme for Immunization (EPI) the TB epidemic continues to rage globally. BCG is inconsistent in protecting infants, adolescent and adult forms of TB in high burden countries and inadequate to stem the global TB epidemic. It is adolescent and adult pulmonary TB that accounts for most transmission and for the bulk of the morbidity and mortality worldwide. To significantly impact TB, there must be a focus on disease prevention. A vaccine that prevents adolescents and adults from developing infectious tuberculosis would be the single greatest advance in the global fight against the disease.[4]

Although ongoing efforts over the last decade have successfully moved 15 novel TB vaccine candidates into Phase I & II clinical trials, the capacity and infrastructure development for large-scale Phase III trials is severely lacking. TB vaccine development has to be a part of keeping health high on the agenda of "sustainable development" and at the center of economic and social environments.

Even with considerable progress being made in the field of TB vaccine development, scientific infrastructure and financial challenges remain. Economic evaluations are viewed as one of the most important tools for informing a wide variety of stakeholders, including country decision makers, policy makers, donors and funders on investment decisions.

To begin the discussion of economic evaluations for investments, Aeras convened a meeting of health economic and TB experts on July 18-19, 2012, to develop a research agenda that would evaluate the economic value of a TB vaccine. Nearly 30 participants at the meeting reviewed the global TB epidemiology and health economic literature to identify the key factors that drive health and economic impact of TB vaccination and to pinpoint where better information or research would fill critical knowledge gaps to better inform decision makers. The result of the meeting was a rich research agenda to guide the economic work needed to answer key questions the value of TB vaccine development investment and inform public health decision-making at the global and country levels.

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[1] WHO: 2011/2012 Tuberculosis Global Facts . http://www.who.int/tb
[2] Economic Benefit of Tuberculosis Control, Laxminarayan R, Klein E , Dye C, Floyd K, Darley S, Adeyi O. The World Bank Human Development Network Health, Nutrition & population Team August 2007
[3] The Standard of Living Gains Generated by elimination of Tuberculosis in Twentieth Century England and Wales, Kerry Hickson, March 2008 http://www.ehs.org.uk/ehs/conference2008/Assets/HicksonFullPaper.pdf
[4] Small, P. 2012. Planning in the Context of a Virtuous Cycle for Tuberculosis Vaccine Development. Tuberculosis. Vol 92. Supplement

Key recommendations from workshop participants include the following:

- *No single model will adequately address the economic questions posed by a variety of stakeholders:* Multiple models will be needed to accommodate a variety of requests from global and regional donors, country level policy decision-makers, and investment funders on financing priorities. The economic modeling will need to balance efforts to put into context several different investment strategies to increase funding for vaccine development, show the benefits and risks related to the cost-effectiveness of vaccines compared to current interventions, and incentives for commercialization. Participants presented a variety of views on how to balance the near- and long-term agenda to make the case for investment.

- *Use current epidemiology data and modeling to build base case costs:* With the understanding that we cannot achieve TB elimination with the tools we have now, new technologies focusing on prevention, such as vaccines, that can interrupt both etiological pathways (i.e. primary disease and reactivation from latent infection) are needed. A simple, global model that is based on readily available WHO data is a practical starting point and one that can relatively quickly fill the immediate need. The focus would be to understand TB vaccines impact on preventative health versus drug treatment and applying a standard model of costs of interventions against their benefits. Participants discussed the approach to quickly develop a model that is accessible and relevant on a global level, building towards a more sophisticated and country-level detailed model as data becomes available.

- *Consider modeling challenges for countries and regions with unique differences in TB prevention and control:* Modeling vaccination strategies can be challenging with a disparate group of countries. High burden countries such as China, India, and South Africa all have unique health environments from unregulated health systems, to out-of-pocket payment issues. A potential strategy for India, assuming a ≥50% vaccine efficacy and mass vaccination program could produce drastic effects, but may differ somewhat from a strategy for South Africa where high HIV rates and impact of anti-retroviral therapy (ART) rollout and other complications must be taken into consideration. Designing models that considers both pre and post infection vaccines might be the best approach. Other considerations might include focusing on non-high burden countries, e.g. European countries, due to specific donor interest. Participants reviewed the possibility of building a rich country-specific model that could be modified for various situations.

- *Research agenda and priorities of the economic framework for supporting TB vaccine R&D:* Building a value proposition that is based upon credible data will foster a continuous dialogue amongst key stakeholders across the spectrum. A critical issue to keep in mind is to put into the context the varying needs of different stakeholders and the type of data and information they require.. The research agenda recommendations include:

  - Leveraging a model developed for Aeras by Applied Strategies as a starting point to develop a simple high level global TB economic model, with a broader perspective than simply the cost/DALY. Validating the assumptions, to the greatest extent feasible, will be extremely important
  - Using current epidemiological information and economic modeling that is already completed to build base case costs that include MDR TB and current treatment levels

- Building flexibility into the model design to be able to alter for specific situations, i.e., subgroups, hotspots, heterogeneity, etc. Vaccination models often use whole population mass vaccination assumptions but TB vaccination will likely require prioritizing specific target populations to optimize public health impact while maintaining feasibility. China and India will likely need their own vaccination strategy due to size of the population and their vaccine business model
- Considerations and important model domains include:
  - global/country/region specific data
  - static vs. dynamic model to capture transmission and if possible potential herd immunity
  - flexibility for various vaccine strategies and alternative treatments
  - detail of valuation of costs and benefits (treatment and vaccine delivery and administration, general health care costs, societal perspective on costs of morbidity/mortality)
- Developing strategies to model cost-effectiveness of new vaccines as the quality of information improves over time and is updated.

The near term goal (within the next 6 months) is to develop an understanding of all inputs and outputs and a structure that can be reviewed by an expert panel followed by the development of a simple high level global TB economic model. The longer term goal timeframe is a fully loaded cost-effectiveness model that can credibly inform evidence-based decisions by key audiences such as policy-decision makers, product manufacturers, and funders and donors. MDR TB was also discussed at length from an advocacy perspective with the realization that it is a substantial problem today; current treatments are not scalable and MDR-TB hospitals and clinics are not desirable places to work.

The two-day meeting focused on three topics: (1) Clarifying the types of economic valuations needed to support TB vaccine R&D investment and portfolio management, resource mobilization, and global and country policy decision-makers, (2) Identifying the key factors that drive health and economic impact of TB vaccination and pinpointing where better information or research would fill critical knowledge gaps to better inform decision makers (3) Identifying and prioritizing the key elements of a health economics research agenda for TB vaccines. This report summarizes the discussion and key contexts identified for each of these topics.

Day 1

Tuberculosis Epidemiology, Control Strategies and R&D for Vaccines (Dye)

Epidemiology
More than 9 million people still develop active TB each year and nearly 2 million die. TB global incidence rate worldwide currently stands at 1,280/million per WHO 2011 report. All countries are affected with 85% of cases occurring in Africa (30%) and Asia (55%), while India and China together represent 35%.

Control Strategies
The BCG vaccine is administered to newborns and there is little evidence that it protects adults. As a result the focus for TB elimination is TB control through diagnosis and treatment. The MDGS (introduced in 2000) give specific number targets for prevalence, incidence, and mortality; to reduce prevalence and incidence by 2015 to half what they were in 1990. The Global Plan to Stop TB 2006-2015 also has specific goals for control including to reduce TB prevalence to 1/million population. Although most countries with a high burden of TB have adopted and widely implemented the WHO's Global Plan to Stop TB 2006-2015, the rate of decline in case numbers has been slower than expected. Transmission has not been cut enough and is the dominant problem with current TB control strategies as evidenced by data from India showing new and re-infections accounting for most cases.[5]

To date forty million people have been treated and 6 million saved, but still, estimated cases continue to go upwards, particularly for South Africa, which has the steepest incline. With TB incidence worldwide at 1,280/million and current reduction rates at 2%/year, the goals set out by Global Plan to Stop TB of 1/million by 2050 will not be met. A minimum of 20%/year reduction is needed but the maximum possible decline with drug treatment alone is 10%/year and the current decline is ~1%/year in actuality.

More recently a Strategic Blueprint for the Next Decade – 2012 outlines a vision for developing and introducing safe and effective TB vaccines. Ultimately a multifaceted approach including novel drugs, rapid diagnostics and efficacious vaccines needed to reach elimination targets by 2050.

Region/ Country-Specific Issues
Different countries and regions face unique challenges for TB control. India poses specific challenges with inadequate and unregulated health care systems potentially delaying diagnosis of TB. Examples included patients visiting an average of three doctors before correct diagnosis with some patients seeing as many as seven physicians; each additional doctor causing a 12 day delay in treatment.

Immigration, a demographic phenomenon contributing to the population growth has also complicated control strategies; positive rates of TB are associated within areas of high immigration including Europe and within China.

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[5] Christopher Dye, et al. 2010. The Population Dynamics and Control of Tuberculosis. Science 328, 856; DOI: 10.1126/science.1185449

TB Vaccine Development - Status and Challenges (Ginsberg)

The need for a new TB vaccine is overdue. BCG introduced 90 years ago, despite reducing the risk of severe pediatric TB, is unreliable for prevention of adult pulmonary disease and is clearly inadequate to control the global epidemic. It is not recommended for HIV + newborns, and is not known to protect against latent TB infection. Additionally, due to the many genotypes of BCG circulating, current strains may not even be as effective as the original BCG.

There is optimism for new TB vaccines. New candidates have shown protection in animal models and have boosted CD4 and CD8 cellular immune responses in clinical studies.

Currently there are 13 TB vaccine candidates in clinical development representing a range of platforms including mycobacterial, viral vectors, rBCG, and protein/adjuvant. The first Phase IIb data will be available in 2013 and will provide the first human efficacy data for a novel TB vaccine. The population targets of the new vaccines include:

Preventative Vaccines:
- Newborns (pre-exposure)
- adolescents and adults (novel booster vaccines)

Therapeutic Vaccines
- adjunctive immunotherapeutics for TB patients or those with latent TB infections of all ages (shorten treatment course, improve efficacy)

Despite the rapid progress over the past decade in TB vaccine development there exists numerous challenges that must be solved, these include:

- The host protective response is not yet well-defined
- cell-mediated immunity is complex
- no validated animal model or surrogate marker
- large, expensive Phase IIb trials are needed to provide efficacy proof of concept
- endpoint definition of trials is not straightforward (especially infants)
- limited number of field sites with the experience and incidence for a good trial
- Phase III trials will require very large sample size significantly increasing costs

Scientific infrastructure and financial challenges remain and the solutions will require broadening the global community to support TB research, global partnership, and commitment towards aligning early R&D investments with economics of TB vaccines. However with the right resources a vaccine could be available by the end of the decade.

Literature Review of Economics of the Future of TB Vaccines (Polsky)

Few papers have explored economics of novel TB vaccines. Because BCG doesn't address adult TB disease and currently no other vaccines are available, the results in these papers are derived from modeling of hypothetical situations.

Three papers were reviewed:

(1)Bishai, D.M., Mercer, D. Modeling the economic benefits of better TB vaccines. Int J Tuberc Lung Dis 2001; 5(11):984–993.

(2) Tseng et al. Cost-effectiveness of novel vaccines for tuberculosis control: a decision analysis study. BMC Public Health 2011, 11:55. (http://www.biomedcentral.com/1471-2458/11/55)

(3) Laxminarayan et al. Global Investments In TB Control: Economic Benefits. Health Affairs 2009; DOI 10.1377/hlthaff.28.4.w730

(1) - In the Bishai paper results demonstrated that health sector benefits are great when vaccine prices are ≤$25/dose for 1 billion people vaccinated with the number of people who can benefit increasing as the price declines. The vaccine profile assumed 100% protection for 75% of the recipients, protection the same for pre and post infection, and a 10 year duration of the vaccine. The model included costs and benefits based on health care and indirect costs.

The paper summarized the need to consider multiple stakeholders' perspective to overcome the barriers leading to action and that each stakeholder will act according to their own specific costs and benefits and will only invest if the benefits of vaccination are greater than their own costs.

(2) - The Tseng et al paper reviewed the economic impact for one country, Zambia. The vaccine of choice was a new BCG-like vaccine that demonstrated a 50% reduction of risk of pulmonary TB in early childhood for ten years. The paper accounts for DOTS, case detection, treatment outcomes, smear positive, HIV, resistance and more detailed in the epidemiology of the disease than the Bishai paper. It does however ignore transmission and herd immunity and incorporates many uncertainty issues. The authors suggest a booster dose for developing countries which initially would be expensive but with lowering costs over time

(3) – The Laxminarayan et al paper looks at the global burden of disease in terms of lost productivity and from infected caretakers, as well as from mortality. They use value of statistical life, not human capital. The results showed that implementing and sustaining DOTS in the 22 high burden countries would result in economic gain of $1.6 trillion dollars from 2006-15, relative to no DOTS.

Donor Perspective

A Gates Foundation representative identified several major considerations when undertaking economic evaluation from a donor perspective. Key to the discussion was that advocacy is no longer about stories and medical need; the value lies in data that illustrates impact or potential impact of interventions. Other key concepts were:

- While the preferred parameter for measurement is Cost/DALY it is a complex concept and favors infants and children as patients due to the calculations. TB is also still a relatively 'rare disease' compared to HIV although globally there are 9 million cases. Previous data showed that 85% of adults returned to work within two years after AIDS treatment, but currently no such data is available for TB

- An intervention can be cost effective but doesn't mean it's affordable under the current budget; a host of added costs must be included in the analysis such as administration and delivery costs overlaid by the complexity of regional and age differences
- Vaccines should not be placed in opposition to drugs. Low-priced vaccines for large numbers of people must have benefit; it is a matter of balancing a portfolio
- Incorporating economic considerations with the epidemiological ones will be important to make a powerful case for the economic impact of TB
- Different investors will have different discount rates and returns that they expect from investing. Since the effects of TB vaccines are decades in the future, it is understanding what the investor wants to see as the results for their investment decisions that is critical and will impact the parameters on returns for investment.

Framing the Research Agenda

There is a global market for TB vaccines; while middle and low income countries would realize the greatest health impact, high income countries also benefit which is advantageous, industries such as mining, prisons populations and especially health care workers to name a few would benefit from TB vaccines.

A problem specific to TB is that TB is essentially a chronic disease, and stakeholders do not necessarily prioritize long term investments whose benefits will accrue over several decades. Investors will want to know what will cash flow look like after commercialization or how many years will it take to get to commercialization. These issues require a viable financial model in line with the funding available. The most likely solution is to generate a range of outcomes and risks with returns measured against these risks. A chronic economists' worry is how to frame a potential long term investment, when an investment alternatively could be made in a current social problem with more immediate returns.

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Day 2

Aeras Applied Strategies Model

After a brief recap of Day 1 discussions, the discussion turned to the Applied Strategies Model developed for Aeras TPP valuation to support research candidate decision-making and estimations of market value. The model is populated with current WHO TB epidemiology data in 197 countries and approximates a 2020-2050 timeline and leverages existing epidemiological models in a simple, credible way (TB assumptions reviewed and approved by Chris Dye).

The model offers a wide range of inputs from vaccine efficacy and coverage rates to country introduction dates and vaccine pricing. It is a rich model that allows for calculating multiple scenarios in a variety of TB vaccine profiles, health impact (incident cases averted and deaths averted) target populations, and vaccine availability, introduction and pricing assumptions. The demonstrated health impact output of any given TB vaccine candidate is highly dependent upon the assumptions' inputs and so they must be credible and feasible from a vaccine supply and country capability perspective. In addition HIV and ART can have a significant impact on the model outputs.

The group suggested that leveraging the Applied Strategies model is a starting point to develop a simple high level global TB economic model but with a broader perspective than simply the cost/DALY; validity of the assumptions will be extremely important.

Group Work on Developing the Research Agenda

To help frame the research agenda, a list of questions asked by stakeholders was presented to the group:

- What are the direct health impacts of vaccination?
- What is the estimated economic disease burden of TB?
- What are the social/ economic benefits of a TB vaccine?
- What is the lasting impact on lives of beneficiaries?
- What is the potential impact on poverty and health?
- What is the potential impact on health systems?
- What is the evidence of the benefits of TB vaccination will be greater than the costs?
- What is the relative cost-effectiveness of intervention?
- How does the intervention improve value for money?

Using these questions to help guide the discussion, participants were split into 2 working groups with the task of each group begin to develop the research agenda.

The Research Agenda Proposed Studies

The results from the working groups were several key recommendations:

- Leveraging a model developed for Aeras by Applied Strategies as a starting point to develop a simple high level global TB economic model, with a broader perspective than simply the cost/DALY. Validating the assumptions, to the greatest extent feasible, will be extremely important

- Using current epidemiological information and economic modeling that is already completed to build base case costs that include MDR TB and current treatment levels

- Building flexibility into the model design to be able to alter for specific situations, i.e., subgroups, hotspots, heterogeneity, etc. Vaccination models often use whole population mass vaccination assumptions but TB vaccination will likely require prioritizing specific target populations to optimize public health impact while maintaining feasibility. China and India will likely need their own vaccination strategy due to size of the population and their vaccine business model

- Considerations and important model domains include:
    - global/country/region specific data
    - static vs. dynamic model to capture transmission and if possible potential herd immunity
    - flexibility for various vaccine strategies and alternative treatments
    - detail of valuation of costs and benefits (treatment and vaccine delivery and administration, general health care costs, societal perspective on costs of morbidity/mortality)

- Developing strategies to model cost-effectiveness of new vaccines as the quality of information improves over time and is updated.

Based upon these recommendations, three proposed economic studies would likely be needed to influence investments for the R&D of TB vaccines and determine the global value of TB vaccination.

1. **Case for Investment:** This study would leverage the Applied Strategies TPP Valuation model to show the global health impacts and cost-benefits of several different TB vaccine candidates and vaccination strategies. By modeling the potential economic value of the likely number of incident cases and deaths averted worldwide including high burden countries. The timeline for completion is March 2013.

2. **Cost-effectiveness** – This study would be a more robust and rigorous study than the case for investment in that results of TB vaccine clinical trials could inform and potentially add greater clarity around the inputs into the model such as vaccine efficacy and dosing schedule. Requirements of the study would also include modeling different TB vaccine vaccination strategies in varying populations and birth cohorts. The results of the study would be used to inform policy makers, investors and other key stakeholders. The timeline for completion no later than December 2014.

3. **Value of Vaccination** – Purchase & Delivery: This last in the series of TB economic studies would be a cost-effectiveness model with specific vaccine profiles, full manufacturing scalability and feasible vaccination strategy to maximize global and /or country health impact. Supportive data to encourage investment in vaccine purchase and delivery. The timeline is dependent upon Phase II-III clinical trial results.

Next Steps

The valuable and actionable insights gained at the workshop will guide the development of TB economic valuation. Looking ahead in the short term, by January 2013, the TB economic expert group may be asked to review a structure, all inputs and outputs of a simple, credible, high level economic TB model leveraging the Applied Strategies work.

Over the longer term the development of a robust cost-effectiveness model that will offer policy-makers, investors, industry and other key stakeholders the data and information to make the economic argument for investment and evidence-based decision-making to support policies and the introduction of TB vaccines.

Appendix I

Working Groups 1 &2 Results

Group 1 results

Criteria used to frame the research questions

Audience
- Which stakeholder(s)?
  - WHO, other global/ regional bodies
  - Private investors (institutional, individual)
  - Industry
  - Donor
  - Government
- How can country-level stakeholders (e.g. Russia, China, India) be engaged early?

Policy
- Level of decision-making
  - Global
  - Country-level
- How does TB rank as a priority? How can research influence advocacy/ communications regarding this?
- What criteria, other than profit, are used by pharma in making investment decisions – e.g. "halo effect?"

Scientific
- What are the key information gaps?
  - Example: Real costs to systems of vaccine (e.g. regulation)
  - In-country risk groups (e.g. socioeconomic strata)
- What are the choices – e.g. types of models that are available for development? (taxonomy of models that can be drawn upon)

Social/ public health
- Lasting impact on the lives of beneficiaries at a population-level
  - Gates credo and principles
  - Evidence that expected benefits "outweigh" costs
  - How does this differ by country-level, high burden, low income, emerging market, etc)

Temporal
- Keeping the eye beyond discovery and pre-qualification – evidence needed down the line that can be acquired now during clinical development – example of meningococcal A vaccine.

Policy research
- Key drivers of decision-making (political will) at a global, regional and country-level (quantitative/ qualitative interviews, conjoint analysis); what sort of process leads to that collective decision? Example of Hib, mening A, China pre- and post-SARS.
- Early role for key country-level stakeholders (e.g. China, India, others)

Investment models
- What is the market for this product? How will that be influenced by potential future outbreaks and the spectra of MDR/ XDR TB?

Cost-effectiveness models
- What is the clinical and public health impact and how does this influence the cost-effectiveness?
- What is the value proposition for vaccine intro and its implementation?
- Special emphasis on China, India, and South Africa.
- Should we focus also on non-high burden countries, e.g. European countries, due to criteria such as donor interest?

Other models
- How can futures markets/ crowd-sourcing be used to estimate the value of TB vaccines?

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Group 1 results (cont.)

Research Questions

Model structure
- How can models introduce sub-group analysis (risk groups) to inform the vaccine proposition? How can this inform introduction decisions?
- What is the impact of MDR/ XDR TB on vaccine's value proposition?
  - Disease burden of MDR/ XDR TB, Cape Town outbreak and lessons from there regarding transmissibility of drug-susceptible versus MDR strains
  - Immigration patterns

Model inputs
- How does vaccine efficacy impact eventual demand?
- How do vaccine performance characteristics – assumptions regarding – impact TB vaccine's value proposition? (efficacy and duration of efficacy)
- How does the participation of emerging market pharma impact the costs of vaccine and its introduction?
- What will the costs of vaccine delivery in particular settings be? (e.g. mass vaccination campaigns)

Other model outputs
- How does a TB vaccine ameliorate the long-term challenges of TB control using traditional methods (e.g. late 1980s/ 1990s in the U.S. and Russia)
- What are the start-up versus ongoing costs of developing and introducing vaccine?

Group 2 Results

Making the Case

Overall goal: To give consumers realistic expectations with the model and real outcome predictors

Cost of Disease
- Cost of MDR
- Burden of untreated
- Cost of all treated
- Health care workers
- Testing cost
- Cost of treatment with specific treatment X and the number treated
- Morbidity and mortality costs (this fraction can drive the cost up in a way that hasn't been fully captured yet)

Program Costs and Revenues
- Complicated by hotspots both geographic and institutional, and unknown how much transmission is related to these areas
- Demand targets and cost of mass vaccination; cost in high income countries with specific high risk populations such as, health care workers, prisoners, military
- Vaccinate anyone contacted by an active TB patient
- Infections based on screening for example, North India has more TB than south (opposite of HIV) but the factor is not large or most TB in China is in central and northwest, east is lower except in the immigrant population
- How much discrimination do you need between treatment and prevention
- If incidence comes down the question becomes does the country need to maintain the interventions, i.e. DOTS vaccination
- Country-specific models need flexibility and to be detailed so that cost-effectiveness can be addressed across a number of scenarios

Effectiveness outcomes
- Transparent and simple global model
- Key questions:
  - Who and how many should adopt based on incremental cost-effectiveness criteria?
  - What would be assumed coverage, cost, and vaccine effectiveness be?
  - How can the model accommodate different income groups and risk groups?
  - What is the ideal coverage level for different scenarios?
  - As efficacy varies, how many people are covered/ what is cost/ what is incidence?
  - How much immunity can you develop in those areas where most transmission is occurring?

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Appendix II – Agenda

Economics of TB Vaccine Workshop

Date & Time: July 18, 2012 – 12:00pm-5:00pm

July 19, 2012 -   8:00am-2:00pm

Location: Aeras

Board Room, 3rd Floor

1405 Research Blvd.

Rockville, MD. 20850

Aims of the workshop

- To clarify the types of economic valuations needed to support TB vaccine R&D investment and portfolio management, resource mobilization, and global and country policy decision-makers
- To identify and prioritize the key elements of a health economics research agenda for TB vaccines
- To identify the key factors that drive health and economic impact of TB vaccination and to pinpoint where better information or research would fill critical knowledge gaps to better inform decision makers

Expected Outcomes of the Workshop

- Research agenda identified and prioritized
- Economic framework developed for prioritizing and supporting TB vaccine R&D including:
  - Long term socio-economic value of TB vaccines for disease endemic countries measured
  - Potential impact(s) of TB vaccines (by target product profile) on the TB epidemic (MDR/XDR-, as well as DS) measured

Agenda: Day 1 – Wednesday, July 18, 2012

Time	Topic	Presenter
12:00 - 12:30	**Lunch**	
12:30 – 12:45	Welcome and Introductions	A. Ginsberg C. Dye (Chair Day 1)
12:45 - 1:30	Global state of TB - Epidemiology of TB infection and disease Q&A	C. Dye
1:30 – 2:00	Status and Scientific challenges of TB vaccine development Q&A	A. Ginsberg
2:00 – 3:00	Literature review - current work around the economics of TB Q&A	D. Polsky
3:00 – 3:15	**Break**	
3:15 – 3:45	Donor Perspective	Gates Foundation
3:45 – 5:00	Moderator Framing the research questions – Discussion	B. Bloom
6:30 -	**Dinner**	

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Agenda: Day 2 – Thursday, July 19, 2012

Time	Topic		Presenter
8:00-8:30	**Breakfast**		
8:30-8:45	Recap of Day 1		D. Polsky (Chair Day 2)
	TBD – Group Discussion or Breakout – Group formation and discussion of research questions		
8:45 – 10:45	**Group 1** C. Dye A. Sinha D. Bishai J. Chiu L. Sacks Y. MuKadi K. Elkins J. Gheuens	**Group 2** D. Polsky G. Garnett D. Dowdy S. Morris A. Ou R. White B. Bloom D. Curry	
10:45 – 11:00	**Break**		
11:00 – 11:30	Group 1 Results		
11:30 – 12:00	Group 2 Results		
12:00 – 12:30	**Lunch**		
12:30 -1:45	Group Discussion: Formation of research agenda, Summation		C. Dye/D. Polsky/B.Bloom
1:45 – 2:00	Closing and next steps		A. Ginsberg/K. Stoever

Appendix III – List of Participants & Affiliation

Name	Affiliation
EXPERTS	
Christopher Dye, PhD	WHO
Dan Polsky, PhD	University of Pennsylvania
Anushua Sinha, MD, MPH	New Jersey Medical School
Leonard Sacks	FDA
Richard White	London School of Hygiene& Tropical Medicine
Karen Elkins	FDA
David Dowdy	Johns Hopkins Bloomberg School of Public Health
David Curry	Center for Bioethics, University of Pennsylvania
Joseph Chiu	NIAID
Geoff Garnett	BMFG
Jan Gheuens	BMGF
Sheldon Morris	FDA
YaDiul MuKadi	USAID
Barry Bloom, PhD	Harvard University
David Bishai, PhD	Johns Hopkins Bloomberg School of Public Health
Alan Ou	NIAID/DMID/RDB/Tuberculosis Section
AERAS	**Title**
Ann Ginsberg	VP, Scientific Affairs
Kari Stoever	VP, External Affairs
Angeline Nanni	Director, Market Access
Michael Brennan	Sr. Advisor Global Affairs
Jennifer Wooley	Director, Advocacy
Salma Samad	Director, Donor Relations
Annemarie Leadman	Director, Communications
Lew Barker	Sr. Medical Advisor
KPMG	
Christopher J. Mercier	Managing Director
Sean J. Sullivan	Director