

Beyond Efficacy: the full public health impact of vaccines in addition to efficacy measures in trials

"Les Pensières"

Fondation Mérieux Conference Center
Veyrier-du-Lac - France

Steering Committee:

- Robert Breiman
- Brad Gessner
- Duane Gubler
- Olaf Horstick
- Jacques Louis
- Christophe Nelson
- Umesh Parashar
- Roberto Tapia
- Valentina Picot
- Jean-Antoine Zinsou

22-24 June 2015

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Background

Vaccine efficacy reflects the proportionate reduction in disease incidence between unvaccinated and vaccinated individuals . While vaccines are typically licensed on the basis of demonstrated efficacy, the ultimate goal of vaccination is to achieve a significant public health impact in addition to the prevention of infection in an individual. In this respect, there is a need to provide a broader perspective that encompasses the capacity of a vaccination program to reduce microbial transmission, avert disease, disability and premature deaths, and to lessen the pressure on health system and to reduce health inequities between populations. These issues are particularly relevant for some of the newer vaccines (e.g., rotavirus, dengue, and malaria vaccines) that demonstrate lower efficacy in high burden settings than traditional vaccines, but nevertheless could have a substantial overall public health impact in these settings.

Data on a vaccine's public health benefit are often not available or may be incomplete . As a consequence, decision-makers and target populations may underestimate the justification for vaccine use, leading to delays in public immunization program introduction, and ongoing preventable disease burden. The slow introduction of rotavirus vaccine in developing countries despite evidence of enormous decreases in severe disease and hospital utilization is one example .

In addition to helping inform decision-makers and target populations, measures beyond efficacy may have a role in vaccine licensure. Specifically, there is no a priori reason why regulatory agencies would not consider the total disease burden preventable by vaccine as a complement to vaccine efficacy .

Objectives of the meeting- To discuss how to integrate vaccine efficacy/effectiveness with preventable disease burden:

1. in the context of vaccine licensure
2. in the context of developing evidence-based immunization program policy for public sector vaccination programs
3. in the context of developing communication strategies for target populations

Key issues to be addressed

- The concept of partially effective vaccines and the limits of vaccine efficacy
- Preventable disease burden outcomes and measurement
- Vaccine impact on transmission
- Assessing vaccine potential to prevent epidemics but not eliminate disease
- Key examples from the past and potential examples from the future
- The role of modeling in assessing preventable disease burden
- Use of preventable disease burden to inform economic assessments
- Preventable disease burden and social justice
- The potential for regulatory agencies to consider preventable disease burden as a criterion for vaccine licensure



Scientific programme

Monday 22 June 2015		
17:30 - 18:30	Registration	
18:30 - 18:50	Welcome address	Fondation Mérieux
18:50 - 19:30	Key-note address : The costs and effectiveness of large pre-licensure phase III clinical trials: time for a new paradigm?	Steve Black
19:40	Welcome Dinner	

Tuesday 23 June 2015

Session 1

Public Health impact of Vaccination: General concept and methodological approaches

Chair: Jean-Antoine Zinsou

08:30-08:50	Vaccination outcome measures and methods. The use of Phase III trials to assess public health impact through “vaccine probe” analyses.	Robert Breiman
08:50-09:05	Discussion	
09:05-09:25	Importance of measuring baseline vaccine preventable disease incidence (against clinical disease syndromes, with clear case definition) in addition to vaccine efficacy in clinical trials	Umesh Parashar (on behalf of Brad Gessner)
09:25-09:40	Discussion	
09:40-10:00	The Concept of Herd Immunity/Protection-Efficacy vs effectiveness; The Importance of Cluster-Randomized Trials to assess Vaccine Herd Protection	Ana Lena Lopez
10:00- 10:15	Discussion	
10:15-10:45	Coffee Break	
10:45-11:05	Cost effectiveness of vaccines: assessment of the decision-making tools	John Edmunds
11:05- 11:20	Discussion	
11:20- 11:40	What modeling can and cannot bring to impact assessment of vaccines	Ira Longini
11:40- 11:55	Discussion	



Scientific programme

11:55- 12:15	Corrolaries of vaccine introduction: benefits beyond vaccine efficacy	Annelies Wilder-Smith
12:15- 12:30	Discussion	
12:30-14:00	Lunch	

Session 2

Appraisal of the effect of vaccines on the Vaccine Preventable Disease incidence against different outcomes or in different settings: case study examples

Chair: Olaf Horstick and Umesh Parashar

14:00- 14:20	Hib and Pneumococcal conjugate vaccines	Rana Hajjeh (pending)
14:20-14:35	Discussion	
14:35 - 14:55	Rotavirus vaccine: assessing the risk and benefits	Umesh Parashar
14:55- 15:05	Discussion	
15:05- 15:25	Possible effect of a Malaria vaccine on the preventable burden	Kevin Marsh
15:25 - 15:40	Discussion	
15:40-16:10	Coffee break	
16:10-16:30	Possible effect of a Dengue Vaccine on the preventable burden	Duane Gubler
16:30 - 16:45	Discussion	

Session 3

Expanding the Regulatory and Immunization Policy decision-making from an Individual Benefit/Risk to a population-level (Public Health Impact) Benefit/Risk

Chair: Chris Nelson

16:45-17:05	Elements from the EU regulatory landscape	Frank Vandendriessche
17:05 - 17:20	Discussion	
19h30	Diner	

Wednesday 24 June 2015

09:00-09:20	A Regulatory Authority's (USA) perspective	Norman Baylor
09:20-09:35	Discussion	
09:35- 09:50	Regulatory challenges for registration of novel vaccines	Nora Dellepiane
09:50 -10:05	Discussion	
10:05-10:35	Coffee Break	
10:35- 10:55	New Paradigms in Vaccine Evaluation and Promotion: a View from a Developing Country	Helder Martins
10:55-11:10	Discussion	
11:10-11:30	A Funder perspective: the Bill and Melinda Gates Foundation	Peter Dull
11:30-11:45	Discussion	
12:15-14:00	Lunch	
14:00-15:30	Workshop/Round Table Discussion: Importance of Public Health Impact on decision-making in relation to a) licensure and b) choice of vaccines to be introduced in vaccine programmes	Olaf Horstick and Chris Nelson with the participation of speakers
15:40	End of Meeting	