

Estimating the full public health value of vaccines

Les Pensières
Fondation Mérieux Conference Center
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5-7 December 2016

Steering Committee:

- Kathy Neuzil
- Kate O'Brien
- David Kaslow
- Brad Gessner
- Umesh Parashar
- Tikki Pang
- Chris Nelson
- Jean-Antoine Zinsou
- Valentina Picot
- Jacques Louis
- Cindy Grasso, Meeting Coordinator

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Background and rationale

Several new candidate vaccines have reached a level of efficacy that has triggered discussions in the public health community on how to assess and incorporate the full public health value (FPHV) of preventive vaccines into the evidence-based decision-making process of vaccine licensure and public health use.

In June 2015, a group of experts discussed how to define what criteria should be considered to assess the FPHV of vaccines in addition to efficacy measured in clinical trials. (1) They've reached the conclusion that we were entering in an era of a new paradigm in vaccine evaluation where all aspects of public health value of vaccines beyond efficacy should be assessed.

It was clear for this group of experts that assessing the full benefit of vaccines can no longer rely on largescale Phase III trials and vaccine effectiveness studies only. Going a step further and considering additional outcomes, measures, and designs becomes extremely valuable, as does the consideration of vaccines role in facilitating equitable access to public health. They also considered that in addition to benefit-risk assessment based on the information collected through the traditional regulatory process, a substantial body of additional information is needed to inform policy and other required decision-making at the global, national and sub-national levels. Therefore, to assess the wider scope of vaccine benefits, improvement in risk assessment, partnership and coalition building across interventions and data sharing needs to occur.

With this new paradigm, alternative regulatory pathways involving stakeholders as a process for low and middle-income countries (LMICs), and conditional licensure of vaccines based on collection of outcome results should both be considered, to lower the financial barriers to development of new vaccines and thus increase portfolio of vaccines to be developed and introduced in these countries.

Now that the components of this new paradigm are well defined, there is a need to evaluate their feasibility for the proper assessment of the FPHV.

This meeting will continue a discussion that has been engaged starting at the Global Vaccine and Immunization Research Forum in 2014 and was continued in 2015 and into 2016 starting with the Health Affairs special issue (HEALTH AFFAIRS, Volume 35, Issue 2: Vaccines), and discussions at the Global Vaccine and Immunization Research Forum (March) and the Geneva Health Forum (April).



Background and rationale

Objective of the meeting:

To advance discussions on the definition, evidence and communication of the Full Public Health Value (FPHV) of vaccines:

- To challenge the definition of what constitutes the FPHV of vaccines.
- To review examples of Public Health Value with existing vaccines used in outbreak settings and others used in endemic disease settings.
- To propose designs, measures, and outcomes for assessing the FPHV of vaccines in phase III trials and phase IV assessments and integrated/hybrid phIII/IV strategies.
- To apply these concepts to specific vaccines: malaria, dengue, Group B Streptococcus (GBS), Respiratory syncytial virus (RSV), Neisseria meningitidis B (NMB), and Oral Cholera Vaccine (OCV).
- To strategize on how to communicate the FPHV of vaccines to regulatory and program policy makers.

(1)Saadatian-Elahi M, et al. Beyond efficacy: The full public health impact of vaccines. Vaccine (2016), <http://dx.doi.org/10.1016/j.vaccine.2016.01.021>



Scientific programme

Monday, December 5th 2016

16:00 - 16:30	Registration	
16:30 - 16:45	Welcome address	Fondation Mérieux
16:45 - 17:00	Objectives of the meeting	Tikki Pang
17:00 - 17:45	Key-note address 1: The importance of the full public health value of vaccination in decisions of policy makers: where do we stand and where should we go	Brad Gessner
17:45 - 18:00	Discussion	
18:00 - 18:45	Key-note address 2: QALYs or the social rate of return: what's the right benefit measure?	JP Sevilla
18:45 - 19:00	Discussion	
19:00	Welcome dinner	

Tuesday, December 6th 2016

Session 1

The public health value of vaccines: socio-economic aspects

Chair: Kathy Neuzil

8:30 - 8:50	Examples of the public value of some health interventions other than vaccines (the example of HIV treatment)	Till Bärnighausen
8:50 - 9:05	Discussion	
9:05 - 9:25	Are current cost-effectiveness «thresholds» for low- and middle- income countries useful? An example from the «world of vaccines»	Jessica Ochalek
9:25 - 9:40	Discussion	
9:40 - 9:55	Public health value and broader impact of vaccines	Raymond Hutubessy
9:55 - 10:10	WHO activities in immunization implementation research	Ana Maria Henao-Restrepo
10:10 - 10:25	Discussion	
10:25 - 10:45	Coffee break	
10:45 - 11:05	The public health value as an important attribute of potential vaccines in a priority-setting aid for new vaccine candidates	Rino Rappuoli



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11:05 - 11:20	Discussion	
11:20 - 11:40	Quantifying the equity and financial risk protection benefits of vaccines using extended cost-effectiveness analysis (ECEA)	Stephan Verguet
11:40 - 11:55	Discussion	
11:55 - 12:15	Vaccination as an essential element of reducing health inequities	Ulla Griffiths
12:15 - 12:30	Discussion	
12:30 - 14:00	Lunch	

Session 2

Panel discussion: health systems disruption resulting from epidemics: effect on vaccination programmes

Chair: Jean-Antoine Zinsou

14:00 - 14:10	Introduction	Guenael Rodier
14:10 - 14:25	Impact of the 2014-15 Ebola outbreak on health systems, vaccination programmes and population health	James Elston
14:25 - 14:40	Health system disruption by epidemics: the example of Zika	João Bosco Siqueira
14:40 - 14:55	Flexibility in pandemic planning, preparedness, response and international health regulation (IHR), implementation, H5N1 experience in Indonesia	I Nyoman Kandun
14:55 - 15:30	General discussion: "considerations for vaccination programmes during acute health emergencies"	Facilitator: Guenael Rodier
15:30 - 15:50	Coffee break	

Session 3 a)

Extending the evaluation of specific vaccines beyond the traditional efficacy measures evaluated in phase III trials: case studies of the full public health value of vaccination against endemic and non-seasonal diseases

Chair: Chris Nelson

15:50 - 16:10	Unique considerations of public health value of vaccines given to pregnant women	Kathy Neuzil
16:10 - 16:25	Discussion	



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16:25 - 16:45	Group B streptococcus vaccination of pregnant women: potential for impacting on maternal, fetal and infant health	Shabir Madhi
16:45 - 17:00	Discussion	
17:00 - 17:20	Potential public health impact of RSV vaccines	Ruth Karron
17:20 - 17:35	Discussion	
17:35 - 17:55	Rotavirus vaccines – Efficacy and public health impact	Umesh Parashar
17:55 - 18:10	Discussion	
19:00	Dinner	

Wednesday, December 7th 2016

Session 3 b)

Extending the evaluation of specific vaccines beyond the traditional efficacy measures evaluated in phase III trials: case studies of the public health value of vaccination against seasonal and epidemic/outbreak-prone diseases

Chair: David Kaslow

8:30 - 8:45	How to make best use of an imperfect malaria vaccine	Brian Greenwood
8:45 - 9:00	Optimal use of Malaria vaccine II	Matthew Laurens
9:00 - 9:30	Panel discussion: optimal use of Malaria vaccines in relation to other control measures; The role of vaccines in Malaria eradication	Facilitator : David Kaslow
9:30 - 9:50	Optimal use of Dengue vaccines	João Bosco Siqueira
9:50 - 10:05	Discussion	
10:05 - 10:30	Coffee break	



Scientific programme

Session 4

Specific evaluations that should be considered either pre- or post-licensure to extend to the public health impact of vaccines the information obtained from phase III trials

Chair: Kate O'Brien

10:30 - 10:50	How undervaluing vaccination can undermine vaccination ecosystem sustainability and diversity	Michael Watson
10:50 - 11:05	Discussion	
11:05 - 11:25	The perceived full public health value of vaccines and vaccine hesitancy among patients and providers	Pauline Paterson
11:25 - 11:40	Discussion	
11:40 - 12:40	General discussion: VE is not quite as "robust" as it is commonly understood to be	Facilitator : Kate O'Brien
12:45 - 14:00	Lunch	

Session 5

Round table discussion: How do policy makers see the public health value of vaccines

Chair and facilitator: Tikki Pang

14:00 - 14:15	Vaccination and public health: "a governments' obligation"; "Every childrens' right" / Philippines	Janette Loreto Garin
14:15 - 14:30	Vaccination program: governance and policy decision process in Malaysia	Puan Dr. Safurah Binti Hj. Jaafar
14:30 - 14:45	Expanded program on immunization in indonesia and it's public health implication	I Nyoman Kandun
14:45 - 15:15	Discussion	
15:15 - 16:15	Comprehensive valuation of vaccines: summing up and the way forward. Closing of the meeting	Facilitator: Kate O'Brien

