Rapporteurs: Birgitte Giersing (WHO), Angela Hwang (Consultant)

Session Outline

Chairs:

Robert Breiman (Director, Emory Global Health Institute)

David Kaslow (Vice President for Essential Medicines, Director of the PATH Center for Vaccine Innovation and Access, PATH)

Presentations:

Development of WHO Full Public Health Value Propositions (FPHVPs) for vaccines to prevent infectious diseases, David Kaslow (Vice President for Essential Medicines, Director of the PATH Center for Vaccine Innovation and Access, PATH)

Additional Panelists:

Suresh Jadhav (Executive Director, Serum Institute of India)

Gagandeep Kang (Professor, Christian Medical College, Vellore)

Yot Teerawattanaon (Programme Leader, Health Intervention and Technology Assessment Program, Ministry of Public Health, Thailand)

Anita Zaidi (Director, Vaccine Development, Surveillance, and Enteric and Diarrheal Diseases, Bill & Melinda Gates Foundation)

Jean-Antoine Zinsou (Senior Director of Strategy-Vaccination Policy and Advocacy, Sanofi Pasteur)

Objectives of the session

To discuss:

- What is meant by "Full Public Health Value Proposition" (FPHVP)
- The benefits and utility of describing vaccine value propositions in this broader sense

Main outcomes

- Consensus that there is benefit and value in developing FPHVPs for vaccines against priority pathogens.
- FPHVPs are living, evolving documents that will need to be current, and within the context of other preventive and curative interventions and evolving epidemiology, to remain relevant

Summary

Vaccines historically have been implemented in low- and middle-income countries (LMICs) based on based on direct health benefits captured in incremental cost effectiveness ratios, particularly for lives saved. For newer vaccines that have more complex value propositions, there is a risk of a "second Valley of Death", or an introduction gap between licensure and uptake. FPHVPs are a tool in development to help bridge this gap. They will articulate the value of a vaccine from the perspective of multiple stakeholders, provide an end-to-end compendium of available evidence to support advocacy and inform decision making at various stages of product development, and identify evidence gaps that must be addressed to inform funding decisions and assessment of risk. FPHVP will go beyond the customary

perspective of individual, direct health benefits to describe the full population-based economic and societal benefits of vaccination. They will be used to align stakeholders, support advocacy for product development, inform investment decisions, and ultimately accelerate access to suitable new vaccines in LMICs while facilitating accelerated uptake by ensuring that the characteristics of (and information about) products address and resonate with the priorities of local and international decision-makers and stakeholders.^b

There was strong support and endorsement for the development of FPHVPs from both the panel and the session audience. Stakeholders agreed on the need to structure and systematize the collection of data to inform decision-making for investment in product development and policy recommendations.

FPHVPs will help funders and manufacturers to assess the economic and public health return on investment and establish investment priorities, and, once priorities are established, to focus on specific product characteristics and collect needed investigational data. Vaccine producers serving LMICs need predictable demand because profit margins are slim and unused manufacturing capacity is costly. FPHVP can help sustain funder and manufacturer engagement by increasing the probability that demand will materialize as anticipated and that the predicted impact will be achieved.

FPHVPs could play an instrumental role in generating the political will that led to the success of MenAfriVac, albeit in a more tangible and accessible way than traditional cost-effectiveness analyses. Information on programmatic suitability and broader economic benefits will be of interest to National Immunization Technical Advisory Groups (NITAGs) and can support decision-making by other stakeholders such as the ministries of health and finance. However, it was noted that NITAG capacity building and more systematic decision-making processes are needed in some countries to ensure that better evidence leads to better decision making.

It was noted that it will be important to look beyond mortality impact and include assessment of potential impact on well-being, health systems, poverty and equity, particularly as mortality rates for many diseases are dropping. Showing how a vaccine may benefit the most impoverished will help to generate public demand and political accountability. This is particularly important for countries that are transitioning from Gavi support and facing difficult budget decisions as they become fully self-financing.

Finally, it needs to be understood that public health and disease prevention options are constantly changing, along with epidemiology of diseases, and a sustained approach to the development and maintenance of FPHVP will be needed.

Key references or quotes

- a. O'Brien KL, Binka F, Marsh K, Abramson JS. Mind the gap: jumping from vaccine licensure to routine use. Lancet. 2016 May 7;387(10031):1887-9. doi: 10.1016/S0140-6736(16)30394-4.
- b. Gessner BD, Kaslow D, Louis J, Neuzil K, O'Brien KL, Picot V, Pang T, Parashar UD, Saadatian-Elahi M, Nelson CB. Estimating the full public health value of vaccination. Vaccine. 2017 Nov 1;35(46):6255-6263. doi: 10.1016/j.vaccine.2017.09.048. Epub 2017 Oct 3.