2020 WHO Product Development for Vaccines Advisory Committee (PDVAC)
Virtual Consultation: Full Value of Vaccine Assessment (FVVA) for *Shigella* vaccines
18 May 2020
CHAIR: David Kaslow

Concept note

A vaccine candidate will encounter a number of inter-dependent hurdles along the pathway to use and impact. These have been characterized by Piot et al (2019)[1]. The phases of product development, licensure, policy recommendation, financing and procurement exist along a continuum, and early engagement, alignment and co-ordination of the respective stakeholders could be enhanced through information and incentives. The Full Vaccine of Vaccines Assessment (FVVA) is a concept that describes the global value of a vaccine and aims to articulate the full direct (individual) and indirect (population) effects of a vaccine. The intent of FVVA is to support decision-making across the continuum of vaccine development and uptake, with a line-of-sight to sustainable socio-economic and public health impact.

Several *Shigella* vaccine candidates are currently in Phase II trials. At least one of them will require evaluation in a costly Phase III field efficacy study to support licensure in the priority target population of infants and children below 5 years of age, in low and middle countries. Considering the number of candidates that are in late state development across a number of diseases, the relative 'value' of vaccines is becoming increasingly crucial to quantify, to inform priority setting for investment and introduction decisions. This need is particularly pertinent for a Shigella vaccine, given the reduction in mortality from Shigella infections over the last decade (although the morbidity burden remains significant and poorly characterised) and its heterogenous epidemiology. This means that Shigella vaccine introduction may be most cost-effective at a subnational level, or if used in combination with other enteric vaccines. In addition, there is evidence of increasing antimicrobial resistance (AMR) to *Shigella* which could be addressed by a vaccine. As such, the broader population-based benefits, including economic and macro-economic outcomes, will be imperative to describe as part of comprehensive vaccine value assessment.

PATH have identified the major themes to inform a FVVA for Shigella vaccines. This session is to discuss the critical questions that could inform the assessment *from the PDVAC perspective*, and their relative importance, at this point in time.

Objectives of the meeting:

- To seek feedback on the proposed questions, to be addressed by the Shigella FVVA.
- To identify gaps or other questions that could be addressed as part of the Shigella FVVA.

Background reading:

- Shigella PDVAC backgrounder – Bill Hausdorff (PATH)
- DRAFT manuscript: The Full Value of Vaccine Assessments (FVVA): a framework to guide assessment and communication of the value of and decision making for vaccines – Hutubessy et al (*PDVAC only*)
- DRAFT manuscript: Accelerating global health vaccines against *Shigella* – MacLennan et al (*PDVAC only*)

[1] Piot P, Larson HJ, O'Brien KL, N'kengasong J, Ng E, Sow S, Kampmann B. Immunization: vital progress, unfinished agenda. Nature. 2019 Nov;575(7781):119-129. doi: 10.1038/s41586-019-1656-7.

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06:00 Seattle; 8:00 Lima; 9:00 Washington DC; 14:00 London; 15:00 Johannesburg; 15:00 Geneva; 18:30 New Delhi, 21:00 Beijing; 22:00 Seoul

Time (Geneva CEST)	**Topic**	**Duration**	**Detail**	**Moderators, speakers**
15.00 – 15.10	Introduction: session overview & objectives			David Kaslow / Birgitte Giersing
15.10 – 15.20	Why do we need a FVVA for Shigella vaccines?	10’	**For information:** Overview of proposed key elements that are needed to define the Shigella vaccine value assessment	Bill Hausdorff (PATH)
15.20 – 15.30	Questions for clarification			
15.30 – 15.55	What has changed in our perception of Shigella burden in the last decade?	15 + 10	**For information:** Evolving mortality estimates, subnational vs national heterogeneity, recent data or models that many inform impact of stunting	Karen Kotloff (UMD)
15.55 – 16.10	AMR as an incentive for vaccine development/use	10 + 5	**For information:** Overview of ongoing studies of potential impact of a Shigella vaccine on AMR	Mateusz Hasso (WHO)
16.10 – 16.25	The potential impact and cost-effectiveness of a Shigella vaccine.	10’ + 5’	**For information:** Includes an overview of key impacts considered and omitted and the rationale for considering the relationship between stunting, cognition, learning and macroeconomic effects.	Farzana Muhib (PATH)
16.25 – 16.30	Questions for consideration	5’	**For discussion and input:** ➢ Do you consider a comprehensive analysis of the association of Shigella with stunting and AMR to be a critical part of a FVVA of Shigella? ➢ Do you consider a macroeconomic assessment of a Shigella vaccine’s impact on stunting and other long-term sequelae to be crucial? ➢ What modifications, if any, to current cost effectiveness analyses should be included based on new data, or understanding of the disease, AMR impact or epidemiology?	Birgitte Giersing (WHO)

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			➢ (When) should we model the incremental cost-effectiveness ratio for different vaccine combinations? ➢ How should we engage with / gather information on current national stakeholder and health care practitioner perceptions of Shigella burden and of a vaccine's potential impact on diarrheal disease burden, stunting, and AMR, either as a standalone or a combination, to help determine vaccine preferences, affordability and access requirements and to inform vaccine demand analyses?	
16.30 – 17.00	Discussion (open session)			
17.00 . 17.30	Discussion (closed session)			