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WHO expert review of Group A Streptococcus vaccines:

Hybrid Consultation by IVIR-AC and PDVAC

London, United Kingdom

30 September 2022, 11am-3pm UK time

Agenda and Concept Note

Background

On 31 May 2017, the Executive Board of the World Health Organization (WHO) proposed a Resolution on 'Rheumatic Fever and Rheumatic Heart Disease' for adoption at the Seventy-first World Health Assembly in May 2018. This resolution led, in 2018, to the development of a WHO Preferred Product Characteristics (PPC) and a Group A Streptococcus (GAS) Vaccine Development Technology Roadmap that provided guidance to the development of novel GAS vaccines. In parallel, the Strep A Vaccine Global Consortium (SAVAC) developed a Full Value of Vaccine Assessment (FVVA) to better understand the health, social and economic value of GAS vaccines, if licensed and used in relevant target populations. The FVVA for GAS vaccines is to be published soon.

These developments, and the fact that the existing WHO PPC and Roadmap are have reached their 5 year lifespan, have prompted the need for WHO to review the latest information on GAS vaccine development and economic evaluation to inform potential revisions to the current PPC and R&D Roadmap. The FVVA, performed by SAVAC, will also be assessed by WHO for its relevance and applicability. In this context, WHO is convening a joint session with the Product Development for Vaccines Advisory Committee (PDVAC) and the Immunization and Vaccine-related Implementation Research Advisory Committee (IVIR-AC) to review the latest body of evidence on GAS vaccines and to deliberate on the need to revisit current WHO guidance in light of the latest available information. Members of SAVAC will be invited to provide some of the key information needed to achieve the proposed objectives.

Objectives of the meeting:

The proposed objectives are to: 1) review recent advances in GAS Vaccines Research and Development (R&D) and the soon to be published Full Value of Vaccine Assessment (FVVA) for GAS vaccines; and 2) agree on key priorities to ensure the WHO PPC and Vaccine Development Technology Roadmap for GAS vaccines remain current and relevant.

Specifically:

- IVIR-AC is invited to review quantitative methods supporting the development of the GAS FVVA and discuss its relevance and applicability.
- PDVAC is invited to review recent progress in GAS Vaccine R&D and to provide recommendations on the need to update the current WHO PPC and R&D Roadmap on GAS vaccines.

AGENDA

Friday 30 September 2022 – 11am-3pm UK time

Chairs: David Kaslow (PDVAC) & Paula Mendes Luz (IVIRAC)

Time	Topic	Proposed speaker
11:00 – 11:05	Opening remarks Context for and objectives of the meeting	M. Friede, WHO/D. Kaslow Birgitte Giersing / Philipp Lambach, WHO
11:05 – 12:20	**PART I – GAS Vaccine R&D** GAS vaccine pipeline (10 min) 2018 WHO R&D Roadmap and PPC of GAS vaccines (10 min) Implementing roadmap priorities and progress (15 min) Questions for clarification (5 min) Key additional gaps for the roadmap and PPC (10 min) Recommendations on elements to be revisited in the roadmap and PPC (10 min) Discussion (15 min)	 A. Steer, MCRI P. Gsell, WHO A. Steer, MCRI J. Carapetis, Telethon Kids Inst. J. Kim, IVI
12:20 – 13:30	**PART II – FVVA of GAS vaccines** Opening by IVIR-AC Chair Paula Mendes Luz Investment cases for prospective Strep A vaccines (20 min) Strep A Vaccine Business Case from Developer's Perspective (10 min) Q&A led by 3 IVIR-AC members (30 min) <u>Questions to IVIR-AC:</u>	 Paula Mendes Luz D. Cadarett, Harvard School of Public Health, USA D. Walkinshaw, Shift Health, Canada IVIR-AC focal points: H. Hasan G Pitzer, D Lyimo +FVVA investigators

	• IVIR-AC is asked to review the results of the value assessment undertaken and comment on/recommend any additional studies that may complement/broaden these initial FVVA analyses of GAS vaccines. • Does IVIR-AC have feedback on how to communicate the FVVA work to GAS vaccine R&D stakeholders?	
13:30 – 14:05	**PDVAC Closed session** (IVIR-AC members can join as observers) <u>Questions to PDVAC:</u> 1) In the context of the current GAS pipeline, and the progress in defining the FVVA for GAS vaccines, which elements of the current WHO PPC and Vaccine Development Technology Roadmap guidance documents require updating? 2) Is there a need for more than one PPC, given the breadth of clinical outcomes encompassed by the current PPC? 3) Are there specific recommendations for vaccine product parameters that PDVAC recommends for inclusion, or critical roadmap activities that should be initiated as a priority?	Chair – David Kaslow
14:05 – 14:40	**IVIR-AC Closed session** (PDVAC members can join as observers) 1) IVIRAC is asked to review the results of the value assessment undertaken and comment on/recommend any additional studies that may complement/broaden these initial FVVA analyses of GAS vaccines. 2) Does IVIR-AC have feedback on how to communicate the FVVA work to GAS vaccine R&D stakeholders?	Chair – Paula Mendes Luz
14:40 – 14:45	**Next Steps Closed session** Operationalization of the key recommendations	WHO
14:45 – 15:00	**Open session** PDVAC reporting / recommendations 5’ IVIR-AC reporting / recommendations 5’	Plenary
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