



**World Health
Organization**

Improving Vaccine Effectiveness Studies: A vital step before the next pandemic

14 September 2023

14:00 – 18:30 CET

Agenda



R&D Blueprint

Powering research
to prevent epidemics

BACKGROUND

Valid and rigorous observational vaccine effectiveness studies are needed, especially during an epidemic or outbreak, to advance evidence-based programmatic and policy decisions. The goal of this consultation is to summarize critical issues in vaccine effectiveness studies with discussions on best practices and standards. Epidemiologic and statistical experts will explore aspects of study design and analysis regarding the follow components – sources of bias, methods to address bias, and transparent reporting and synthesis.

DRAFT

Chairperson: Lindsey Baden (Harvard University, US)

Time	Topic	Speakers
14:00 – 14:10	Opening Remarks	Michael J. Ryan (WHO)
14:10 – 14:20	The need for standards for vaccine effectiveness studies	Philip Krause
14:20 – 14:30	Considering factors that may influence protective results of vaccination	Ira Longini (University of Florida, US)
Session 1. Sources of Bias in Vaccine Effectiveness Studies		
14:30 – 14:40	Confounding	Joseph Lewnard (Berkeley, US)
14:40 – 14:50	Healthy Vaccinee Bias	Tracy Hoeg (UCSF, US)
14:50 – 15:00	Misclassification	Paolo Eusebi (University of Perugia, Italy)
15:00 – 15:10	Selection Bias	Korryn Bodner (Unity Health Toronto, Canada)
15:10 – 15:20	Biases specific to the TND	Eric Tchetgen Tchetgen (Univ. Pennsylvania, US)
15:20 – 15:30	Differential depletion of susceptible people	Rebecca Kahn (Harvard Univ., US)
15:30 – 15:40	Waning Immunity	Noam Barda (Univ. of the Negev, Israel)
15:40 – 16:10	Panel Discussion <ul style="list-style-type: none"> - Can we assess the size and direction of the bias? - How can we recognize the potential biases and plan to address them in the design of observational studies? - What standards should all observational studies adhere to? 	<u>Moderated by Lindsay Baden (Harvard Univ., US)</u> Ben Cowling (University of Hong Kong) Cheryl Cohen (University of the Witwatersrand, South Africa) Cynthia Whitney (Emory, US) Chongsuvivatwong Virasakdi (Prince of Songkla University, Thailand) Greg Poland (Mayo Clinic, US) Hector Izurieta (FDA, US)
Session 2. Methods to Address Bias		
16:10 – 16:30	Design – use of large public databases	Vajeera Dorabawila (NY Dept Health, US) Ron Brookmeyer (UCLA, US)
16:30 – 16:40	Target trials to avoid design-related biases	William Hulme (Univ. of Oxford, UK)
16:40 – 16:50	Conducting Observational Studies	Jennifer Verani (CDC, US)
16:50 – 17:00	Analysis	Matt Hitchings (Univ. of Florida, US)
Session 3. Reporting and Synthesis		
17:00 – 17:10	Sharing results and primary data	Vasee Moorthy (WHO)
17:10 – 17:20	Transparent discussion of limitations in analysis and Interpretation	Lori-Ann Linkins (McMaster Univ., Canada)
17:20 – 17:30	Discussion of reproducibility and generalizability	Emily Ricotta (NIH, US)
17:30 – 17:40	Randomization during vaccine deployment	Prof Sir Richard Peto (Univ. Oxford, UK)
17:40 – 18:20	Panel Discussion <ul style="list-style-type: none"> - How can we report and synthesize studies to assess and correct for bias? 	<u>Moderated by Peter Figueroa (Univ. of West Indies, Jamaica)</u>

Time	Topic	Speakers
	- What standards should all observational studies adhere to?	Biswas Bijit (All India Institute of Medical Sciences, Deoghar) George Gao (Univ. of Chinese Academy of Sciences) Jeffrey Morris (Univ. of Pennsylvania, US) Karla Soares (Cochrane) Narendra Arora (Inclen, India)
18:20 – 18:30	Main conclusions	
	END OF MEETING	