

Announcing the Publication of a WHO Guide to the Design and Interpretation of Observational Influenza Vaccine Effectiveness Studies

Dear Editor,

Influenza causes considerable death and suffering and is responsible for substantial socioeconomic disruption globally [1]. The World Health Organization (WHO) recommends that countries use influenza vaccine in high-risk individuals, including children aged 6–59 months, pregnant women, individuals with specific chronic medical conditions, elderly adults, and healthcare workers to prevent severe illness and death [1].

Historically, influenza vaccines are mainly used in high-income countries [2], where placebo controlled trials would generally be considered unethical due to recommended vaccine use in defined risk groups. As a result, observational research methods have become increasingly important. Observational influenza vaccine effectiveness (VE) studies play critical roles in influenza vaccine regulation [3], policy [1, 4], and investment [5]. Further, observational influenza VE studies are now being used to inform the twice-annual WHO influenza vaccine strain selection recommendations [6]. Given the global implications of these studies, there is a need to ensure their quality and their critical appraisal by decision makers.

WHO has recently produced the technical document “Evaluation of influenza vaccine effectiveness: A guide to the design and interpretation of observational studies.” The document is freely available on the WHO website [7]. This guide aims to help researchers who conduct observational influenza VE studies and public health scientists who interpret and apply the results of these studies. For researchers, the guide describes critical considerations in designing and

analyzing influenza VE studies, as VE studies can give biased results even in settings where data completeness and quality are high. As global standards for the reporting of observational studies are not specific to VE studies [8], the guide includes reporting recommendations for the inclusion of vaccine and pathogen-specific information necessary for interpretation of reports. For public health scientists, the guide addresses contextual information that is necessary to properly interpret VE results and study limitations and errors that can lead to biased VE estimates.

This document was published by the Initiative for Vaccine Research of the WHO Department of Immunization, Vaccines, and Biologicals. The project was initially discussed in a WHO expert consultation in February 2014, and participants provided document development advice and technical input during the writing process. Numerous other experts provided advice during a 3-month call for public comments, and then finally the document was reviewed by the WHO Immunization and Vaccine-related Implementation Research Advisory Committee and technical experts within WHO. We invite the immunization community to use this reference, and we hope it will be a valuable resource for the design and interpretation of observational influenza VE studies.

Notes

Disclaimer. Justin R Ortiz and Joachim Hombach work for the World Health Organization. The authors alone are responsible for the views expressed in this publication, and they do not necessarily represent the decisions, policy, or views of the World Health Organization.

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