ACIP Ebola Virus Vaccine Work Group

Sharon Frey, MD
Saint Louis University Medical School
Chair, Ebola Vaccine Working Group

Advisory Committee on Immunization Practices

February 26, 2020
Ebola Vaccine ACIP Work Group

ACIP Members
Sharon Frey (Chair)
Beth Bell
Robert Atmar

Ex Officio Members
Rebecca Reindel (FDA)
Stephanie Polo (FDA)
Eric Deussing (DOD)
Amanda Zarrabian (BARDA)
Dan Wolfe (BARDA)
Elizabeth Higgs (NIH)
Richard Davey (NIH)

CDC Lead
Mary Choi

Liaison Representatives
Alexander Isakov (ACEP)
Laura Riley (ACOG)
Sandra Adamson Fryhofer (AMA)
Christine Hahn (CSTE)
Milan Patel (NACI)
Chris Nyquist (AAP)
Daniel Lucey (IDSA)
David Weber (SHEA)

Consultants
Colleen Kraft (Emory University)
Jim LeDuc (UTMB)
Pierre Rollin
Allison Liddell (Texas Health Dallas)
Armand Sprecher (MSF)
John Redd (ASPR)
Stacy Hall (AIM)
Grade Consultants/CDC Contributors

GRADE Consultants
Rebecca Morgan
Doug Campos-Outcalt

CDC Contributors
Caitlin Cossaboom
Amy Whitesell
Jonathan Dyal
Allison Joyce
Susan Gorman
Jessica MacNeil
Sarah Mbaeyi
Marissa Person
Brian Harcourt
Terri Hyde
Rita Helfand
Yon Yu
Susan Goldstein
Inger Damon

Susan Gorman
Michael Bell
Shah Roohi
Julianne Gee
Jennifer McQuiston
Elizabeth Ervin
John Su
Joel Montgomery
Trevor Shoemaker
Julie Villanueva
Recap of Ebola Virus Vaccine Session, October 2019

- Introduction of the work group (WG)
- Introduction of Terms of Reference
  - Review available data on the rVSVΔG-ZEBOV-GP* vaccine and inform domestic vaccine policy options for ACIP consideration
  - Inform recommendations for use of the rVSVΔG-ZEBOV-GP vaccine in pre-exposure vaccination of healthy adults ≥ 18 years of age in the United States at occupational risk for exposure to Ebola virus (species Zaire ebolavirus)

* rVSVΔG-ZEBOV-GP = recombinant vesicular stomatitis virus with substituted envelope glycoprotein of the Zaire ebolavirus (Kikwit 1995 strain).
Key Events Since October 2019

- November 2019, rVSVΔG-ZEBOV-GP vaccine (ERVEBO®, Merck) granted EU-wide conditional marketing authorization. Vaccine is indicated for immunization of individuals 18 years of age or older to protect against Ebola virus disease caused by Ebola virus (species *Zaire ebolavirus*)

- December 19, 2019, US FDA approved rVSVΔG-ZEBOV-GP vaccine (ERVEBO®, Merck) for individuals 18 years of age or older for the prevention of EVD

- February 12, 2020, World Health Organization’s Emergency Committee unanimously agreed that the ongoing EVD outbreak in eastern Democratic Republic of Congo still constitutes a “Public Health Emergency of International Concern” (PHEIC)

WG Activities and Discussions Since October 2019

- Identified 3 U.S. populations at highest risk for potential occupational exposure to Ebola virus (species *Zaire ebolavirus*) for whom potential policy options are most urgent:
  - Individuals responding to an outbreak of EVD due to Ebola virus (species *Zaire ebolavirus*)
  - Individuals who work as laboratorians and support staff at biosafety-level 4 (BSL-4) facilities that handle replication competent Ebola virus (species *Zaire ebolavirus*)
  - Healthcare personnel¹ (HCP) at a federally-designated Ebola Treatment Centers involved in the care and transport of confirmed EVD patients

¹ See slide #10
WG Activities and Discussions Since October 2019

- Additional U.S. populations with potential risk for occupational exposure include:
  - HCP at state/jurisdictionally-designated Ebola Treatment Centers
  - HCP at Ebola Assessment Hospitals
  - HCP at Frontline facilities

- WG discussions on recommendations for additional populations at potential occupational risk are continuing
Activities and Discussions Since October 2019

- Discussions to develop the protocol for systematic review of vaccine data and to select critical outcomes
- Systematic review of vaccine literature for GRADE analysis and evidence to recommend (EtR)
- Discussions on proposed policy options
Agenda Overview

- Review of Ebola virus disease and rVSVΔG-ZEBOV-GP vaccine
  - Dr. Mary J. Choi, CDC/VSPB

- GRADE
  - Dr. Caitlin Cossaboom, CDC/VSPB

- Evidence to Recommendations (EtR)
  - Dr. Mary J. Choi, CDC/VSPB

- Summary of WG considerations and proposed policy options
  - Dr. Mary J. Choi, CDC/VSPB
Healthcare Personnel Definition

1. Healthcare personnel (HCP) refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, clinical laboratory personnel, autopsy personnel, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

Adapted from https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/index.html
For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.