



Work Group Considerations: Proposed Recommendation Text for Policy Options

Caitlin Cossaboom, DVM, PhD, MPH

Lieutenant, U.S. Public Health Service

Viral Special Pathogens Branch

Division of High-Consequence Pathogens and Pathology

Advisory Committee on Immunization Practices

February 24, 2021

Ebola vaccination policy issue for consideration today

- Should preexposure vaccination with rVSV Δ G-ZEBOV-GP be recommended for adults aged ≥ 18 years in the U.S. population who are at potential risk for occupational exposure to EBOV because they are working as
 - HCP¹ at state-designated Ebola Treatment Centers in the United States, or
 - Staff in LRN facilities that receive, process, and perform diagnostic testing on suspect cases of EVD?

Work Group Considerations for Expansion of Ebola vaccine Recommendations to State Designated ETCs

Ebola vaccination policy issue for consideration today

- Should preexposure vaccination with rVSVΔG-ZEBOV-GP *be recommended* for adults aged ≥ 18 years in the U.S. population who are at potential risk for occupational exposure to EBOV because they are working as HCP¹ at a state-designated Ebola Treatment Center in the United States?
 - Two options discussed by Work Group:
 - Recommend, or
 - Recommend with shared clinical decision making
 - Considerations are ongoing, but preliminary discussions suggest the Work Group favors recommending with shared clinical decision making

Discussion: Work Group members who favored “Recommend”

- **Comparable level of risk to HCP¹ in state-designated vs federal ETCs**
 - Provide HCP at state designated ETCs the same protection as federally designated ETCs
 - HCP¹ at state designated ETCs may have a higher risk of being exposed to an EVD patient without prior notification
 - More state designated ETCs compared to federally-designated ETCs (51 vs 11)
 - Federally designated facilities more likely to receive EVD patients transferred to them; giving them the advanced notice to prepare
- **A “shared clinical decision making” recommendation would essentially pass the responsibility to employees/healthcare providers when individual level of risk within this population is very difficult to assess**

¹ See final slide

Discussion: Work Group members who favored “Recommend”

- **Recommending would improve preparedness of frontline HCP**
 - Side effects of the vaccine do not make it amenable for a just-in-time vaccination strategy (i.e., reactogenicity difficult to differentiate from symptoms of EVD post-exposure)
 - It is difficult retrospectively to figure out the movements of potentially infectious materials and who was exposed. By recommending the vaccination, the same prevention tools are offered to potentially-exposed personnel.
 - Would encourage state-designated management team to be better prepared, by evaluating in advance the movements of materials and identifying the persons who could be exposed

Discussion: Work Group members who favored “Shared clinical decision making”

- **Occupational health programs may require employees to be vaccinated if it is recommended by ACIP**
 - Concerns for unintended negative career consequences for persons who don’t want this vaccine or those with contraindications
- **Attrition rates in state-designated ETC staff and facilities**
 - Turnover among staff may be more of an issue with state-designated ETCs
 - Because they are not federally funded, state designated ETCs can decide to stop providing this service at any time

Discussion: Work Group members who favored “Shared clinical decision making”

- **Risk vs benefit of vaccine in this population is not as clear**
 - The vaccine is efficacious but not without some side effects and contraindications
 - Not all individuals working at designated ETCs are at equal risk
 - PPE works and not all staff at these facility will want the vaccine but should be available for those that choose to take it
 - Personnel duties may change placing an individual at greater or lesser risk with their assumption of new duties
- **Health insurance coverage is not a benefit of recommending this vaccine as it will be made available at no cost through U.S. government**

Work Group Considerations for Expansion of Ebola vaccine Recommendations to LRN Facility Personnel

Ebola vaccination policy issue for consideration today

- Should preexposure vaccination with rVSVΔG-ZEBOV-GP *be recommended* for adults aged ≥ 18 years in the U.S. population who are at potential risk for occupational exposure to EBOV because they are working as staff in LRN facilities that receive, process, and perform diagnostic testing on suspect cases of EVD?
 - Two options proposed by Work Group:
 - Recommend, or
 - Recommend with shared clinical decision making
 - Considerations are ongoing, but preliminary discussions suggest the Work Group favors recommending with shared clinical decision making

Discussion: Work Group members who favored “Recommend”

- **Recommending would improve preparedness of frontline laboratory personnel**
 - LRN personnel receive the un-inactivated clinical samples from suspect EVD patients
 - It is important to provide LRN personnel same protections as lab workers affiliated with federally designated ETCs/BSL4 facilities

Discussion: Work Group members who favored “Shared clinical decision making”

- Occupational health programs may require employees to be vaccinated if it is recommended by ACIP
 - Concerns for unintended negative career consequences for persons who don't want this vaccine or those with contraindications
- Health insurance coverage is not a benefit of recommending this vaccine as it will be made available at no cost through U.S. government

Discussion: Work Group members who favored “Shared clinical decision making”

- **Risk vs benefit of vaccine in this population is not as clear**
 - The vaccine is efficacious but not without some side effects and contraindications
 - PPE works and not all staff at these facility will want the vaccine but should be available for those that choose to take it
 - Not all individuals in a given facility are at equal risk
 - Personnel duties may change placing an individual at greater or lesser risk with their assumption of new duties

Policy Options and Language

1st Vaccination Policy Issue for Consideration

Should pre-exposure vaccination with the rVSVΔG-ZEBOV-GP vaccine ***be recommended*** for individuals ≥ 18 years of age working as HCP in state-designated Ebola Treatment Centers?

– or –

Should pre-exposure vaccination with the rVSVΔG-ZEBOV-GP vaccine ***be recommended with shared clinical decision making*** for individuals ≥ 18 years of age working as HCP in state-designated Ebola Treatment Centers?

2nd Vaccination Policy Issue for Consideration

Should pre-exposure vaccination with the rVSVΔG-ZEBOV-GP vaccine **be recommended** for individuals ≥ 18 years of age working as staff in facilities within the Laboratory Response Network that handle replication competent Ebola virus (species *Zaire ebolavirus*)?

– or –

Should pre-exposure vaccination with the rVSVΔG-ZEBOV-GP vaccine **be recommended with shared clinical decision making** for individuals ≥ 18 years of age working as staff in facilities within the Laboratory Response Network that handle replication competent Ebola virus (species *Zaire ebolavirus*)?

Discussion and Committee Feedback

- What are the perceived advantages and disadvantages of *recommending use of rVSVΔG-ZEBOV-GP* in these populations?
- What are the perceived advantages and disadvantages of *recommending use of rVSVΔG-ZEBOV-GP with shared clinical decision making* in these populations?
- What additional information will be useful for the committee for decision making?

Footnotes

¹ Health care 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, 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). <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/index.html>

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.