



Zoster Vaccines Session: Introduction

ACIP Meeting

February 25, 2021

Grace Lee, MD, MPH

ACIP Chair, Herpes Zoster Work Group

2021 Herpes Zoster Work Group

ACIP Members	
Grace Lee, MD, MPH (Chair)	
Lynn Bahta, RN, MPH	
Camille Kotton, MD	
Ex Officio Members	
Paula Agger, MD, MPH	FDA
Jeffrey Cohen, MD	NIH
Darcie Everett, MD, MPH	FDA
Jeffrey Kelman, MD	CMS
Liaison Representatives	
Carol Baker, MD	IDSA
Mary Pat Friedlander, MD	AAFP
Sandra Fryhofer, MD	ACP/AMA
Elizabeth Rausch-Phung, MD, MPH	AIM
William Schaffner, MD	NFID
Kenneth Schmader, MD	AGS
Adam Welch, PharmD	APhA

Invited Consultants
Robin Avery, MD
Edward Belongia, MD
Al Benson, MD
Paul Cieslak, MD
Jeffrey Curtis, MD, MPH
Jay Fishman, MD
Rafael Harpaz, MD, MPH
Kelly Moore, MD, MPH
Vicki Morrison, MD
Steven Pergam, MD
Lisa Prosser, PhD
CDC Lead
Tara Anderson, DVM, MPH, PhD

Recombinant Zoster Vaccine (RZV, Shingrix) Updates

- **41.3 million doses distributed in U.S. from launch through end of 2020**
- **European Medicines Agency approved an expanded indication on August 25, 2020**
 - Shingrix now approved in the European Union for prevention of herpes zoster (HZ) and postherpetic neuralgia in adults 50 years of age or older, and adults 18 years of age or older at increased risk of HZ
 - <https://www.ema.europa.eu/en/medicines/human/EPAR/shingrix#assessment-history-section>
- **Supplemental biologics license application submitted to FDA to support use in immunocompromised adults 18 years of age or older**
 - <https://www.gsk.com/media/6189/q3-2020-results-announcement.pdf>

October 2020 ACIP Zoster Vaccines Session

- Update on post-licensure safety monitoring of RZV in the Vaccine Adverse Events Reporting System (VAERS)
- Vaccine Safety Datalink (VSD) update on post-licensure safety monitoring of RZV
- Risk of Guillain-Barré syndrome following HZ
- Summary and planned risk-benefit analysis regarding use of RZV in immunocompetent adults

Herpes Zoster Work Group Activities since October 2020

- **Four work group meetings**
- **Reviewed and discussed**
 - Findings regarding risk of GBS following vaccination or disease
 - FDA assessments of the risk of GBS following RZV using Medicare data
 - RZV risk-benefit analysis, which incorporated new data on risk of GBS associated with disease and vaccination
 - PICO for use of RZV in immunocompromised adults and Evidence to Recommendations Framework

Agenda for Today's Session

- Risk of GBS following RZV
- RZV risk-benefit analysis
- Work group interpretation
- Introduction of the Evidence to Recommendations Framework for use of RZV in immunocompromised adults

Acknowledgments

- **ACIP HZWG:** Paula Agger, Robin Avery, Lynn Bahta, Edward Belongia, Al Benson, Paul Cieslak, Jeff Cohen, Jeff Curtis, Jeff Duchin, Darcie Everett, Jay Fishman, Mary Pat Friedlander, Sandra Fryhofer, Rafael Harpaz, Jeff Kelman, Camille Kotton, Vicki Morrison, Kelly Moore, Steve Pergam, Lisa Prosser, Elizabeth Rausch-Phung, Bill Schaffner, Ken Schmader, Adam Welch
- **HZWG CDC Lead:** Tara Anderson
- **CDC, Other Contributors:** Jessica Anderson, Stephanie Bialek, Tom Clark, Amanda Cohn, Kathleen Dooling, Jeffrey Duchin, Jonathan Duffy, Richard Forshee, Angela Guo, Theresa Harrington, Alexandra Hess, Elisabeth Hesse, Lisa Jackson, Jessica Leung, Shainoor Ismail, Kathryn Ivy, Tara Jatlaoui, Andrew Kroger, Andrew Leidner, Mona Marin, Karen Mason, Jennifer Nelson, Mark Pallansch, Manisha Patel, Paul Rota, Ismael Ortega-Sanchez, Coleman Rotstein, Jeanne Santoli, Tom Shimabukuro, Jeannette St. Pierre, John Su, Megan Wallace, Eric Weintraub, Kirsten Yates

Thank You

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.

