Zoster Vaccines Session: Introduction

ACIP Meeting
February 25, 2021

Grace Lee, MD, MPH
ACIP Chair, Herpes Zoster Work Group
# 2021 Herpes Zoster Work Group

<table>
<thead>
<tr>
<th>ACIP Members</th>
<th>Invited Consultants</th>
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<tbody>
<tr>
<td>Grace Lee, MD, MPH (Chair)</td>
<td>Robin Avery, MD</td>
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<td>Lynn Bahta, RN, MPH</td>
<td>Edward Belongia, MD</td>
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<td>Camille Kotton, MD</td>
<td>Al Benson, MD</td>
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<td>Ex Officio Members</td>
<td>Paul Cieslak, MD</td>
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<td>Paula Agger, MD, MPH</td>
<td>Jeffrey Curtis, MD, MPH</td>
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<td>Jeffrey Cohen, MD</td>
<td>Jeffrey Kelman, MD</td>
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<td>Darcie Everett, MD, MPH</td>
<td>CMS</td>
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<td>Jeffrey Kelman, MD</td>
<td>FDA</td>
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<td>Liaison Representatives</td>
<td>NIH</td>
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<td>Carol Baker, MD</td>
<td>FDA</td>
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<td>Mary Pat Friedlander, MD</td>
<td>NFID</td>
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<td>Sandra Fryhofer, MD</td>
<td>AGS</td>
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<td>Elizabeth Rausch-Phung, MD, MPH</td>
<td>AIM</td>
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<td>William Schaffner, MD</td>
<td>CDC Lead</td>
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<td>Kenneth Schmader, MD</td>
<td>Tara Anderson, DVM, MPH, PhD</td>
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<td>Adam Welch, PharmD</td>
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**Invited Consultants**

- Robin Avery, MD
- Edward Belongia, MD
- Al Benson, MD
- Paul Cieslak, MD
- Jeffrey Curtis, MD, MPH
- Jeffrey Kelman, MD
- 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
- Supplemental biologics license application submitted to FDA to support use in immunocompromised adults 18 years of age or older
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
