Why is this important?
Seasonal influenza causes an estimated 30,000 deaths per year in the United States. Adults over age 65 account for most deaths and hospitalizations. A high dose vaccine for adults over age 65 which is more immunogenic than the standard vaccine in this age group, was approved in 2009. The clinical effectiveness of this high-dose vaccine compared with a standard-dose vaccine has not been well established.

Facts
- The authors conducted a randomized, double-blind, controlled trial at 126 sites across the United States and Canada during the flu seasons in 2011-2013. They randomized 31,989 adults over age 65 (mean age 73.3) to receive high-dose (HD) trivalent inactivated flu vaccine or standard-dose (SD) trivalent inactivated flu vaccine. Most enrollees had at least one chronic condition (67.2%) and had received the flu vaccine in the prior season (73.5%).
- The primary outcome, laboratory confirmed influenza, occurred in 1.4% of HD subjects and 1.9% of SD subjects (RRR 24.2%, 95% CI 9.7-36.5%; ARR 0.46%, NNT 217). A secondary outcome of influenza like illness (without lab confirmation) occurred in 23.4% high dose subjects and 23.9% standard-dose subjects (difference not significant).
- Similar relative risk reductions were seen in pneumonia and hospitalizations within 30 days of specified illness, but the differences were also not significant due to a small number of outcomes.
- Serious adverse events (e.g. serious illness or hospitalization) during 6 to 8 months follow up occurred in 8.3% high dose subjects and 9.0% standard-dose subjects. Only 3 events in the high dose group were judged to be potentially related to vaccine (0.02% of subjects).
- This study did not compare high dose influenza vaccination to the currently available quadrivalent vaccine, which is now available for all age groups.

Effectiveness of the High-Dose Influenza Vaccine in Older Adults

The Bottom Line
Both standard dose and high-dose trivalent influenza vaccine are effective in reducing laboratory confirmed influenza in adults over age 65. Older patients should be encouraged to receive the influenza vaccine in either form, though the high-dose vaccine is slightly superior and preferable when readily accessible and affordable for the patient.
Quality of Evidence
(Adapted from Guyatt G BMJ, 26 April 2008)
This refers to the degree to which the findings of this study are likely to be free of bias.

<table>
<thead>
<tr>
<th></th>
<th>High</th>
<th></th>
<th>Moderate</th>
<th></th>
<th>Low</th>
<th></th>
<th>Very low</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td></td>
<td>+</td>
<td></td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>++</td>
<td></td>
<td>+</td>
<td></td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+</td>
<td></td>
<td>+</td>
<td></td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+</td>
<td></td>
<td>+</td>
<td></td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tips for Discussion of Results with Patients

- Influenza vaccine significantly reduces the risk of influenza (average year benefit 50-60% reduction).²
- Many studies suggest the reduction in influenza infection leads to fewer cases of pneumonia and lower rates of hospitalization.³
- The overall rate of any respiratory illness is usually unchanged with vaccination, because most respiratory illnesses are due to other viruses.

References


Written by the Evidence-Based Medicine Task Force

Bill Kormos, MD  Jocelyn A. Carter, MD, MPH  Clark Veet, MD
Devan Kansagara, MD  Jamie A. Jarmul, BS  James Yeh, MD, MPH
Zackary Berger, MD, PhD  Rani Nandiwada, MD  M.E. Beth Smith, DO, MCR
Michael E. Bowen MD, MPH, MSCS  Heather Sateia, MD
Harry B. Burke, MD, PhD  Jeff Tice, MD

The Bottom Line summaries reflect the expertise and opinions of the SGiM EBM Task Force as of the date of release of this summary.