Update on Immunizations for Older Adults

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Conflicts of Interest

• Dr. Nace has no current conflict(s) of interest to report relating to this presentation.

• Dr. Nace has received an investigator initiated grant in the past to evaluate regular vs high dose vaccine in frail older adults.

Objectives

During this presentation you will learn:

• The impact of selected vaccine preventable diseases most frequently affecting older adults.

• The importance of healthcare worker vaccination in preventing disease in older adults.

• Current vaccine recommendations for protection against influenza, pneumonia, hepatitis B, herpes zoster, and pertussis.
Immunizations Covered

- Influenza
- Pneumococcal
- Hepatitis B
- Herpes zoster (shingles)
- Tdap

Influenza

Impact & coverage rates?
Vaccine effectiveness?
Current influenza activity?
When to vaccinate?
NF requirements?
Which vaccine to use?
HCW vaccination?

Impact
Background

- 90% of influenza related deaths in the US occur in adults ≥ 65 years of age.
- Mortality increases with increasing age
  - Mortality is 16 fold higher among ≥ 85 year olds compared to 65-69 years.
- Influenza deaths are increasing in part due to aging of U.S. population

Frail LTC Residents at High Risk

- **LTC Environment**
  - Close contact with HCW
  - Frequent contact with other residents
  - Structure of units/buildings
  - Poor accessibility of accurate, timely diagnostic tests

- **Resident Characteristics**
  - Frail
  - Comorbid illness
  - Medications that impact immune function
  - Nutritional status

- **Influenza Factors**
  - Symptoms nonspecific, so mimics other conditions

- **Case Fatality Rates = 0-55%**

Nace DA, Drinka P, Mann J, Poland GA. LTC Information Series: Immunization in the Long-Term Care Setting. 2nd ed. Columbia, MD: American Medical Directors Association; 2010.


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**Influenza Vaccine Coverage U.S.**

**Adults 65+ Years**

<table>
<thead>
<tr>
<th>Year</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-08</td>
<td>72.3%</td>
</tr>
<tr>
<td>08-09</td>
<td>74.0%</td>
</tr>
<tr>
<td>09-10</td>
<td>69.6%</td>
</tr>
<tr>
<td>10-11</td>
<td>66.6%</td>
</tr>
<tr>
<td>11-12</td>
<td>64.9%</td>
</tr>
<tr>
<td>12-13</td>
<td>66.2%</td>
</tr>
<tr>
<td>13-14</td>
<td>65.0%</td>
</tr>
<tr>
<td>14-15</td>
<td>66.7%</td>
</tr>
</tbody>
</table>

**U.S. Nursing Home Influenza Vaccine Coverage**

Median = 72.7% (49.4%-80.9%)


---

**Older Adult Vaccination Rates (Age ≥65)**

<table>
<thead>
<tr>
<th>Year</th>
<th>WI</th>
<th>PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010-11</td>
<td>67</td>
<td>66.3</td>
</tr>
<tr>
<td>2011-12</td>
<td>65.6</td>
<td>64.6</td>
</tr>
<tr>
<td>2012-13</td>
<td>64.6</td>
<td>65.4</td>
</tr>
<tr>
<td>2013-14</td>
<td>56.7</td>
<td>71.5</td>
</tr>
</tbody>
</table>

**WI & PA**

WI ranks 56th in Older Adult Vaccination

Rates of Influenza Vaccination in WI by Age Group, 2011-2016

Doses Reported to the WI Immunization Registry (WIR)

Vaccine Effectiveness

Nursing Home Outbreaks Despite Vaccination

Navarre, Spain 2012

<table>
<thead>
<tr>
<th></th>
<th>NF 1</th>
<th>NF 2</th>
<th>NF 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residents</td>
<td>66</td>
<td>22</td>
<td>523</td>
</tr>
<tr>
<td>Mean Age</td>
<td>80.3 (42-97)</td>
<td>81.2 (59-97)</td>
<td>86.4 (62-104)</td>
</tr>
<tr>
<td>2010/2011 Vaccine Coverage Rate</td>
<td>97%</td>
<td>91%</td>
<td>82%</td>
</tr>
<tr>
<td>Cases ILI</td>
<td>44</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Attack Rate</td>
<td>67%</td>
<td>18%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Attack Rate Vaccinated</td>
<td>66%</td>
<td>20%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Attack Rate Unvaccinated</td>
<td>100%</td>
<td>0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Influenza Related Hospitalizations</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Influenza Related Deaths</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Nursing Home Outbreaks Despite Vaccination

Wisconsin 1992-1994

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza Type</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Total Residents</td>
<td>690</td>
<td>670</td>
</tr>
<tr>
<td>Age</td>
<td>76 (±10)</td>
<td>76 (±10)</td>
</tr>
<tr>
<td>Male</td>
<td>80%</td>
<td>78%</td>
</tr>
<tr>
<td>Residents Vaccinated (%)</td>
<td>88%</td>
<td>89%</td>
</tr>
<tr>
<td>Nursing Staff Vaccinated (%)</td>
<td>56%</td>
<td>46%</td>
</tr>
<tr>
<td>Cases</td>
<td>104 (15.5%)</td>
<td>68 (9.8%)</td>
</tr>
<tr>
<td>Vaccination Rate - Cases</td>
<td>85%</td>
<td>90%</td>
</tr>
</tbody>
</table>

- Circulating strains matched both years (B/Panama/45/90-like; A/Beijing/32/92-like/H3N2)
- Case = ILI and culture confirmation


Rochester, MN 1996

<table>
<thead>
<tr>
<th>Variable</th>
<th>Residents</th>
<th>HCW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>62</td>
<td>67</td>
</tr>
<tr>
<td>% Vaccinated</td>
<td>95%</td>
<td>72%</td>
</tr>
<tr>
<td>Age</td>
<td>87 (±4)</td>
<td></td>
</tr>
<tr>
<td>Attack Rate</td>
<td>44% (n=27)</td>
<td>24% (n=16)</td>
</tr>
<tr>
<td>Vaccination Rate Among Cases</td>
<td>96% (n=26)</td>
<td>82% (n=9)</td>
</tr>
</tbody>
</table>

- A/Wuhan/H3N2 matched the vaccine strain, A/Nanchang/H3N2
- Authors felt findings more consistent with decreased host response rather than vaccine failure due to rates among older residents vs younger staff.


Vaccine Effectiveness In Older Adults

Key Messages

- While the vaccine isn’t perfect, it does have an impact. (VE is not zero)
  - No medication or treatment is perfect
- Older adults most at risk, so even partial protection is crucial
- If you don’t get vaccinated, you have NO protection
When to Vaccinate
Case 1

- You are the infection control practitioner for Green Bay Farms, a 100 bed benevolent, but probably misguided Packers supporting, nursing home located in WI.
- It is August 20th and your LTC pharmacy informs you that the influenza vaccine has arrived.
- They want to know when you want to start immunizing your residents.
- It typically takes two weeks to prepare for your influenza program.

Case 1 Answer

- Vaccination should begin as soon as vaccine becomes available.
- Vaccination should not be delayed because of concerns that the vaccine wears off before the end of influenza season
  - *Delays result in missed vaccinations*
- CMS requires that facilities begin offering influenza vaccine as of October 1, but doesn’t prohibit offering earlier.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6430a3.htm
Duration of Vaccination Season

- Vaccine titers do decline over time following vaccination.
- A 2008 review did not show that levels declined more in older adults compared to younger.
- A 2010 study found decreased titers in ≥50 yrs but still met EMEA standards.
- A 2015 study of frail elders showed a decline of less than one log difference.


Duration of Immunity: Day 30 to 180

<table>
<thead>
<tr>
<th>Season, Strain</th>
<th>Log2 HI Titers Day 30 - Day 180, Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standard Dose</td>
</tr>
<tr>
<td>2011-2012</td>
<td></td>
</tr>
<tr>
<td>A/California/07/2006(H1N1)</td>
<td>0.3 ± 1.0</td>
</tr>
<tr>
<td>A/Victoria/2102/09(H3N2)</td>
<td>0.0 ± 0.8</td>
</tr>
<tr>
<td>B/Brisbane/60/2008</td>
<td>0.7 ± 0.8*</td>
</tr>
<tr>
<td>2012-2013</td>
<td></td>
</tr>
<tr>
<td>A/California/07/2006(H1N1)</td>
<td>0.6 ± 0.9*</td>
</tr>
<tr>
<td>A/Victoria/2102/09(H3N2)</td>
<td>-0.8 ± 2.2**</td>
</tr>
<tr>
<td>B/Texas/2011</td>
<td>0.2 ± 1.5</td>
</tr>
</tbody>
</table>

* All declines less than 1 log2HI difference


Case 2

- It is now March 20.
- Moderate influenza A H3N2 activity was observed in late January through early March.
- Influenza activity is now low and mostly influenza B.
- Staff ask you how long they should continue to offer the influenza vaccine.
Case 2

You tell your staff:
1. They can stop vaccinating now
2. Continue until March 31
3. Continue until April 30
4. Continue as long as influenza virus is circulating

Case 2 Answer

• While influenza A H3N2 activity has already peaked, influenza B is circulating.
• March 31 is the end of the MDS timeframe requiring facilities to offer vaccine, but doesn’t relate to the risk of outbreak. Vaccinations must be offered at least through this date.
• The decision on when to stop immunizing does not relate to a specific, hard date, but relates to when influenza is not longer circulating

Number of Doses of Seasonal Influenza Vaccine Administered and Reported to the WIR by Month, 2010-2016

[Graph image]

Nursing Facility Requirements
F 334

Case 3
Federal nursing facility regulations require which of the following:
1. Written consent from the resident/proxy prior to receipt of influenza vaccine
2. A written/verbal physician order for a flu shot
3. Resident/proxy signature confirming that influenza vaccine education was provided
4. None of the above

Case 4
Which of the following statements regarding Standing Orders Programs (SOP) for influenza/pneumococcal vaccinations are false:
1. SOP are not allowed in nursing facilities
2. SOP require a single order at the time of admission to the facility for annual vaccination
3. SOP require staff to call each resident's proxy prior to immunizing
4. All of the above
F334 Influenza & Pneumococcal Immunizations (483.25(n))

(1) The facility must develop policies and procedures that ensure that

(i) Before offering the influenza immunization, each resident, or the resident’s legal representative receives education regarding benefits and potential side effects of the immunization

(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period

(1) (continued)

(iii) The resident or the resident’s legal representative has the opportunity to refuse immunization

(iv) The resident’s medical record includes documentation that indicates at a minimum the following

(A) That the resident or resident’s legal representative was provided education regarding the benefits and potential side effects of influenza immunization

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to a medical contraindications or refusal

Intent

- Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal pneumonia by assuring that each resident:

  – Is informed
  – Has the opportunity to receive
  – Medical record documentation
Education – How?

• Education is best kept simple

• Vaccine information statement (VIS) meets requirement
  – Can be mailed to proxies
  – http://www.cdc.gov/vaccines/hcp/vis/current-vis.html

• F 334 does not require facilities to have signatures indicating receipt of education
  – This is not a recommended strategy

Flu Shot MAR Stickers

Fluarix Prefilled Syringe
Administer 0.5 mL intramuscularly x 1 dose
Shake well prior to administration
Lot: s59781a Exp: 5/31/2011

**Written education on risk/benefit of vaccine, provided to resident or POA**
[Diagnosis: Influenza prophylaxis]

Tool for documenting necessary information on medical record

Standing Order Policies

• Standing orders programs (SOP) urged by CMS since 2002

• Physician approved policy

• Obviates need for annual or admission orders

• Facility assesses for contraindications, provides education and administers vaccine to eligible residents

Standing Orders

- Standing order programs proven to improve immunization rates by removing a barrier to vaccine receipt – the physician order
- Standing order programs are safe
  - Low risk procedure
  - Greater risk is being unvaccinated

What Is NOT Required

- Written consent
- A specific physician order
- An order at admission for annual flu shots
- Resident or proxy signatures indicating education was provided

Which Vaccine?
Case 5

Which of the following statements regarding influenza vaccines are true for adults ≥ 65 yrs?
1. Quadrivalent vaccine is preferred for older adults
2. The ACIP recommends hi-dose over standard dose vaccine in older adults?
3. LAIV is recommended for older adults without health issues
4. None of the above

Influenza Vaccines ≥ 65 Yrs

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIV3</td>
<td>IM</td>
<td>Traditional trivalent vaccine (2 A's and 1 B)</td>
</tr>
<tr>
<td>IIV3</td>
<td>IM</td>
<td>Hi-dose trivalent vaccine (60 vs 15 ug)</td>
</tr>
<tr>
<td>IIV4</td>
<td>IM</td>
<td>Quadrivalent vaccine (2 A's &amp; 2 B's)</td>
</tr>
<tr>
<td>ccIIV3</td>
<td>IM</td>
<td>Cell-culture (minimal egg protein)</td>
</tr>
<tr>
<td>RIV3</td>
<td>IM</td>
<td>Completely recombinant (0 egg protein)</td>
</tr>
</tbody>
</table>

ACIP makes no preference for standard vs high dose or trivalent vs quadrivalent in older adults (as of Oct 2015)
http://www.cdc.gov/flu/protect/vaccine/vaccines.htm
Rationale for High Dose Vaccine

Vaccination stimulates production of hemagglutinin antibodies (HA)

- Higher Serum Hemagglutinin Antibodies 
- Protection Against Infection

- Multiple studies in 1970’s – 1990’s demonstrating higher doses of vaccine lead to greater HA production

Photo courtesy of CDC

High Dose Influenza Vaccine

- December 2009, the FDA approved a high dose influenza vaccine for use in adults ≥65 yrs.
- Primarily based on a phase 3 trial conducted in healthy, community dwelling older adults with a mean age = 73 years, comparing high vs. standard dose vaccine.
  - Statistically higher GMTs and seroconversion rates in the high dose vs standard dose group to all 3 strains
  - It may not possible to extrapolate these results to frail long-term care (LTC) residents.


Randomized Trial of High Dose Influenza Vaccine in Long Term Care Setting

David A. Nace, MD, MPH
Chyongchien Jing Liu, PhD
Ted M. Ross, PhD
Stacey Saracco, RN
Roberta M. Churilla, RN, CRNP
Richard K. Zimmerman, MD, MPH

Objectives

• Compare the immunogenicity of high dose (HD) versus standard dose (SD) influenza vaccine in frail LTC residents vaccine at 30 days and 6 months post-vaccination using HAI titers.

• Evaluate the persistence of titers over 6 months period following vaccination


Subjects and Settings

• Residents of Long-Term Care facilities in Western PA
  – Nursing
  – Assisted living
  – Dementia care
  – "Independent" living

• Approved by University of Pittsburgh IRB
• Approved by PA Department of Health
• Registered at ClinicalTrials.gov

Inclusion Criteria

• Residents of participating LTC sites

• ≥65 years of age

• Required full or partial impairment in
  – ≥2 Instrumental Activities of Daily Living and/or
  – ≥1 Activities of Daily Living
Methods

• Randomized single-blind* controlled trial in 2011-12 and 2012-13 vaccination seasons.

• At baseline, 205 consented subjects
  – provided a venous blood sample
  – received SD or HD inactivated vaccine.

• 1 & 6 months later, blood sampling repeated.

• Hemagglutinin inhibition (HAI) titers
  *Lab, Statistician, PI, Co-PI all blinded. Only Research Coordinator and Assistant were un-blinded.

Methods

• Primary Outcome
  – Geometric mean titers (GMTs) at 0, 30, 180 days

• Secondary Outcomes (0, 30, 180 days)
  – Seroprotection (titer of at least 1:40)
  – Seroconversion (titer at least 1:40 and fourfold rise from baseline)
  – GMT change from day 30 - 180

Descriptive Statistics

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=98)</th>
<th>Standard Dose (N=59)</th>
<th>High Dose (N=39)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (%)</td>
<td>68%</td>
<td>72%</td>
<td>64%</td>
<td>0.22</td>
</tr>
<tr>
<td>White (%)</td>
<td>99%</td>
<td>98%</td>
<td>100%</td>
<td>0.18</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>87±6.6</td>
<td>86±6.6</td>
<td>87±6.6</td>
<td>0.37</td>
</tr>
<tr>
<td>Age ≥85 years (%)</td>
<td>71%</td>
<td>69%</td>
<td>73%</td>
<td></td>
</tr>
<tr>
<td>BMI ≥25 (%)</td>
<td>54</td>
<td>61</td>
<td>45</td>
<td>0.0001</td>
</tr>
<tr>
<td>Frailty measurement:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gait Speed (m/sec), mean (SD)</td>
<td>0.7±0.3</td>
<td>0.7±0.3</td>
<td>0.7±0.3</td>
<td>0.88</td>
</tr>
<tr>
<td>ADL (score), mean (SD)</td>
<td>11.4±3.7</td>
<td>11.4±3.7</td>
<td>11.4±3.7</td>
<td>0.77</td>
</tr>
<tr>
<td>IADL (score), mean (SD)</td>
<td>7.9±4.2</td>
<td>7.8±4.3</td>
<td>7.9±4.3</td>
<td>0.88</td>
</tr>
</tbody>
</table>
### Geometric Mean Titers by Randomized Group

**2011-2012 – Day 30 – Significant differences**

<table>
<thead>
<tr>
<th>Influenza Vaccine Strain</th>
<th>Year 1</th>
<th>Standard</th>
<th>High Dose</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N=33</td>
<td>N=31</td>
<td></td>
</tr>
<tr>
<td>A/California/07/2009 (H1N1)</td>
<td>27.4</td>
<td>78.2</td>
<td>.005</td>
<td></td>
</tr>
<tr>
<td>(H3N2)</td>
<td>(17.4-44.3)</td>
<td>(45.1-95.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/Victoria/210/2009</td>
<td>10.2</td>
<td>26.2</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>(H3N2)</td>
<td>(7.0-14.8)</td>
<td>(17.1-40.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B/Brisbane/60/2008</td>
<td>14.3</td>
<td>25.6</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(11.1-18.4)</td>
<td>(18.3-34.9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Geometric Mean Titers by Randomized Group

**2011-2012 – Day 180 – Significant differences**

<table>
<thead>
<tr>
<th>Influenza Vaccine Strain</th>
<th>Year 1</th>
<th>Standard</th>
<th>High Dose</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N=24</td>
<td>N=26</td>
<td></td>
</tr>
<tr>
<td>A/California/07/2009 (H1N1)</td>
<td>28.1</td>
<td>59.7</td>
<td>.074</td>
<td></td>
</tr>
<tr>
<td>(H3N2)</td>
<td>(15.3-52.4)</td>
<td>(31.5-106.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/Victoria/210/2009</td>
<td>9.4</td>
<td>22.3</td>
<td>0.006</td>
<td></td>
</tr>
<tr>
<td>(H3N2)</td>
<td>(6.4-14.8)</td>
<td>(14.5-34.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B/Brisbane/60/2008</td>
<td>15.4</td>
<td>22.9</td>
<td>0.069</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(11.8-20.2)</td>
<td>(16.3-32)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Geometric Mean Titers by Randomized Group

**2012-2013 – Day 30 – Two significant differences**

<table>
<thead>
<tr>
<th>Influenza Vaccine Strain</th>
<th>Year 2</th>
<th>Standard</th>
<th>High Dose</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N=65</td>
<td>N=98</td>
<td></td>
</tr>
<tr>
<td>A/California/07/2009 (H1N1)</td>
<td>50.0</td>
<td>45.6</td>
<td>.672</td>
<td></td>
</tr>
<tr>
<td>(H3N2)</td>
<td>(37.4-97)</td>
<td>(32.9-102)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/Victoria/361/2011</td>
<td>14.2</td>
<td>23.4</td>
<td>.011</td>
<td></td>
</tr>
<tr>
<td>(H3N2)</td>
<td>(11.0-18.4)</td>
<td>(17.6-31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B/Texas/6/2011</td>
<td>17.4</td>
<td>26.0</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(13.9-21.9)</td>
<td>(21.2-31.9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 26% repeat enrollment between years
Geometric Mean Titers by Randomized Group
2012-2013 – Day 180 – Two significant differences

<table>
<thead>
<tr>
<th>Influenza Vaccine Strain Year 2</th>
<th>Standard</th>
<th>High Dose</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 59</td>
<td>N= 53</td>
<td></td>
</tr>
<tr>
<td>GMT (95% CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/California/07/2009 (H1N1)</td>
<td>51.8</td>
<td>46.8</td>
<td>0.663</td>
</tr>
<tr>
<td></td>
<td>(37.8-71.1)</td>
<td>(33.2-66.9)</td>
<td></td>
</tr>
<tr>
<td>A/Victoria/361/2011 (H3N2)</td>
<td>13.4</td>
<td>24.7</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>(10.3-17.5)</td>
<td>(18.3-33.2)</td>
<td></td>
</tr>
<tr>
<td>B/Texas/6/2011</td>
<td>18.9</td>
<td>25.3</td>
<td>0.063</td>
</tr>
<tr>
<td></td>
<td>(14.9-23.9)</td>
<td>(20.8-30.9)</td>
<td></td>
</tr>
</tbody>
</table>

* 26% repeat enrollment between years

Key Points
- HD vaccine produced GMT responses superior to SD vaccine in five of 6 strains
  - H1N1 in year two was non-inferior
  - H3N2 superior in both years
- There was little change in GMT between 30 and 180 days (all < 1 log2 HI)
- No serious adverse events related to the trial reported.

Discussion Points
- Comparison to DiazGranados¹
  - DiazGranados et al found HD vaccine resulted in GMT roughly double those of SD – similar to present study
  - 24% reduction in clinical disease
  - GMT in our study; however, were a fraction of those in the DiazGranados study

<table>
<thead>
<tr>
<th>Type</th>
<th>Division of Geriatric Medicine</th>
<th>Patient Immunization</th>
<th>Strategies to Stop Transmission of Flu in Healthcare Facilities</th>
<th>Healthcare Worker Immunization</th>
<th>Antiviral Agents</th>
</tr>
</thead>
</table>

**Table:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
<th>Immunization</th>
<th>Immunization</th>
<th>Immunization</th>
<th>Immunization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type B</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: The table above represents data from various studies evaluating the effectiveness of different immunization strategies in healthcare facilities. The numbers provided are hypothetical and are used for illustrative purposes. Further research is necessary to determine the actual impact of various strategies on reducing the transmission of flu in healthcare settings.
Impact of Healthcare Worker Immunization on Mortality of Nursing Home Residents

<table>
<thead>
<tr>
<th>Study</th>
<th>HCW Non-Vaccinated Homes</th>
<th>HCW Vaccinated Homes</th>
<th>Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potter 1997</td>
<td>17%</td>
<td>10%</td>
<td>0.4 - 0.8</td>
</tr>
<tr>
<td>Carman 2000</td>
<td>22.4%</td>
<td>13.6%</td>
<td>0.4 - 0.84</td>
</tr>
</tbody>
</table>


Impact of HCW Immunization on Mortality of LTC Residents

- Hayward 2006
  - Cluster study of LTCF
  - Reduction in mortality of 5 deaths/100 patients during influenza season
- Salgado - hospital study – in 12 years period, vaccination coverage increased from 4% – 67%
  - Lab-confirmed flu cases among HCW decreased from 42% to 9%
  - Nosocomial cases decreased 32% to 0%.

Hayward AT, et al. BMJ 2006;333;1241-7
Salgado et al. Inf Cont Hosp Epi 2004;25:923-8

Flu vaccination coverage among healthcare personnel by work setting, internet panel survey, November 2014, United States

BHWP HCW Rates

PLTCVP HCP Results

Staff Turnover

- Prevalent issue
  - 43.9% turnover rate in 2012
- Focus groups identified staff turnover as major barrier to HCW immunizations
  - Frequent key staff changes = frequent policy changes
  - Vaccination culture never has chance to develop

Vaccination Rates
RISE Program


Division of Geriatric Medicine
AHRQ Innovations Exchange

• Cede Vaccination Policy to Pharmacy Control
• Standing Orders
• Eliminate Consent Forms
• Require Declinations

AHRQ Innovations Exchange
http://www.innovations.ahrq.gov/content.aspx?id=4095
HCP Immunization Program Models

Green - Mandatory
Tan - Hybrid
Yellow - Voluntary

Influenza of Vaccination Requirements on HCP Vaccination Rates

Percentage vaccinated among HCP with and without an employer requirement for vaccination

<table>
<thead>
<tr>
<th>Percentage of HCP with an employer requirement for vaccination</th>
<th>Required</th>
<th>Not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unweighted n</td>
<td>Weighted %</td>
<td>Weighted %</td>
</tr>
<tr>
<td>Hospital</td>
<td>457</td>
<td>56.0</td>
</tr>
<tr>
<td>Ambulatory care / Physician office</td>
<td>262</td>
<td>37.7</td>
</tr>
<tr>
<td>Long-term care facility</td>
<td>83</td>
<td>17.7</td>
</tr>
<tr>
<td>Other setting</td>
<td>108</td>
<td>20.9</td>
</tr>
<tr>
<td>Total</td>
<td>686</td>
<td>33.9</td>
</tr>
</tbody>
</table>


Pneumococcal Vaccinations

Impact?
Which pneumococcal vaccine?
Timing of vaccination?
Pneumonia
• Significant Issue in LTC & older adults
  – Frequent
    • Incidence 1/1000 patient days
    • 10 times more frequent than community acquired pneumonia
  – Leading cause of death among LTC residents
    • Mortality increases with age ≥ 65 yrs
    • Mortality rate is 6-28%
  – Frequent cause of hospital transfers

Pneumococcal pneumonia
• Pneumonia has many causes (bacterial, viral, etc)
• *Streptococcus pneumoniae* (pneumococcus) is a bacteria which causes a significant proportion of pneumonia cases
  – 25-35% of community acquired pneumonia
  – 0-39% of nursing home acquired pneumonia
• In 2013, ~ 13,500 cases of invasive pneumococcal disease in (blood stream infection or isolation in normally sterile body sites)
  [http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf)

Pneumococcal pneumonia
• Associated with NF outbreaks
  – 2001 outbreak in NJ ([MMWR 2001;50(33):707-10](http://www.cdc.gov/mmwr-pdf/mm6337.pdf))
    • 114 beds with 200 staff
    • 9 cases among residents
    • 4 deaths
    • 49% vaccinated prior to outbreak
    • None of cases vaccinated
Pneumococcal pneumonia

- Drug resistance a concern
  - Macrolides (erythromycin, zithromycin)
    - 33.2% (Jenkins, Farrell. EID 15(8);2009)
  - Penicillin's (PCN, ampicillin, amoxicillin)
    - Up to 32% (Barry. Am J Med 107(1 Sup 1);1999)
- Multidrug resistance
  - 13% of residents

Case 6

- Mrs Smith is a 78 year old female with arthritis, HTN who is admitted to your subacute rehab unit following a total knee replacement.
- You learn that she has not had a pneumonia vaccine in the past.

At this point you recommend:
1. Pneumococcal polysaccharide 23 (PPS)
2. Pneumococcal conjugate 13 (PVC)
3. Both vaccines administered at the same time in different arms
4. Wait till she returns to her PCP
Case 7

- Mrs Smith is a 78 year old female with arthritis, HTN who is admitted to your subacute rehab unit following a total knee replacement.
- You learn that she is unsure if she had a pneumonia vaccine in the past.

At this point you recommend:

1. Pneumococcal polysaccharide 23 (PPS)
2. Pneumococcal conjugate 13 (PCV)
3. Both vaccines administered at the same time in different arms
4. Wait till she returns to her PCP

Case 8

- An 84 year old male is admitted to your facility due to deconditioning and dementia. He has no other chronic health problems.
- His family reports having had a pneumonia vaccine in the early 2000’s
Case 8

At this point, what should you recommend?

1. Repeat vaccination with PPS 23
2. Vaccination with PCV 13
3. Vaccination with both vaccines
4. No additional vaccination is needed

Pneumococcal Vaccines

- Pneumococcal polysaccharide (PPS 23 or PPV 23)
  - Recommended for decades
  - Protects against invasive pneumococcal disease
  - Covers 11 serotypes not found in the PCV 13

- Pneumococcal conjugate vaccine (PCV 13)
  - Recommendation for all older adults since 2014
  - Protection against community acquired pneumonia and invasive pneumococcal disease
  
  [Link](http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf)

ACIP Recommendations

- In Sep 2014, the ACIP began recommending PCV 13 for all older adults.
- PCV 13 reduces both invasive disease and noninvasive pneumococcal disease
- PPS 23 reduces invasive disease, but results on noninvasive disease inconclusive
- PPS 23 covers more serotypes
ACIP Recommendations

- In Sep 2015, ACIP changed recommendation of interval between pneumococcal vaccines to one year
  - Simplifies
  - CMS covers > 11 months apart
  - CMS will not retroactively look for prior vaccination coverage

http://www.cdc.gov/mmwr/pdf/wk/mm6434.pdf

New ACIP interval recommendations for pneumococcal vaccinations

Hepatitis B

Impact?
Resident vaccination?
Healthcare worker vaccination?
Case 9

True statements about hepatitis B include which of the following?

1. Hepatitis B is rare in the nursing home setting.
2. Diabetes is a significant risk factor for hepatitis B in the NF setting.
3. Mortality from hepatitis B is low among nursing home residents.
4. 1 and 3 above.

Hepatitis B

- Many LTC Outbreaks associated with ambulatory blood glucose monitoring devices
- 2011 ACIP Hepatitis B Immunization of Adults with Diabetes
  - Recommended 19-59 years
  - Consider ≥ 60 years
  
  [Link](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm)

U.S. Hepatitis B Outbreaks 2008-2014

- 23 total outbreaks
- 175 cases
- 10,700 notified for screening
- 17 (74%) occurred in LTC facilities

[Link](http://www.cdc.gov/hepatitis/Outbreaks/HealthcareHepOutbreakTable.htm)
Case 10

- A local assisted living facility administrator reaches out to you about requirements for the hepatitis B vaccine.
  - The facility reports they do not offer the vaccine to their staff.
  - The facility cares for older adults with chronic medical problems, but does not provide any skilled services such as IV fluids or medications.
  - Assisted living facilities are not considered healthcare facilities by the state’s Department of Health.

- What do you advise the facility administrator?
Case 11

• A 22 year old female is being hired by your nursing facility as a nurse aide. Your facility offers her the hepatitis B vaccine. She is uncertain if she had the vaccine as a child. Her solo practice pediatrician retired 4 years ago and no records are available.

• What do you recommend?

Hepatitis B Cases 10 & 11 Answers

• The ALF would be required to offer hepatitis B vaccine
  – Blood glucose monitoring
  – Potential exposure to body fluids

• The nurse aide candidate should be offered the complete 3 shot vaccine series since she does not have documentation

Acute Hepatitis B Cases in U.S.
National Notifiable Diseases Surveillance System
2000–2011

2011
2890 reported
18,800 estimated
89% reduction
since 1990
Most new cases in HCP

OSHA Standard

• 1910.1030(f)(1)
  – Employer shall make the hepatitis B vaccine and series available to all employees who have a risk of occupational exposure
  – No cost to employee
  – Laboratories are conducted at no cost
  – Employer must also provide any post-exposure evaluation and follow-up
  – Employees who decline vaccination must sign an OSHA declination

https://www.osha.gov/SLTC/bloodbornepathogens/standard s.html

OSHA Standard

• Applies to all potential occupational exposures

• Regardless of job or industry

• Contact with blood or infectious body fluids
  – Regardless or parenteral or not

https://www.osha.gov/SLTC/bloodbornepathogens/standard s.html

Hepatitis B Vaccination Challenges

• 2011 Hepatitis B Coverage Rates
  – 91.1% - children 19-35 months
  – 92.3% - adolescents 13-17 years
  – 35.9% - adults 19-49 years
  – 63.8% - HCP aged ≥ 19 years

• Entry of new cohort as HCP
  – Previously vaccinated HCP
    • Serologic testing is not recommended for infants/adolescents
  – The uncertain HCP

[cited: 10; noninfluenza vaccination coverage among adults – United States, 2011; MMWR 2013;62:66; below HP 2020 goal of 90%]
2013 CDC Guidance

**Pre-Exposure Approach**
- Applies to those with documented full 3 shot series
- Unvaccinated should get 3 shot series
- Incompletely vaccinated should complete series
- HCP without documentation should be considered unvaccinated and get the 3 shot series

**Post-Exposure Approach**
- Vaccine offered to those without documented series
- Serologic testing & treatment if an exposure occurs


---

Pre-Exposure Approach

- HCP has proof of documentation with 3 shot series
- At time of hire, anti-HBs measured
  - If < 10 mIU/ml → one dose hep B vaccine followed by repeat testing
    - If still < 10 mIU/ml → 2 shot series
  - If ≥ 10 mIU/ml → no further testing or action for hepatitis B


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Pre-Exposure Approach

- Advantages
  - Primary prevention
  - Obviates need for testing if an exposure occurs
  - Protection from hepatitis disease lasts at least ≥ 22 years
  - In LTC where turnover is high, completion of series is very challenging
  - In LTC, follow-up coordination of testing at high risk of being delayed

Pre-Exposure Approach

- **Disadvantages**
  - Record keeping within facility
    - tracking who had what & when within the facility
  - Record keeping outside facility
    - General lack of reporting to vaccination (IIS) registries
  - Titers not incorporated into IIS systems


Post-Exposure Approach

- HCP with documented vaccination history (but no pre-exposure testing results) reports exposure when occurs
- Test HCP for anti-HBs immediately
- Test source patient for HBsAg immediately
- Don’t wait for results from HCP to test the source patient

Post-Exposure Approach

• Advantages
  – Simpler in that testing only done if exposure occurs
    • Should be less common in LTC facilities
  – Lower initial costs


Post-Exposure Approach

• Disadvantages
  – Secondary prevention
  – Relies on self reporting of exposures
  – Relies on prompt availability of test results
    • May not be feasible in LTC settings where labs are sent out to reference labs

Case 12

• Clara is an 88 year old resident with Alzheimers, diabetes, progressive weight loss, and congestive heart failure.
• Her 78 year old sister was recently diagnosed with shingles.
• Clara’s daughter approaches you and asks whether the resident should receive the shingles vaccine.

Case 12

Which of the following statements about the shingles vaccine is incorrect?

1. The shingles vaccine is recommended for those over the age of 60.
2. Effectiveness of the shingles vaccine does not decrease as one gets older.
3. The decision on whether to get the shingles vaccine should include consideration of age, frailty status, and prognosis.
4. Shingles vaccine is typically covered under Part D Medicare.
Herpes Zoster

- Painful, often debilitating, skin rash
  - Reactivation of varicella zoster (chicken pox virus)
- Most common complication is post-herpetic neuralgia (PHN)
- Risk increases with age and immunosuppression

Incidence of Herpes Zoster in SPS (1000 person-years)


Herpes Zoster Vaccine Efficacy for Incidence of Herpes Zoster

Herpes Zoster Vaccine Efficacy for Herpes Zoster Incidence

Merk & Co. FDA Clinical Briefing Document. Dec 15, 2005

Herpes Zoster Vaccine Efficacy for PHN


Incidence of PHN in SPS (1000 person-years)

Controversies with Herpes Zoster Vaccine

- Vaccine for non-life threatening disease
- Reduced efficacy with increasing age
  - Despite increased risk with increasing age
  - Unlikely to be effective in LTC populations
- Impact of frailty on immune status not known

Controversies with Herpes Zoster Vaccine

- Complex coverage
  - Part D
- Complex storage requirements
- Safety questions raised in frail LTC residents


Controversies with Herpes Zoster Vaccine

- NQF addressed zoster vaccine in adult immunization measures gap analysis
  - Recommendation measure development for 60-64 yr olds
  - Permissive recommendation with caveats in those > 64 yrs
    - Considering frail, competing health issues, mortality risk

NQF file:///C:/Users/nace/Downloads/adult_immunization_final_report%20(3).pdf
Tdap

Tetanus
- Tetanus boosters recommended every 10 years.
- Tetanus is been associated with wounds including pressure ulcers

Pertussis
- Often considered a disease of children
  - Impacts adults as well
- Least well-controlled vaccine preventable illness
- Symptoms include:
  - Paroxysmal coughing followed by
    - Inspiratory whoop, or
    - vomiting
Pertussis

- Complications include pressure effects related to coughing
  - Rib fractures
  - Hernia
  - Transient urinary incontinence

- Not all cases have cough
- Potential to spread to others

Pertussis

- Cough can persist for months

- Adults tend to have milder course
  - Partial immunity

- Immunity wanes after 5-10 years
  - Rarely last 12 years

Pertussis

- Shifting epidemiology
  - Cases shifting to older children, adolescents and adults including healthcare workers

- Healthcare worker outbreaks
- Up to 5 in 100 adults with pertussis may be hospitalized for complications
Division of Geriatric Medicine

Tdap Vaccine
ACIP Recommendation 2012
Adults 19 Years and Older

• All adults should get a booster dose of Td every 10 years.

• All adults, including those over 65 year, who have never gotten Tdap should receive a dose of Tdap as soon as feasible.

• Can be administered regardless of interval.

http://www.cdc.gov/vaccines/pdv-vac/pertussis/recs-summary.htm
Resources

• AMDA – The Society for Post-Acute and LTC Medicine
  - http://www.AMDA.com
  - Immunization in the LTC Setting. LTC Physician Information Toolkit Series, 2010
  - Critical Issues in Infection Control: LTC Physician Information Toolkit Series, 2002

• Society of Healthcare Epidemiologist of America
  - http://www.Shea-online.org

• Infectious Diseases Society of America
  - http://www.IDSociety.org

Resources

• CDC
  - http://www.cdc.gov/flu
  - http://www.cdc.gov/hepatitis/populations/healthcaresettings.htm
  - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm

• Influenza Vaccination Information for Healthcare Professionals
  - http://www.flu.gov/professional/hospital/hcworkers_vaccine.html