Protecting your Vaccine: Protecting Your Patients

Guest Speakers
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Thank you!
Disclosures

The Speaker is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation.

No off-label use of vaccines will be discussed.

The speaker will not discuss vaccines currently not licensed by the Food and Drug Administration.

Learning Objectives

- Identify the financial and practical cost of vaccine mishandling
- Explain the roles and responsibilities of nurses in protecting vaccines from storage errors and mishandling
- Identify critical components of a vaccine storage and handling emergency plan

Vaccines Have Great Value

- Monetary
- Disease Prevention
- Public trust in vaccines
- Public trust in healthcare

Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>20th Century Annual Morbidity</th>
<th>2009 Reported Cases</th>
<th>Percent Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>28,005</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>21,053</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Measles</td>
<td>530,217</td>
<td>61</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Mumps</td>
<td>162,344</td>
<td>982</td>
<td>99%</td>
</tr>
<tr>
<td>Pertussis</td>
<td>206,752</td>
<td>13,506</td>
<td>93%</td>
</tr>
<tr>
<td>Polio (paralytic)</td>
<td>16,316</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>4</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>152</td>
<td>1</td>
<td>99%</td>
</tr>
<tr>
<td>Tetanus</td>
<td>580</td>
<td>14</td>
<td>98%</td>
</tr>
<tr>
<td>Neisseria influenzae</td>
<td>28,000</td>
<td>245</td>
<td>99%</td>
</tr>
</tbody>
</table>

*Source: JAMA. 2007;298(18):2155-2163
† † Source: MMWR. January 8, 2010;58(51,52):1458-1468. (provisional, 2009 week 52 NNDSS data)
*25 type b and 218 unknown (<5 years of age)

Comparison of Pre-Vaccine Era Estimated Annual Morbidity or Mortality with Current Estimate: Vaccine-Preventable Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Pre-vaccine Era Annual Estimate</th>
<th>2008 Estimate</th>
<th>Percent Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A</td>
<td>117,333</td>
<td>11,049</td>
<td>91%</td>
</tr>
<tr>
<td>Hepatitis B (acute)</td>
<td>66,232</td>
<td>11,269</td>
<td>83%</td>
</tr>
<tr>
<td>Pneumococcus (invasive)</td>
<td>44,000</td>
<td>4,167</td>
<td>99%</td>
</tr>
<tr>
<td>all ages</td>
<td>63,067</td>
<td>7,500#</td>
<td>88%</td>
</tr>
<tr>
<td>&lt; 5 years of age</td>
<td>16,067</td>
<td>1,314</td>
<td>98.9</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>4,005,126</td>
<td>449,363</td>
<td>99.0</td>
</tr>
</tbody>
</table>

* Source: JAMA. 2007;298(18):2155-2163
† Source: CDC. MMWR. February 6, 2009 / 58(RR02);1-25
II Source: Active Bacterial Core surveillance
### Source: New Vaccine Surveillance Network

Comparison of Pre-Vaccine and Current Reported Morbidity of Vaccine-Preventable Diseases, United States

<table>
<thead>
<tr>
<th>Disease</th>
<th>Pre-vaccine Era*</th>
<th>2008**</th>
<th>% decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria</td>
<td>175,885</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Measles</td>
<td>503,282</td>
<td>132</td>
<td>99.9</td>
</tr>
<tr>
<td>Mumps</td>
<td>152,209</td>
<td>376</td>
<td>99.8</td>
</tr>
<tr>
<td>Pertussis</td>
<td>147,271</td>
<td>9,499</td>
<td>93.5</td>
</tr>
<tr>
<td>Polio (paralytic)</td>
<td>16,316</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
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<td>47,745</td>
<td>17</td>
<td>99.9</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>823</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Tetanus</td>
<td>1,314</td>
<td>15</td>
<td>98.9</td>
</tr>
<tr>
<td>H. influenzae type b and unknown (&lt;5 yrs)</td>
<td>20,000+</td>
<td>344</td>
<td>98.3</td>
</tr>
<tr>
<td>Total</td>
<td>1,064,854</td>
<td>10,383</td>
<td>99.0</td>
</tr>
</tbody>
</table>

* Baseline 20th century annual morbidity
** Source: MMWR 2008;57(52);provisional
Consequences of Handling and Storage Errors

- Patient care, risk, and liability.
  - A patient is not fully protected if the patient is immunized with a vaccine that is not stored and handled correctly.
- Vaccine Cost.
  - Replacement vaccine costs are burdensome in terms of money and time.
- Loss of trust.
  - Can a practice or the VFC afford the loss of patient confidence?

How much money is in your storage unit?

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Private Cost</th>
<th>VFC Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Box of Varicella</td>
<td>$805.80</td>
<td>$670.81</td>
</tr>
<tr>
<td>Two boxes of Varicella</td>
<td>$1476.61</td>
<td></td>
</tr>
</tbody>
</table>

Total Cost = $10558.99

Total Cost of Storage Unit’s Contents = $12035.60
Based on July 16, 2010 Pricing

Calculate The Value Of Your Vaccines

# of Doses x $Private/Public = Total $ value

**Example - Pediatric**

- DTaP x 23.75/14.15 =
- Hep A x 30.31/13.50 =
- MCV x 103.42/79.75 =

**Example - Adult**

- Hep A x 63.10/21.59 =
- Hep B x 52.50/28.00 =

For additional information on vaccine pricing:
http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm

Source: Michigan Immunization Program

Current Problem

- CDC administers ~ $3 billion of vaccine through Vaccines for Children (VFC) program each year
- A meta analysis estimates that 14 to 35% of delivered vaccines are subject to inappropriate storage temperatures
- Storage temperature control is vital to maintaining vaccine potency
- Storage outside 2°C to 8°C range can render vaccines ineffective
- A meta-analysis estimates 14 to 35% of delivered vaccines are subjected to inappropriate storage temperatures
- Social and economic costs of improperly stored vaccines
  - Cost of manufacturing and delivering vaccine wasted
  - Vaccine delivery delayed
  - Reported vaccination rates are erroneously high
  - Recipients are not protected

$3 B/yr program X 30% loss due to known thermal excursions = $900 M/yr loss

NYS Vaccine Cost

(Projected 2008 Upstate Public & Private Patients*)

Reported problems with Storage and Handling

- 82%** of VFC/CHP Practices in NYS with 1 storage problem.*NYS DOH site visit data based 2008

** Typical problems:
- Thermometers missing from 1 or more refrigerator/freezer.
- No thermometer and complete log for all compartments
- 1 or more freezers measured too warm
- Refrigerator too cold (1°C or lower) (2°C or lower)
- Refrigerator too warm (9°C or higher)
- Expired vaccines found in cold storage but not labeled

*Source: NYSDOH Vaccine Program, Census Data
“This is a substantial problem that needs to be addressed through prevention…”

- 12%* of VFC/CHP practices with refrigerator and/or freezer out of range at the time of visit.

- At 12% vaccine annual vaccine loss due to storage and is:
  - State (12% of 224 million) = $26,900,000
  - Private = 15.6 million
  - Public = 11.3 million

*2008 NYS Site Visit Database

**Oversight and Accountability By The Vaccine Program (Vaccines for Children Program)**

- Managing publicly funded vaccine is one of the most important activity conducted by Immunization Programs!!
- Provide education and support.
- Promote high standards for vaccine storage and handling.
- Provide oversight and accountability as responsible caretaker of public funds.

**The Cost of Revaccination**

- When you DO catch it

- When you DON’T catch it

**The Cost of Revaccination**

- Risk of vaccine preventable disease
- Staff time in determining affected patients
- Patients/parents make ultimate decision on revaccination
- Contacting patients and media

**Number Of Vaccines In The Routine Childhood Immunization Schedule Has Increased**

```
1985 (7) | 1995 (10) | 2005 (14) | 2009 (16)
Measles | Measles | Measles | Measles
Rubella | Rubella | Rubella | Rubella
Mumps | Mumps | Mumps | Mumps
Diphtheria | Diphtheria | Diphtheria | Diphtheria
Tetanus | Tetanus | Tetanus | Tetanus
Pertussis | Pertussis | Pertussis | Pertussis
Polio | Polio | Polio | Polio
Hib (Infant) | Hib (Infant) | Hib (Infant) | Hib (Infant)
Hepatitis B | Hepatitis B | Hepatitis B | Hepatitis B
Varicella | Varicella | Varicella | Varicella
Pneumococcal Disease | Pneumococcal Disease | Pneumococcal Disease | Pneumococcal Disease
Influenza | Influenza | Influenza | Influenza
Meningococcal | Meningococcal | Meningococcal | Meningococcal
Hepatitis A | Hepatitis A | Hepatitis A | Hepatitis A
HPV | HPV | HPV | HPV
Rotavirus | Rotavirus | Rotavirus | Rotavirus
```

**Vaccines Can Be Destroyed By Too Hot, Too Cold, Too Long Out Of Correct Temperature**

- Source: CDC Storage and Handling Toolkit
How A Refrigerator Works

DORM-STYLE REFRIGERATOR
• Consistently unacceptable performance, regardless of vaccine storage location
• Placement on/near floor, cooling Dormitory-Style Refrigerators
and freezer unit further reduces temperature stability
• No “good” storage area
The dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance!

There Are Just A Few Critical Points In The Cold Chain You Need To Remember
• Goal: to keep vaccine cold throughout its lifespan
• Focus: the Provider’s Office or clinic
• Storage Units
• Assuring temperatures that keep vaccines viable
• The importance of plans

The Immunization Logistics System
Four things to remember

- Trained personnel
- Reliable Equipment
- Monitoring
- Written plan

Vaccine Storage Equipment

Be sure your storage unit is:

- in good working order
- able to maintain required temperatures year round
- dedicated to storage of vaccines

Temperature Monitoring

Use only certified, calibrated thermometers

Record temperatures twice daily and store temperature logs for at least 3 years

Source: CDC Storage and Handling Toolkit

Vaccine Management Plans

Keep The Refrigerator Working: Take Preventive Measures

- Use a plug guard or safety-lock plug
- Post a warning sign at the plug and on the refrigerator
- Label fuses and circuit breakers
- Install a temperature alarm

Examples

- Writing down wrong temps but not realizing they are wrong or ignoring that they are wrong.
- Not using logs that show out-of-range temps.
- Writing down the same temperature day after day.
- Confusing Fahrenheit and Celsius.
- No temperature monitoring.
- Use of dorm style refrigerator.
- Not setting a lower alarm on electronic monitoring systems.

Source: CDC Storage and Handling Toolkit
Examples Continued

- Confusing negative and positive temperatures
- Checking temperatures only once per day

Criteria for Handling and Storage Mishaps

- The errors range from small practices to large.
- Public and private.
- A few days to a few years.
- Many have involved recalling thousands of patients for reimmunization.

Develop A Vaccine Emergency Plan (1)

- Designate personnel / 24-hour to respond
- Have a system to notify you and/or your back up person
- Assure proper storage and handling of vaccines during an emergency.
- Identify an alternate power source and procedures that allow access to alternate facilities
- Keep a cooler in the office; place a copy of the Emergency Response Plan Worksheet in the cooler.
Develop A Vaccine Emergency Plan (2)

- DO NOT automatically discard the vaccine that has been compromised. Mark and store separately in refrigerator
- Call state or local health department for further instructions

What Happens When A Series Of Unfortunate Events Meets The Perfect Vaccine Management Plan?

Technology vs. Human Factor:
The problem of relying heavily on technology without recognizing the need and benefit of human interaction and involvement.

What NYSDOH is Doing

- Handling and Storage Plan
  - Delineates responsibilities of the practice
  - Must be signed
- Site Visits
- Establishing internal policies and procedures
- Education
- Requiring submission of temperature logs once per year for review

NYSDOH Vaccine Storage and Handling Plan

- Designate a vaccine coordinator and backup
- Store vaccine properly
  - Follow proper storage procedures
  - Use appropriate freezer, refrigerator and temperature monitoring equipment

NYSDOH Vaccine Storage and Handling Plan

- Monitor Temperatures- NYSDOH requirements
  - Monitor temperatures twice daily
- Use the IAC logs that clearly show when temps are out of range
- Follow appropriate vaccine mishap policies and procedures
- Call the NYSDOH Vaccine Program
**Education**

- Provider Manual
- Handling and Storage Guidelines for Staff
- Webinars-planned
- Requiring temps log submission once per year and more often as required (both education and monitoring)
- Considering future requirements of payment for lost vaccine

**Manage Vaccine Safely**

- Role of Clinician in Vaccine Safety:
  - Screen for contraindications/precautions
  - Communicate vaccine risks/benefits
  - Proper administration
  - Manage possible vaccine reactions
  - Assure proper vaccine storage and handling at the practice level
  - Document and report vaccine adverse events.
- Provide Leadership and Commitment

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"Never forget that getting big things done all year long isn't about magic. It's about leadership."

Santa

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**Resources Available Online**

- CDC Storage and Handling Toolkit http://www2a.cdc.gov/vaccines/ed/shtoolkit/default.htm
- NIPINFO nipinfo@cdc.gov
- Pink Book http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm
- ACIP General Recommendations http://www.cdc.gov/vaccines/pubs/acip-list.htm
- Immunization Action Coalition http://www.immunize.org/

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**Special Thank You To**

- Oregon Immunization Program
- Michigan Immunization Program
- New Jersey Department of Health & Senior Services, Vaccine Preventable Disease Program
- National Institute of Standards & Technology
- Colorado Department of Public Health & Environment, Immunization Program
- California Immunization Program
- University at Albany, School of Public Health, Center for Public Health Continuing Education
Thanks

- Gary Rinaldi-NYSDOH
- Patricia Moran-NYSDOH
- Susan Flavin-NYSDOH
- Betsy Rausch-Phung-NYSDOH
- Tony Richardson-CDC

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