Biologials Management

Cheryl McIntyre, BCCDC
Associate Nurse Epidemiologist
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Cold Chain

“Vaccine providers are the final guardians of vaccine quality, but few seem aware of this important role.”

Dimayuga, RC et al, BCMJ, 1996,:38:74
Cold Chain

- As health professionals we need to ensure that we are providing an effective product.
- Vaccines are damaged by exposure to excessive cold, heat or light
- Vaccines have an “expiry” date
- Loss of vaccine potency and damage to vaccines:
  - risk of adverse events
  - failure to protect = increased risk of disease
  - loss of public confidence in vaccine programs
100 infants and toddlers

- 300 doses INFANRIX hexa
- 300 doses Prevnar
- 200 doses Neis Vac C
- 100 doses Varicella
- 200 doses MMR
- 100 doses Pediacel

Total = $ 42,768.00
Decision making regarding vaccine safety and efficacy following cold chain incidents

Staff training for cold chain management

Confirmation that criteria are met for vaccines being returned for redistribution

Stability Chart (2005) and Addendum (2009)
Biological Product Monitors

- Ordering vaccines
- Receiving and storing vaccines; monitoring inventory
- Tracking cold chain incidents and vaccine “history”
- Temperature monitoring 2X daily
- Refrigerator maintenance

Know your refrigerator!
VACCINE REFRIGERATOR

- Store only vaccine in refrigerator
- Check and log temperature twice a day
- Open the door when necessary
- Stock vaccine on a first-in is the first-used basis
- Keep vaccine between 2°-8°C
- Never leave vaccine outside the refrigerator
- Don’t store vaccine on the door shelves
- Stock full bottles of water on empty shelves and in the door
- Stock only a one month supply

Ordering

- Order according to Vaccine and Pharmacy Services delivery schedule
- Establish a base order

Consider:
- Age cohort
- # of doses in routine programs
- Seasonal and program demands
- Small buffer amount

“Excess” = wastage
Ordering

- Consider what you have on hand
- School programs – order only the first dose in the series
- Do not stockpile vaccines
- Review base orders quarterly and revise as needed

Example:

Monthly base order – quantity on hand = amount to order

“Excess” = wastage
INVENTORY

- “First in, first out” management
- Check expiry date on the last business day of the month

When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial.

“Expired” = wasted
Inventory

- Check dates of opening on multi-dose vials

- Must be used within 30 days of first puncture unless product monograph indicates a shorter time

Expired = Wasted
Temperature Monitoring

+2°C to +8°C = recommended range

Temperatures must be recorded at the start and end of each business day
Temperature Monitoring

- +2°C to +8°C is the recommended range

- 0°C to +2°C: consider as “refrigerator conditions”
  - Thermometer accuracy (+/- 1°C)
  - “Worst case scenario”
  - Get fridge back in range quickly
  - DO NOT FREEZE
Forms

- Biologicals Requisition Form
- Cold Chain Incident Form
- Field Return Form

Cold Chain Incident Form: analysis from March 2009

- 62% indicated that there was a thermometer in the refrigerator; of these
  - 15%: no recorded duration for incident
  - 12%: no recorded temperatures before or after incident
Biologica ls Return and Redistribution Form

- Cold chain maintained at +2°C to +8°C
- Products received directly from BCCDC and remained at that site
- Original packaging, sealed, unopened, unused
- Safe and secure storage site
- Temperature recorded twice daily
- 3 months dating prior to expiry
Duration of Exposures

- Most cold chain incidents less than 72 hours
Temperatures

- Most incidents < 25°

Percentage of Cold Chain Incidents by Temperature Range (Calendar Years 2006-2008)
Returns by reason

FY2008/09 Returns: Comparison with and without Influenza Vaccines

<table>
<thead>
<tr>
<th>Reason for Return</th>
<th>Influenza Excluded</th>
<th>All Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold Chain (Field)</td>
<td>29.37213092</td>
<td>18.897369</td>
</tr>
<tr>
<td>Cold Chain (Transit)</td>
<td>42.90963639</td>
<td>27.99065488</td>
</tr>
<tr>
<td>Surplus</td>
<td>6.823743833</td>
<td>3.21453198</td>
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<tr>
<td>Expired</td>
<td>19.61667724</td>
<td>7.06166724</td>
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<tr>
<td>Damaged</td>
<td>0.01521117</td>
<td>0.00095409</td>
</tr>
<tr>
<td>Incorrect Shipment</td>
<td>0.7904759</td>
<td>0.00095409</td>
</tr>
</tbody>
</table>
Vaccine wastage

- Wastage goal: 3%

![Graph showing Wastage Rates for Fiscal Years 2005/06-2008/09](image-url)

- Wastage Percentages:
  - 2005/06: 6.4%
  - 2006/07: 6.2%
  - 2007/08: 6.2%
  - 2008/09: 4.6%

The graph illustrates the wastage rates over the specified fiscal years, with a goal of 3% wastage.
Next Steps

- Revise forms
- Update Stability Chart (2005) and distribute with Addendum (2009) to BPCs
- Training
- ...


Thank you

- Vaccine Wastage Reduction Working Group
- Immunization Team, BCCDC
- Vaccine and Pharmacy Services, BCCDC
- Contact: cheryl.mcintyre@bccdc.ca