Biologicals Management

Cheryl McIntyre & Brittany Deeter, BCCDC
Presentation outline:

- Cold chain overview
- BPM & BPC
- What contributes to vaccine wastage?
  - Cold Chain Breaks in transit from BCCDC Pharmacy
  - Cold Chain Breaks in the field
  - Expiry
  - Surplus vaccine
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
  - Supply of vaccines
Why now?

4,100 doses* of traditional vaccine (polio and measles vaccines pictured here).
$635.50**

625 doses* of new vaccine (rotavirus vaccine pictured here).
$4,687.50**
100 infants

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

Total = $42,768.00
Biological Product Consultants

- 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 (Oct 2009) 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 wastage

- Wastage goal: 3%

**Wastage Rates Fiscal Years 2005/06 to 2009/10 YTD—End of Q3**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>% Value Vaccine Returned/Gross Shipped</th>
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<tbody>
<tr>
<td>2005/06</td>
<td>6.4</td>
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<tr>
<td>2006/07</td>
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<td>2008/09</td>
<td>4.6</td>
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<td>2009/10 YTD</td>
<td>3.5</td>
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</table>
What contributes to wastage?

- Cold chain breaks- in transit
- Cold chain breaks- in the field
- Vaccine expiring in the field
- Surplus vaccine ordered
Returns by reason

Percent of Total Value of Returns by Reason
(FY2009/10 YTD)

- CCB (Field): 31%
- CCB (Transit): 16%
- Expired: 36%
- Surplus: 17%
Cold chain breaks in transit
(BCCDC- Field offices)

Receiving vaccines
Cold Chain Breaks in Transit

- Reefer trucks, vaccine ordering schedule
- Monitoring temperature during travel to the HA
  - Cold chain break indicators
  - Reading and returning temptales
- Reporting cold chain breaks in transit
- Packing and returning all vaccines correctly
- Vaccine tracking after a first strike
- PSLS
Reefer trucks and scheduling

- Time between deliveries may impact the supply of vaccine to be ordered
- Knowing the reefer truck schedule, particularly in remote communities is important as there may be significant time between deliveries
Monitoring temperature in travel

- One time use temperature indicator
  - **Warm indicators**, also known as time and temperature indicators are made for single use only. Warm indicators that are appropriate for vaccine shipping have an activation temperature of +10°C and a run-out time of 48 hours to 7 days.
  - **Cold indicators** are made for single use only. Do not indicate the length of time vaccine has been exposed to temperatures less than 0 degrees. Cold indicators appropriate for vaccine shipping have an activation temperature of 0°C (break when the liquid freezes).
TT4MD: Temperature Monitoring Device Form for COURIER Deliveries

Fax this form to the BCCDC Biological Desk at (604) 707-2581 as soon as your shipment is received and return the TempTale4 (TT4) device ASAP.

TT4 Monitors are numbered with a yellow, pink or green BCCDC label affixed to the side of the device.

Section I (to be completed by BCCDC Shipping Department)  Shipping Clerk: ______________

Area next to vaccine(s)  Client: ______________

Container: _____ of _____  Manifest #: ______________

Start Time: ______________  Date Packed: ______________

TT4 #: __________  TT4 # Recorded on Manifest Audit

Copy □  TT4 Downloaded by: ______

Frozen Ice Pack Used on Top □  How many? _____  Refrigerated Gel Pack Used on Top □

Box Type Used: ThermoSafe □  Regular Corrugated Box Size _______

Section II (to be completed by receiver at delivery site)

READ INSTRUCTIONS ON REVERSE SIDE BEFORE COMPLETING BELOW.

Date received ______________  Time Received ______________  Time Unpacked ______________

Frozen Ice Packs:  Hard/Cold □  Mushy/Cool □  Warm □

Refrigerated Gel Packs:  Cool □  Warm □

Vaccine:  Cool □  Warm □

TempTale4 Bell Symbol: □ Yes □ No

Press the “Stop” button on the TempTale4 and then press the “Start” button to view and record temperature history. Record the temperature information from the display window into the corresponding fields below:

Average Temp ______________

Highest Temp ______________  Duration of Higheest Temp _______ minutes _______ hours

Lowest Temp ______________  Duration of Lowest Temp _______ minutes _______ hours

Name: ______________________  Phone: ______________________  Fax: ______________________

Fax this form IMMEDIATELY to (604) 707-2581. If there is a bell symbol, refrigerate vaccine and label “QUARANTINE” until advised by BCCDC. If no bell symbol, vaccine is OK for use. You will NOT receive a phone call from BCCDC.
Monitoring temperature: Reading and returning Temp tales

Unpack and refrigerate biological products immediately upon their arrival.

- Check for evidence of physical damage, freezing or excessive heat. Remove the temperature monitoring® device from shipping box immediately & stop it.
- Read the TempTale ® & Return the TempTale® monitoring device immediately in the prepaid bubble envelope (enclosed with shipment) to BCCDC.
- Inform your Biological Products Consultant when products have been quarantined and await instruction regarding use of the products from BCCDC Vaccine and Pharmacy Services.
Quarantining vaccine
How a TempTale®4 Monitor Works

- LCD DISPLAY
- CELSIUS OR FAHRENHEIT
- START ICON
- STOP ICON
- MARKED DATA POINT ICON
- ALARM ICON
- IMMEDIATE TIME AND TEMPERATURE DATA
Remove the TempTale from the shipping box.

Check the LCD; is there a “sunshine symbol” in the top left corner of the display?

**No**

QUARANTINE the vaccine.
Contact the Biological Desk, tel: (604) 707-2582, who will provide direction regarding vaccine use after review of the refrigerated truck records.

**Yes**

Firmly press and hold the red “STOP” button located in the bottom right corner of the TempTale for 3 seconds.

A stop sign will appear in the top right hand corner of the LCD display.

Bell symbol appears in the bottom right corner of the LCD display.

QUARANTINE contents of shipment box in the refrigerator, keeping them segregated from other useable inventory while you await a BCCDC response.

No other symbol appears.

Shipment has been sent under cold chain conditions and is fine to use.

Press the green “START” button to view and record the transit temperature history. Record this information on the TT4MD form.

Complete and fax the TT4MD form immediately to the Biologicals Desk at (604) 707-2581.

Return the TempTale4 monitor(s) immediately to BCCDC in the prepaid bubble envelope. Enclose a copy of the TT4MD form.

BCCDC will contact you regarding quarantined shipments as necessary.
TT4 MD: Temperature Monitoring Device Form for REFRIGERATED TRUCK Deliveries

Fax this form to the BCCDC Biological Desk at (604) 707-2581 as soon as your shipment is received and return the TempTale4 (TT4) device ASAP.

TT4 Monitors are numbered with a yellow or pink BCCDC label affixed to the side of the device.

Section I (to be completed by BCCDC Shipping Department)

Shipping Clerk: ______________

Area next to vaccine(s) □

Client: ______________

Container: ______ of ______ Manifest#: ______________

Start Time: ______________ Date Packed: ______________

Record Time

TT4 #: ______ TT4 # Recorded on Manifest Audit Copy □ TT4 Downloaded by: ______________

Section II (to be completed by receiver at delivery site)

READ INSTRUCTIONS ON REVERSE SIDE BEFORE COMPLETING BELOW.

Date received ______________ Time Received ______________ Time Unpacked ______________

Vaccine: Cool □ Warm □

TempTale4 Bell Symbol: □ Yes □ No

Press the "Stop" button on the TempTale4 and then press the "Start" button to view and record temperature history. Record the temperature information from the display window into the corresponding fields below:

Average Temp ______________

Highest Temp ______________ Duration of Highest Temp ______________ minutes hours

Lowest Temp ______________ Duration of Lowest Temp ______________ minutes hours

Name: ______________ Phone: ______________ Fax: ______________

(Please print)

Fax this form IMMEDIATELY to (604) 707-2581. If there is a bell symbol, refrigerate vaccine and label "QUARANTINE" until advised by BCCDC. If no bell symbol, vaccine is OK for use. You will NOT receive a phone call from BCCDC.
Algorithm 2: Cold Chain Incident from BCCDC to Health Authority

1. **Cold Chain Incident from BCCDC to Health Authority**

2. **Warm/Cold Indicator activated**
   - Quarantine affected vaccine in the refrigerator. Label "Do Not Use".
   - Consult with BCCDC Pharmacist at 604-707-2580.

3. **TempTale® alarmed**
   - Quarantine affected vaccine in the refrigerator. Label "Do Not Use".
   - Complete the TempTale® Form (sent with the vaccine) and fax to BCCDC at 604-707-2581.
   - Ship the TempTale® back to BCCDC securely in the pre-paid bubble wrap envelope to be downloaded and analyzed.

4. **Obtain determination of vaccine usability from BCCDC**

5. **Are the vaccines useable?**
   - YES: Inform your BPC.
     - Remove vaccines from quarantine. Label as being exposed to first cold chain incident. Maintain a history of exposure for affected vaccines. Use affected vaccine first.
   - NO: Inform your BPC.
     - Complete the Field Return Form and fax to BCCDC at 604-707-2581 for authorization number.
     - Return vaccines to BCCDC. Do not maintain cold chain.
# FIELD RETURN FORM

**REASON CODES:**

- A - Cold chain incident: power outage
- B - Cold chain incident: equipment malfunction
- C - Cold chain incident: handling error
- D - Damage to product
- E - Expired product
- F - Surplus (for BCCDC redistribution)*
- G - Wrong product shipped by BCCDC or requested by Health Unit
- H - Product recall by manufacturer
- I - Annual influenza harvest
- J - Cold chain incident: in transit BCCDC to Health Unit
- K - Cold chain incident: in transit within HA

*If F code, product must be returned under cold chain conditions with this Field Return Form and Biological's Return Requirements Form as per: Communicable Disease Manual, http://www.bccdc.ca/HPD/documents/74061D06-4829-4A2C-BE46-E5651B02BC02A0/Biologicals_return_and_redistribution_requirements_form.pdf

## VACCINES

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<th>Product Code</th>
<th>Product Code (BCCDC Use)</th>
<th>LOT NUMBER</th>
<th>EXPIRY DATE (YYYY/MM/DD)</th>
<th>REASON</th>
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<td>Other:</td>
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</table>

Fax Form to: 604-707-2581

Biologics Desk at BCCDC
1100-555 West 12th Avenue
Email: biologics@bccdc.ca
Phone: 604-707-2581

Name of Biological Products Monitor:
Packing and returning all vaccines correctly

- Pack the vials in a box with packing material to avoid breakage. Returned unusable vaccine is not considered to be hazardous material, so no special warning signs or special handling notices are necessary.

- Keeping “like with like” is important to the reconciling process (Cam says, “Thanks!”)

- An exception would be vaccines which have been drawn up in a syringe for administration. Do not return these vaccines but report them on the Wasted Vaccine Return Form as “destroyed”.
Vaccine tracking after a first strike

- Vaccines that have been exposed to a temperature outside the recommended range in transit from BCCDC to the field should be labeled with a red dot. BCCDC Vaccine and Pharmacy Services will supply the temperature and duration information for this incident to the field.

- Develop a protocol within the HA for labeling products that have subsequent exposures to temperatures outside the 0°C to +8°C range.
Patient Safety and Learning System

- Cold Chain breaks in transit entered into the database
- Initiated by TempTale reports and manifest
- Entered and approved by Pharmacy
- Breaks then analyzed for:
  - Transportation used
  - Root cause
  - Maximum/minimum temperature exposure
  - Duration of exposure
Cold chain breaks in the field

Section 1: Preventing and interpreting Cold Chain Breaks in the field

Preventing and interpreting CCB in the field

- Vaccine storage equipment evaluation and purchasing
  - Purchasing
  - Maintenance
  - Planning for equipment failure

- Vaccine storage practices
  - Temperature monitoring
  - Vaccine packing for transit (ambient temperature, mass clinics)

- Vaccine Stability Chart
  - Use
  - Reporting of decisions

- Reporting Cold Chain Breaks
  - Returning to BCCDC after a fatal break
Cold Chain Incidents

Cold Chain Breaks by Reason Calendar Year 2009

<table>
<thead>
<tr>
<th>Reason</th>
<th>Incidents</th>
<th>Value</th>
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<tbody>
<tr>
<td>Power Interruption</td>
<td>22.58</td>
<td>26.55</td>
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<tr>
<td>Equipment Problem</td>
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<tr>
<td>Handling Error</td>
<td>41.94</td>
<td>11.60</td>
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</table>
Temperatures

- Most incidents < 25°
Vaccine storage equipment evaluation and purchasing

- What to purchase
  - Fridges
  - Data loggers
  - Min/ max thermometers

- Maintaining equipment

- Vaccine storage practices
  - Monitoring temperature
  - Packing vaccines for transit

- Planning for failures
Purchasing:

Gold standard

1) Temperature regulation
2) Defrost mechanism
3) Spatial temperature differential
4) Effects of changes in ambient temperature
5) Temperature recovery
Domestic Frost Free

- Icepacks
- Varicella, MMR
- Hepatitis B / Hepatitis A, DTP, Hib, Pneumococcal, IPV, Td, TdaP
- Meningococcal, Influenza, Rabies
- Thawed icepacks
- Flexible insulating blankets
Data Loggers:

- Data logger provides real time continuous history of vaccine temperature including time data for exposures
- Libero preferred in field testing
- Temptale® used in Reefer truck shipments from BCCDC
- Smart button in use in FNIH
Min-Max Thermometers:

- Data mixed from field trials
- VWR Sentry Min/Max memory Thermometers generally preferred had a recessed button design and an easily read display
- +/- 1°C sensitivity
- Accuracy is important
Maintaining Equipment:

Maintenance planning

- Maintenance log book should be kept for each piece of equipment, reminder systems should be in place to ensure that tasks are completed on a daily/weekly/quarterly basis.
- BPM to follow up?
- Ensure staff aware to protect vaccine supply first.
Fridge and thermometer maintenance:

- Daily Maintenance Tasks
- Quarterly Maintenance

- Thermometer
  - calibration
Vaccine Storage Practices:

Monitoring temperature

Hand Monitoring Temperature

+2°C to +8°C = recommended range

Temperatures must be recorded at the start and end of each business day
## Daily recording

### Temperature Form (Celsius)

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<td><strong>Exact Time</strong></td>
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<td>≤ -1°</td>
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</tbody>
</table>

*Take immediate action if temperature is in shaded section.*
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**
Adjusting temperature:

- Temperature out of range:
  - Assume the thermometer is accurate
  - Protect the vaccine first

- Adjust the temperature: strive for 5º C
Fridge too hot

- Polysaccharide vaccines at risk
- Decreases the infectivity of live attenuated vaccines.

© WHO Turkey/2004/Gokhan
Has the cold chain gotten too cold?

- Inadvertent freezing is now considered the most important problem affecting vaccine integrity.
- Accidental freezing occurs when vaccines are placed too close to the freezer compartment of the fridge, or placed too closely to frozen ice packs inside insulated containers.
- Do you precondition your ice packs?
DTP vaccine affected by freezing showing large conglomerates of massed precipitates with crystalline structure
Packing for travel:

- Use of tested coolers and thermometers key
- Ambient temperature important (seasonality)
Summer vs. Winter

IGLOO 16 Quart
Summer Configuration
30 Vial Count 5 mL
Seasonal Packaging Date
April 2 - Nov 14

1021g (36 oz) Blue Gel Pak 80802 mixed
pre-conditioned @ -93.6°C
for temperatures over 38°C add 1 additional
30 vs Gel Pack @ -46°C

2 x 12mL 12 x 4 Flexible Insulating Blanket
pre-conditioned @ 5°C
fan folded to fit

Vaccines - 30 x 5mL vials
pre-conditioned @ 5°C

12mL 12 x 4 Flexible Insulating Blanket
pre-conditioned @ 5°C
wrapped around vials

2720g (96 oz) Blue Gel Pak 80503
pre-conditioned @ 5°C
placed into bottom of cooler

Glow Cool 16 Insulated Hand Trolley Cooler
15 L (15Qt) Interior volume
30.4 cm x 37.2 cm x 34.8 cm H
outside dimensions
pre-conditioned @ 22°C

16 Quart Cooler - Winter Configuration
30 Vial Count 5 mL Liquid Fill
Seasonal Packaging Date Nov 15 - April 1

890g (24 oz) Blue Gel Pak
pre-conditioned @ -18.6°C

12mL 12 x 4 Flexible Insulating Blanket
pre-conditioned @ 22°C fan folded to fit
add 1 additional 12 x 4 FIB layer @ 22°C
for every 5°C below -15°C

2 x 12mL 12 x 4 Flexible Insulating Blanket
pre-conditioned @ 5°C fan folded to fit

Vaccines - 30 x 5mL vials
pre-conditioned @ 5°C

12mL 12 x 4 Flexible Insulating Blanket
pre-conditioned @ 5°C
wrapped around vials

2720g (96 oz) Blue Gel Pak 80503
pre-conditioned @ 5°C
placed into bottom of cooler

Glow Cool 16 Insulated Hand Trolley Cooler
15 L (15Qt) Interior volume
30.4 cm x 37.2 cm x 34.8 cm H
outside dimensions
pre-conditioned @ 22°C
Packing an Insulated Cooler

- 624g (22 oz) ice pack
  12cm w x 19cm l x 3 cm h
  pre-conditioned in freezer @-10 to -20°C

- Place frozen ice pack in the interior tray

- Outer 12mL flexible insulating blanket
  pre-conditioned in fridge @ +2° to +8°C and
  wrapped around vaccines and inner flexible insulating blanket

- Vaccines
  pre-conditioned in fridge @ +2° to
  +8°C

- Inner 12mL flexible insulating blanket
  pre-conditioned in fridge at @ +2°
  to +8°C and wrapped around
  vaccines

- 15 liter Insulated
  hard sided cooler
Emergency management:

- Set up procedures in advance:
  - Weather anticipation
  - Continuous monitoring and alarm systems
  - Designated primary and backup vaccine coordinators with emergency contact information
  - Written protocols for situations where power is likely to be out for > 4 hours
  - Alternate vaccine storage facility or facilities with generators and 72 hours of fuel
Cold Chain Incident within Health Authority

Quarantine affected vaccine in the refrigerator. Label “Do Not Use”

Complete Cold Chain Incident Form and consult with BPC

Remove vaccines from quarantine. Label (dot) as being exposed to first (or # if multiple) cold chain incident. Maintain a history of exposure for affected vaccines. Fax a copy of the Cold Chain Incident Form to BCCDC at: 604-707-2581. Use affected vaccine first.

Are the vaccines still useable?

YES

NO

Complete the Field Return Form and fax to Biologicals Desk at 604-707-2581 for authorization number, along with a copy of the Cold Chain Incident Form for analysis.

Return vaccines to BCCDC Do not maintain cold chain.
Vaccine Stability Chart Use

- BPC responsibility
- Information from vaccine manufacturers & WHO
- Vaccine manufacturers- the product monograph or other written communications (direct communications in response to queries, contract clauses)
- 0-2º, major concern is freezing, if vaccine has not gone below zero, there is little to no effect on potency
- Accuracy of monitoring device is the key
- Emphasize that unless otherwise indicated the information in the chart is for a single exposure
- Cumulative nature of exposures- 2nd break generally requires further advice from BCCDC pharmacy
Procedure:

- BPM made aware of a break, completes cold chain incident form
- BPM approaches BPC with completed CCIF
- CCIF compared with VSC to determine usability- action taken as directed
- If there is a discrepancy between the VSC and the incident Pharmacy contacted- CCIF is faxed to assist in determination
- Clearly label affected vaccine (Red dot them)
- Use affected vaccine ASAP to avoid the possibility of a second break
Notes:

- Multi dose vials that have been entered must be discarded after any cold chain incident
- For unreconstituted vaccines only
- The absence of visible signs of freezing is not a viable test, the presence is- even if partial
- Unreconstituted, lyophilized vaccines such as MMR II, Varilrix/ Varivax are not affected by multiple exposures below zero
## Vaccine Stability Chart

### VACCINE STABILITY CHART

Unless specifically stated otherwise the information provided in this chart refers to a single exposure to temperatures outside of 0°C to +8°C.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPOSURE DURING COLD CHAIN INCIDENT</th>
<th>REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GlaxoSmithKline</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boostrix</td>
<td>Do not freeze.¹</td>
<td>Stable for 8 hours at +21°C.¹ Stable at +25°C for 2 weeks.² Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td>Enervix B</td>
<td>Do not freeze.¹</td>
<td>Stable at +37°C for 7 days.¹ Also stable at +25°C for a series of exposures not exceeding a total time of 24 hours.²</td>
</tr>
<tr>
<td>Fluvalir</td>
<td>Do not freeze.¹</td>
<td>Stable at +25°C for 72 hours.² Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td>Havrix</td>
<td>Do not freeze.¹</td>
<td>Stable at +37°C for 3 weeks.¹ Also stable at 25°C for a series of exposures not exceeding a total time of 144 hours.²</td>
</tr>
<tr>
<td>INFANRIX hexa</td>
<td>Do not freeze.¹</td>
<td>Unreconstituted vaccine is stable at +23°C for 2 weeks.² Reconstituted vaccine is stable at +21°C for 8 hours.¹ Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
</tbody>
</table>
Vaccine Stability Chart Interpretation

- **Boostrix®** (data is different because of sources of information)
  - Product monograph - 8 hours at 21°C
  - Contract clause - 2 weeks at 25°C
  - Use the more generous of the two statements

- **Engerix®**
  - 7 days at 37°C (single exposure)
  - Multiple exposures totaling 24 hours at 25°C
# VACCINE STABILITY CHART

Unless specifically stated otherwise the information provided in this chart refers to a single exposure to temperatures outside of 0°C to +8°C.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPOSURE DURING COLD CHAIN INCIDENT</th>
<th>REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 0°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; +8°C to ≤ +25°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; +25°C</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GlaxoSmithKline</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Boostrix</strong></td>
<td>Do not freeze.¹</td>
<td>Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td></td>
<td>Stable for 8 hours at +21°C.¹</td>
<td>¹Product monograph Feb 2008</td>
</tr>
<tr>
<td></td>
<td>Stable at +25°C for 2 weeks.²</td>
<td>²PWGSC contract E60PV-07FERT/002/PH, April 2007 Annex C.</td>
</tr>
<tr>
<td><strong>Engerix B</strong></td>
<td>Do not freeze.¹</td>
<td>Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td></td>
<td>Stable at +37°C for 7 days.¹</td>
<td>¹Product monograph Sept 2008</td>
</tr>
<tr>
<td></td>
<td>Also stable at +25°C for a series of exposures not exceeding a total time of 24 hours.²</td>
<td>²TagALERT® monitor interpretation provided to Ministère de la Santé et des Services Sociaux du Québec from GSK, May 2009</td>
</tr>
<tr>
<td><strong>Fluvirax</strong></td>
<td>Do not freeze.¹</td>
<td>Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td></td>
<td>Stable at +25°C for 72 hours.²</td>
<td>¹Product monograph Jun 2008</td>
</tr>
<tr>
<td><strong>Havrix</strong></td>
<td>Do not freeze.¹</td>
<td>Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td></td>
<td>Stable at +37°C for 3 weeks.¹</td>
<td>¹Product monograph Oct 2008</td>
</tr>
<tr>
<td></td>
<td>Also stable at 25°C for a series of exposures not exceeding a total time of 144 hours.²</td>
<td>²Information obtained by Saskatchewan Ministry of Health from GSK, Sept 2008</td>
</tr>
<tr>
<td><strong>INFANRIX hexa</strong></td>
<td>Do not freeze.¹</td>
<td>Stability information is available on a case-by-case basis. Quarantine vaccine and call 604 707 2580.</td>
</tr>
<tr>
<td></td>
<td>Unreconstituted vaccine is stable at +25°C for 2 weeks.²</td>
<td>¹Product monograph Jul 2008</td>
</tr>
<tr>
<td></td>
<td>Reconstituted vaccine is stable at +21°C for 8 hours.¹</td>
<td>²PWGSC contract E60PH-08HEXA/001/PH December 2008, Annex D.</td>
</tr>
</tbody>
</table>
Vaccine Stability Chart Interpretation

- **Infanrixhexa ®**
  - Unreconstituted vaccine good for 2 weeks at 25C
  - Reconstituted good for 8 hours at 21 degree

- **Gardasil ®**
  - Is allowed multiple exposures up to 25 C not exceeding 72 hours in total

- **Prevnar ®**
  - Is allowed up to 3 separate exposures, each not to be longer than 24 hours, at temperatures up to 21 C
  - Chart also notes stable at 25 C for 6 months, and stable at 37 C for 7 days
  - Consider the maximum allowable temperature and time when making decisions (more allowable exposures may be preferable)
Vaccine Stability Chart Interpretation

- **Imovax Polio/ Td adsorbed**
  - No specific information available for this vaccine
  - The antigen is present in Pediacel, so therefore we use the Pediacel data to interpret breaks for this vaccine

- Similar process for IPV, Td-Polio, the reference vaccine is Quadracel ®.
Vaccine Stability Chart- where to from here?

- In the future, manufacturers may be moving toward including stability information in their product monographs
- Chart will be updated as more information becomes available
- This has been developed with and shared with other jurisdictions within Canada
## Reporting Cold Chain Incidents

### COLD CHAIN INCIDENT FORM

**BC Centre for Disease Control**

**HEALTH UNIT:**

- [ ] Power Outage
- [ ] Equipment Malfunction
- [ ] Handling Error

**Date Discovered:** (YYYY/MM/DD)

**Describe Incident:**

- [ ] Doctor’s Office
- [ ] Pharmacy
- [ ] Private Immunization Service
- [ ] Health Unit
- [ ] First Nations
- [ ] Other

**Temperature (minimum OR maximum):**

**Duration of Exposure (Outside 0-8 °C):**

**HOURS**

**VACCINE**

<table>
<thead>
<tr>
<th>DOSES</th>
<th>LOT</th>
<th>ENTRY DATE (YYYY/MM/DD)</th>
<th>USE (IN)</th>
<th>INITIALS</th>
<th>Previous Exposure Notes (if any)</th>
</tr>
</thead>
</table>

**BFC or BCCDC Use**

- [ ] BFC or BCCDC Use

**Submitting Biological Products Monitor:**

- [ ] PHONE:
- [ ] PHONE:

**Managing Biologicals Products Consultant:**

- [ ] PHONE:
- [ ] FAX:

**BCCDC USE ONLY:**

- [ ] BCCDC USE ONLY

**HEALTH UNIT USE ONLY:**

- [ ] HEALTH UNIT USE ONLY

**PAGE:**

**OF:**
Completing field return forms:

![Field Return Form Image]
Surplus Vaccine
Surplus Vaccine

- Inventory management basics
- Inventory management tools
- Forecasting demand for vaccines
  - based on birth cohorts, school enrollment
- Harvesting Vaccine
- Manufacturer credit system
Inventory management basics

- 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
Ordering

- Order according to Vaccine and Pharmacy Services delivery schedule
- Establish a base order
- New requisition form will require the inputting of a base order and doses on hand.

“Excess” = wastage
Inventory Management tools: The count is key!

### Stock Record (Sample)

**Instructions:** At the end of each stock record page and at the end of each month, conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of the discrepancy cannot be discovered and corrected, make a note of this. Start a new stock record page by recording the physical count from the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines and weekly accounts of doses used.

#### Vaccine Type: PPV

<table>
<thead>
<tr>
<th>Date Received or Usage Talled</th>
<th>Person Receiving Shipment *</th>
<th>Arrival Condition **</th>
<th>Vaccine or Diluent Name</th>
<th>Manufacturer</th>
<th>Vial Type (S, M, Y) ***</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>Expiration Date After Reconstitution</th>
<th>Doses Received/Balance Forward</th>
<th>Doses Used †</th>
<th>Balance (Doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/1/08</td>
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<tr>
<td>01/3/08</td>
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<td></td>
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</tr>
<tr>
<td>01/18/08</td>
<td>LST</td>
<td>✓</td>
<td>Pneumovax 23</td>
<td>Merck</td>
<td>A</td>
<td>0395B</td>
<td>2/1/08</td>
<td>2/4/08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01/21/08</td>
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<tr>
<td>01/23/08</td>
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</tr>
</tbody>
</table>

* The initials of the person who unpacked and checked the vaccine and/or diluent upon arrival.

** ✓ = vaccine arrived in good condition; X = condition of vaccine questionable and state health department immunization program and vaccine manufacturer contacted. Document details/outcome on reverse side of stock record.

*** S = single-dose vial; M = multidose vial; Y = manufacturer-filled syringe.

† Includes number of doses administered, wasted, spoiled, expired, or transferred.

‡‡ Enter the sum of ‘Total Doses Received/Balance Forward’ minus ‘Total Doses Used’

Vaccine Totals: 7 5 2

<table>
<thead>
<tr>
<th>Physical Stock Check (In Doses)</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference (‘Balance’ minus ‘Physical Stock Check’)</td>
<td>0</td>
</tr>
<tr>
<td>Balance Carried Forward (In Doses)</td>
<td>2</td>
</tr>
<tr>
<td>PRODUCT NAME</td>
<td>CODE NAME</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Tetanus Immune Globulin</td>
<td>EATYET-S</td>
</tr>
<tr>
<td>ToIP/ Adsorbed</td>
<td>ELEMENT</td>
</tr>
<tr>
<td>Hepatitis B / terug</td>
<td>FECCOMB 0.5</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>FECCOMB</td>
</tr>
<tr>
<td>Hepatitis B / Engenis</td>
<td>FECCOMB</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>FECCOMB 3.0</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>FECCOMB</td>
</tr>
<tr>
<td>Hepatitis B / K (O)</td>
<td>FECCOMB</td>
</tr>
<tr>
<td>Hepatitis B / K (O)</td>
<td>FECCOMB</td>
</tr>
<tr>
<td>&quot;Influenza (Split)&quot;</td>
<td>FLUVRAL</td>
</tr>
<tr>
<td>Influenza Virus Vaccine</td>
<td>INFUVAC</td>
</tr>
<tr>
<td>DT/IPV</td>
<td>GLEN</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>VACTA1.0</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>VACTA1.5</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>VACTA2.0</td>
</tr>
<tr>
<td>HNI</td>
<td>HNI</td>
</tr>
<tr>
<td>HNI (Non-Aquavited)</td>
<td>HNI</td>
</tr>
<tr>
<td>HNI (Non-Aquavited)</td>
<td>HNI</td>
</tr>
<tr>
<td>Human Papilloma Virus</td>
<td>HPV</td>
</tr>
<tr>
<td>Immune Serum Globulin</td>
<td>ISGU-SO2.0</td>
</tr>
<tr>
<td>Meningococcus</td>
<td>MOSS10</td>
</tr>
<tr>
<td>Meningococcal AncyH M-195, Menetir</td>
<td>MOSS</td>
</tr>
<tr>
<td>Meningococcal AncyH M-195, Menetir</td>
<td>MOSS</td>
</tr>
<tr>
<td>Inactivated Polio IPV</td>
<td>OCEAN</td>
</tr>
<tr>
<td>Inactivated Polio IPV</td>
<td>POLYAVO</td>
</tr>
<tr>
<td>Inactivated Polio IPV</td>
<td>POLYAVO</td>
</tr>
<tr>
<td>Inactivated Polio IPV</td>
<td>POLYAVO</td>
</tr>
<tr>
<td>Inactivated Polio IPV</td>
<td>POLYAVO</td>
</tr>
<tr>
<td>Inactivated Polio IPV</td>
<td>POLYAVO</td>
</tr>
</tbody>
</table>
Inventory control systems: Minimum, Maximum and Safety Stock Levels

- **Reorder level**: Amount of stock which is usually used between orders.
- **Minimum stock**: Amount used in the time between placing and receiving an order.
### BIOLOGICALS ORDER FORM

**EMAIL TO:** biologicals@bcodc.ca

**BIOLOGICALS DESK**

PHONE: 604-707-2582
FAX: 604-707-2581

**HEALTH UNIT**

**ORDER DATE (YYYY/MM/DD):**

**SINCE NAME & PHONE:**

<table>
<thead>
<tr>
<th>STANDARD VACCINES:</th>
<th>BASE ORDER</th>
<th>DOSES ON HAND</th>
<th>DOSES REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>DaPT/IPV/Hib/Hib, Infanrix Hexa, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DaPT/IPV/Hib, Pediacel, 5 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DaPT/IPV, Quadracel, 5 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenza type b, ActHIB, 5 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A, pediatric, Vaqta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A, adult, Havrix 1440</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B, infant, Recombivax-HB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B, dialysis, Recombivax-HB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B, grade 6/adult, Engerix B or Recombivax</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human PapillomaVirus, grade 6 and 9 girls, Gardasil</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inactivated Polio, Imovax Polio, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza, Fluvaral, 10 adult doses per vial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza, Vaxigrip, 10 adult doses per vial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles, Mumps, Rubella, MMR II, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal Conjugate C, Neisvac, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal Conjugate 13, Prevnar, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pneumococcal Polysaccharide 23, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TdsP, Adacel, 5 doses per box, Grade 9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Td Adsorbed, 5 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Td/IPV Adsorbed, 5 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella, Varilrix, 10 doses per box</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON-STANDARD VACCINES:</th>
<th>BASE ORDER</th>
<th>DOSES ON HAND</th>
<th>DOSES REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune Serum Globulin, Gamastan, 2 ml per vial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal conjugate, A/C/Y/W - 135, Menactra</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal polysaccharide A/C/Y/W - 135, Menomune</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Tetanus Immune Globulin, Hypertet</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**NOTES:**

**OTHER:**
Manufacturer credit system

- As part of purchasing incentives, offered to provinces by manufacturers
- About 43% of vaccine returned to BCCDC from the field is creditable
- Credit rates about 5%
Pneumococcal Polysaccharide:

Product Specific Contribution to the Total Value of Returns
(BC End of Period 10 FY2009/10)
Expiry
Expriy

- Varicella’s contribution
- Rotating vaccine in the fridge, inventory management (EEFO)
- Redistribution of vaccine in the field
- Sending vaccine to BCCDC for reallocation
- Returns form completion
Products contributing to value of returns:

![Product Specific Contribution to the Total Value of Returns](image)
Inventory management

- “First in, first out” management vs. “earliest expiry first out”

- 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.

“When expired” = wasted
Inventory management

- 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
Redistribution - why & how

- Vaccine are expensive and can be a scarce resource
- If vaccine is identified as unlikely to be used before its expiry it can be moved within a HA or within the province - everyone wins!
- Certain requirements must be met to ensure that redistributed vaccine is safe
Biologicals 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
BIOLOGICALS RETURN AND REDISTRIBUTION REQUIREMENTS FORM

NOTE: A FIELD RETURN FORM (http://www.bccdc.ca/mm-vac/ImmunizationVaccinesResources/guideform/default.htm) MUST BE SUBMITTED TO THE BIOLOGICALS DESK FIRST. THE DESK WILL THEN CONTACT YOU TO ADVISE ON THE COMPLETION OF THIS FORM.

RETURNING OFFICE: ___________________________ DATE: ___________________________

ADDRESS: ______________________________________

_________________________________ FAX: (____)_____________

CONTACT PERSON: ___________________________ TEL: (____)__________

ALL OF THE FOLLOWING CRITERIA MUST BE MET FOR PRODUCT(S) TO BE CONSIDERED ELIGIBLE FOR RETURN TO AND REDISTRIBUTION FROM BCCDC PHARMACY.
PRODUCTS MUST BE RETURNED VIA REFRIGERATED TRUCK (REEFER).

☐ The cold chain was maintained between 2°C and 8°C for these products, throughout their storage at the site.

☐ Products were received directly from BCCDC and were maintained at all times at the site with no transfer from/to other site(s) prior to being shipped back to BCCDC.

☐ Products are in their original packaging, sealed, unopened and unused states.

☐ Products were stored in a safe and secure location with no public access.

☐ The refrigerator temperature was logged at the start and end of each business day.

☐ The products have at least 3 month dating before the expiry date is reached.

I have checked off all of the boxes and to the best of my knowledge confirm all of these conditions have been met:

Signature of Biological Products Monitor ___________________________ Date ___________________________

Signature of Biological Products Consultant ___________________________ Date ___________________________

Enclose the two-signatory copy of this form with the surplus vaccines. Include a copy of your twice daily vaccine temperature monitoring log for the period of time since products were received at the Health Unit.

Enclose a temperature monitoring device with the vaccines. The monitors and reefer pick ups can be arranged prior to shipment by contacting the BCCDC Biologicals Desk at telephone: (604) 707-2582.

BCCDC USE ONLY  Field Return Report - Reference number __________________

Vaccine and Pharmacy Services Tel 604 707-2580
Updating the bpm/ bpc lists

2 choices for submitting changes:

- 1. Have the consultant forward all changes directly to Jeanie Overy electronically: e.g. They could have a copy of our spreadsheet and where ever they make the changes reflect it in a different color, e-mail it to me and I will up-date our hard copy master, as well as, our distribution lists (these are shown below), or

- 2. Have them e-mail me directly with the following information: Effective date of change, name, email, health unit name, address, phone number, e-mail address, their title: eg Consultant, Monitor, and/or backup.

Below are the distribution lists that are affected, and attached is a copy of the master that can be used for changes.

_bccdc_Biological_Products_Consultants
_bccdc_Biological_Products_Monitors
_bccdc_BPM_Back_Ups
_bccdc_BPC_Back_Ups
Thank you

- Vaccine Wastage Reduction Working Group
- Immunization Team, BCCDC
- Vaccine and Pharmacy Services, BCCDC

Contact: cheryl.mcintyre@bccdc.ca